UK Health Security Agency

Testing Times: striving for quality in the COVID-19 national testing service, April 2020 to March 2022

January 2023

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Contents

Background

The UK Health Security Agency (UKHSA), and previously NHS Test and Trace and the National Testing Programme, operated SARS-CoV-2 testing nationally to find people who had been infected with the virus that caused coronavirus (COVID-19). Testing of symptomatic individuals supported identification and self-isolation of positive individuals. Testing of people who were asymptomatic was carried out to find infectious cases that may not otherwise have been detected in order to reduce community transmission. Asymptomatic testing at scale allowed us to find more people with transmissible virus with the potential to break chains of transmission. In this context, testing is inclusive of surveillance, genotyping, research studies, outbreak and border testing.

At a high level, the structure of testing for coronavirus within the UK was separated under different operational 'Pillars'. Pillar 1 testing was testing in UKHSA laboratories and NHS hospitals for those with a clinical need, and healthcare workers (including some care homes). Pillar 2 testing was testing for the wider population, care homes and prisons, including in-person tests at national drive- or walk-though testing sites and home test kits delivered to individuals.

There were 3 main testing technologies used across Pillar 1 and 2 testing. These are extracted molecular tests, direct molecular tests, and antigen detection tests, including lateral flow devices (LFD). Further details on each of these are included in Appendix A.

This report is a summary of the historic processes, frameworks and governance across UKHSA ensuring the quality of the Coronavirus testing programme, up to March 2022, at which time the government's Living with COVID[1] strategy became active.

1.1 Overview and categories of testing

Pillar 1 swab sample collection for those with a clinical need, and health and care workers, was performed either at a designated testing site, in an NHS hospital or at home with samples sent to an NHS laboratory for analysis.

Pillar 2 symptomatic and asymptomatic testing was assisted-test or self-test via specific delivery channels (for example, Asymptomatic Test Sites (ATS) at schools and workplaces) and home delivery. Testing for symptomatic individuals was provided through established delivery channels including onsite Regional and Local Testing Sites (RTS/LTS), Mobile Tests Sites (MTS), Mobile Test Units (MTU), and home sample collection kit delivery.

The asymptomatic testing programme, through these channels, operated in 4 main testing groups:

[1] COVID-19 Response: Living with COVID-19

Group 1: Repeat testing to detect positive cases amongst asymptomatic individuals (and remove them from circulation).

Group 2: Testing prior to an activity to reduce risk (this may be one or more tests).

Group 3: Asymptomatic testing where there is a signal of a potential outbreak (or where there has been an outbreak) to control infections, or where there is perceived to be a higher risk.

Group 4: Daily testing of contacts to identify positive cases early.[2]

At the end of 2021, new guidance extended the use of LFD antigen tests to include symptomatic people in specific circumstances, namely:

- concurrent testing with an extracted molecular test, for example, RT-PCR, for the purposes of dispensing antiviral medication to eligible individuals with COVID-19
- ending of self-isolation early for individuals with COVID-19 in England testing negative on day 5 and day 6 of their self-isolation period

In March 2022, the Living with COVID strategy was introduced which removed the majority of pillar 2 testing.

1.2 Overview of the testing journey and process

The testing process and organisations involved in testing were dependent on the National Testing Programme Pillar through which the test originated.

Pillar 1 testing was conducted at NHS hospitals and within healthcare facilities for individuals with a clinical need. The samples were processed either on site or in UKHSA and NHS Pathology Network laboratories, dependent on the type of test.

Pillar 2 testing of the wider population was conducted either at national testing sites or through the UKHSA testing service channels. Testing service channels included Asymptomatic Testing Sites (ATS) set up nationally, within organisations, or self-test at home. The samples were processed either on site or in UKHSA Lighthouse Laboratories and Surge Testing Laboratories, inclusive of onboarded private laboratories, dependent on the type of test.

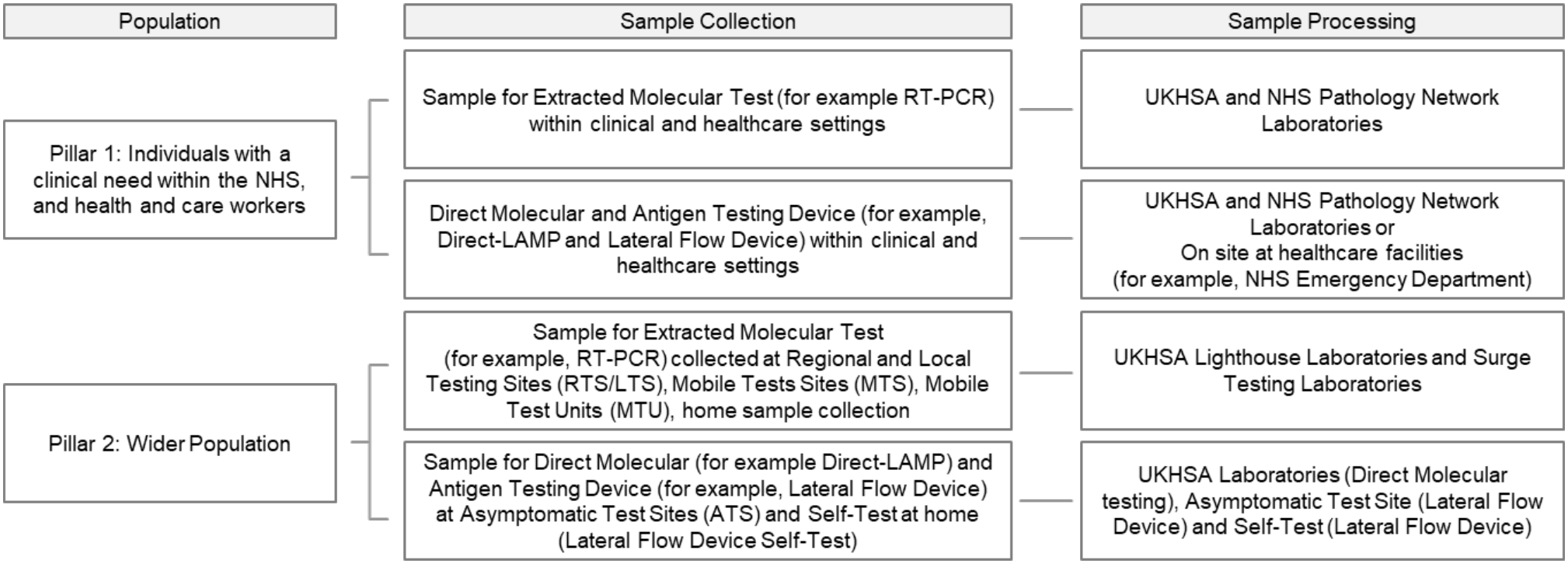
Pillar 1 testing was initiated by the NHS hospital or healthcare facility. Pillar 2 testing was initiated by an individual requesting testing through one of the available digital channels, via

[2] Includes contacts who were not required to self-isolate: fully vaccinated (2 vaccines), aged under 18 years old, have taken or taking part of an approved vaccine trial or not able to get vaccinated for medical reasons. Testing of vaccinated contacts was strongly recommended, in order to reduce risk. Source: Guidance for contacts of people with confirmed coronavirus (COVID-19) infection who do not live with the person (Withdrawn on 24 February 2022):

GOV.UK telephone booking or through organisations that may be part of or receiving services or care from (for example, public and private industry or elective care within an NHS Trust).

Individuals who booked through these routes received an appointment for their test sample collection at a testing site or, if requested, home delivery. Further information on the process flow for test samples and processing is included in Figure 1 and Section 3.

Figure 1. Testing sample collection and processing overview



Accessible text version of Figure 1

Population for Pillar 1 consists of individuals with a clinical need within the NHS and health and care workers, Pillar 2 is the wider population.

Sample Collection included in Pillar 1 samples for extracted molecular tests, for example RT-PCR, within clinical and healthcare settings. These are processed through UKHSA and NHS pathology network laboratories.

Second sample collection for Pillar 1 direct molecular and antigen testing devices such as Direct-LAMP and lateral flow devices within clinical and healthcare settings. These are processed through UKHSA and NHS pathology network laboratories or on site at healthcare facilities, for example, NHS Emergency Departments.

Sample collection included in Pillar 2 samples for extracted molecular tests, for example RT-PCR collected at regional and local testing sites, mobile test sites, mobile test units and home sample collection. These are processed through UKHSA lighthouse laboratories and surge testing laboratories.

Second Sample collection for Pillar 2 samples for direct molecular, for example Direct-LAMP and antigen testing devices, such as a lateral flow device at asymptomatic test sites and self-tests at home. These are processed via UKHSA laboratories for direct molecular testing, asymptomatic test sites and self-test for lateral flow devices.

2. Context

Quality and public health governance has been a core element of UKHSA testing programmes since the initial development of the National Testing Programme in early 2020. This evolved and developed as the landscape changed over time. The products used and services operated throughout Pillar 1 and 2 delivery channels required robust governance and quality assurance systems to maintain and assure quality across the network. The frameworks and processes have been developed to maintain high quality standards and provide the necessary assurance that products and services offered were safe, appropriate, and effective.

UKHSA operated in a unique position as service provider, service commissioner, product procurer and legal device manufacturer. UKHSA led product and laboratory validation oversight and assurance of regulatory compliance both pre-deployment and post-deployment of a testing technology or service in the market. Quality across all these domains was imperative and was viewed as an end-to-end assurance process across the testing pathway. The frameworks and processes in place included, but were not limited to, measurement of key performance indicators against service standards, compliance with relevant standards and regulatory requirements across all organisation functions, continuous quality improvement, and review and monitoring of any risks associated with the delivery of products and services. This was done in conjunction with partner agencies, such as the United Kingdom Accreditation Service (UKAS), and regulators including the Medicines and Healthcare products Regulatory Agency (MHRA).

3. Ensuring quality in testing laboratories

Pillar 1 laboratories processed SARS-CoV-2 test samples from individuals with an immediate clinical need for diagnosis to support identification of COVID-19, self-isolation, and optimisation of treatment for positive individuals[3]. Pillar 2 laboratories were used for testing at scale in the wider population of both symptomatic and asymptomatic individuals, which allowed for individuals to identify if they had COVID-19 and to self-isolate to reduce transmission and spread. Through Pillar 1 and 2 testing, UKHSA operated, commissioned, and provided testing capability and products to testing services across various settings and use cases for individuals.

3.1 National testing programme governance and quality assurance for Pillar 1 laboratories

In light of the unprecedented pressure on laboratory systems from SARS-CoV-2, national NHS Pathology Network Laboratories (that is, Pillar 1) were identified to provide testing capacity for NHS patients and staff, key workers and their families. In some instances UKHSA regional laboratories provided this service from the NHS pathology network. The NHS Pathology Network Laboratories were set up to run SARS CoV-2 testing at scale to complement UKHSA, these labs were commissioned and directly provided capacity to identify individuals with a possible infection of COVID-19. They committed to providing quality results at scale for this single test during this time of national need.

The Pillar 1 Laboratories for SARS CoV-2 testing were set up to have the following aims and objectives:

1. Maximising testing capacity amongst all network laboratories to provide quality assured testing for SARS-CoV-2, committing to a test capacity of 120,000 tests per day for England across all Networks.
2. Logistics support provided and deployed for moving samples, swabs or supplies around the Networks as quickly as possible to balance demand and capacity.
3. Delivery model deployed across 29 Network Laboratories in England, working with UKHSA and other partner laboratories (predominantly universities) as and when on-boarded, to meet the demand for testing across the Networks.
4. Where capacity existed, priority testing was for those NHS patients and workers (symptomatic and asymptomatic) working in Health and Social Care.
5. A Pillar 1 Quality Assurance Leads Group was set up to act as an advisory group, advising NHS England and NHS Improvement and Clinical Leads on quality issues and acting as a forum for peer review, shared learning, and quality development.

[3] Testing of symptomatic individuals was performed via drive-through and walk-in testing sites, mobile outbreak response units, home PCR testing, and within care homes.

Since establishment, the NHS Pathology Network Laboratories received tens of thousands of samples per day from across their networks to target NHS patients, staff and their families, other key worker and care homes. They operated using a variety of equipment platforms, assays and consumables designed to maximise the NHS and UKHSA supply chains. Every week the supply leads of the NHS Pathology Network Laboratories worked with the relevant procurement teams (NHS, DHSC, UKHSA) to make available equipment and consumables where this helps NHS teams target areas of frontline need.

The laboratories were staffed by experienced Health and Care Professionals Council (HCPC) registered and qualified Clinical Scientists and Biomedical Scientists and were overseen by NHS clinicians and answerable for delivery to NHS England and NHS Improvement (NHSE/I). Regulation of the laboratories and assays they used came under the Medicines and Healthcare products Regulatory Agency (MHRA), the Health and Safety Executive (HSE), the Care Quality Commission (CQC), and all NHS and UKHSA laboratories were accredited to UKAS ISO :2012 standards[4]. Any laboratory that was designated as a COVID-19 testing laboratory was required to adhere to the implementation and quality assurance processes of their quality management system as required by ISO 15189:2012 standards.

3.1.1 Pillar 1: laboratories quality assurance development

In February 2020, Public Health England (PHE) began undertaking all formal testing for SARS-CoV-2 and established services in all regional PHE and designated testing laboratories. This initial capacity needed to be supported and increased using NHS laboratories with appropriate facilities and with initial support from PHE.

Due to the nature and need to establish greater testing capability, NHSE/I identified NHS Pathology Network hub laboratories to commence creating both the PHE approved protocol test and to begin validation of commercially available kits that could be automated to further increase the available testing capacity. Due to the public health requirement for this action to be taken at pace there was an expectation that although the laboratories were UKAS Accredited to ISO 15189:2012 standards, these assays that were to be provided, would not be in scope in terms of UKAS ISO 15189:2012 accreditation. It was, however, expected that an in-house validation and verification would be undertaken to demonstrate performance acceptance of these assays and that this would include the use of PHE provided standardised proficiency panels (developed by NIBSC). PHE at that time was also in discussions with MHRA and HSE regarding a derogation in handling of infectious material to containment level 2+ from containment level 3 for testing, which was subsequently granted. Guidance on the detail of this derogation for all assays was provided by PHE. PHE also provided guidance on the preferred commercial kits, which were CE marked. Any in-house assay that was to be used, had to meet

[4] The privately operated Immensa lab in Wolverhampton, used for surge testing, did not receive UKHSA accreditation while utilised by the national testing programme. Immensa did undergo an assessment of their validation and operational requirements prior to going live in the national testing programme as was the standard applied practice for all labs.

locally agreed acceptance criteria, according to local quality management systems for validation, prior to patient use.

Laboratories were asked at that time to consider how services would be provided 7 days per week. Pillar 1 laboratories were required to prioritise this activity and ensure validation and verification was complete within the expected timeline agreed with PHE of 9 March 2020 to meet the anticipated need in England. The participating laboratories became part of the Pillar 1 Laboratory Quality Assurance Group, outlined in Section 3.1.2 below, and the Laboratory Leads and Pathology Incident Directors meeting, outlined in Section 3.1.3.

3.1.2 Pillar 1: Laboratories Quality Assurance Group

Pillar 1 testing, as part of the Government's Testing Strategy, reported into the Chief Scientific Office for England (CSO)/ Director of Testing Technologies, Validation and Regulatory Compliance Operational Delivery Board (UKHSA) and Testing Delivery Board (UKHSA) on a weekly basis. As part of the 'Testing Cell - Laboratory Capacity Group' and UKHSA Testing Cell, the Quality Assurance Leads Group was established and was responsible for assuring the quality and operational development of all laboratories testing for SARS-CoV-2 under Pillar 1. The Quality Assurance Leads Group was brought together to assure the standard of the quality delivery of the NHS Pathology Network Laboratories, and to perform continual monitoring of the service including oversight of service developments.

The Quality Leads responsibilities include alerting and reporting to NHSE/I any quality issues and clinical incidents associated with testing and reporting across their Network, developing and implementing effective and efficient quality assurance processes throughout testing pathways, working with other Network Laboratory Leads, Clinical Leads and scientific staff to implement fully validated and verified testing pathways, working with local Clinical Leads and scientific staff to standardise interpretation and reporting of testing across the Network laboratories, and liaising with other Quality Leads regarding establishment of ISO 15189:2012 quality management systems and sharing of audit data and assay performance across the Network Laboratories and Networks, including sharing of specific documentation and adhering to quality policies and objectives.

As of 1 April 2022, the Pillar 1 Quality Assurance Group moved to be under the Governance of the NHSE/I National Pathology Board. The Group has been further developed to expand beyond the testing for the SARS-CoV-2 pandemic and include cross network communication on all quality matters. This group and its members will work on the NHSE/I Network Maturity Index and ensure that Pathology Networks have a quality representative for each network present at all meetings, reporting into the National Pathology Board. The new overarching format will continue as a National Pathology Quality Assurance Group.

3.1.3 Pillar 1: laboratory leads and pathology incident directors meeting

Due to the nature and severity of the pandemic, NHSE/I initiated command and control of the NHS. At the time, PHE worked closely with the NHSE/I Pathology Network Laboratories to increase capacity of testing pathways within existing NHS infrastructure. Since the start of the testing programme, Pathology Incident Directors provided senior leadership to the pathology network, directed and controlled activity and reporting within testing laboratories, and liaised with clinical and operational teams of partner trusts as part of planning, response and coordination. The testing pathway utilised existing NHS infrastructure – for example, collection and recording of results. Each Pathology Incident Director nominated a capacity planning lead, procurement lead, activity tracking and analytical lead, and quality lead for their testing laboratories within the network. As part of monitoring and ongoing governance, all Pathology Incident Directors and Laboratory Leads of NHS Pathology Network hub laboratories attended a newly established meeting overseen by NHSE/I through the Pathology Transformation Group. This group reported into NHSE/I and the Testing Technologies Oversight Group.

The established Pathology Incident Directors and Laboratory Leads meeting supported the COVID Testing Cell to understand how health services were responding nationally to the pandemic and ensured testing capacity was maximised, ensured Pathology Incident Directors were up to date on national developments, provided reporting of laboratory positions for individual networks, partnership working with NHSE/I and local networks, and set out timelines and scope of work with agreement of corrective plans and actions.
Since its creation at the start of the testing programme, the cadence of this meeting for all Pathology Incident Directors and Laboratory Leads, or their nominated Deputies, was dependent on the stage and landscape of the pandemic. Over this time, the meeting occurrence has flexed between daily, weekly or fortnightly as required.

3.2 Governance and quality assurance of national testing programme Pillar 2 laboratories

In the UK, diagnostic testing for SARS-CoV-2 had to scale significantly from the capacity available in early 2020. Testing of the wider population in Pillar 2 required increasing laboratory capacity outside of the traditional existing structures. The first ‘Lighthouse’ (LH) laboratories were brought online in March 2020 and supported dedicated testing capacity for Coronavirus. A LH laboratory is a high throughput facility that is dedicated to COVID-19 testing for the National Testing Programme. The LH laboratory network was created to perform SARS-CoV-2 RT-PCR and E-PCR tests at high scale, which complemented existing capacity. Since the development of the initial LH laboratory network, additional laboratories were brought online, with over 150 million tests completed to March 2022, with a peak daily processing volume of 557,624 PCR tests on 7 January 2022.

Historically, the main source of quality assurance for laboratory and point of care testing had been through UKAS. UKAS accredits medical laboratories against ISO 15189:2012 (Medical

Laboratories: particular requirements for quality and competence) in conjunction with ISO 22870:2006 (Point of Care Testing: particular requirements for quality and competence) for providers delivering point of care testing. The timelines for accreditation were approximately 6-12 months for a newly established laboratory and approximately 10-12 weeks for an extension to scope or change in scope, for example, addition to assays, platforms used, or change in platform and test used. These timelines extended subject to UKAS capacity, with feedback from some NHS laboratories indicating this can be over 12 months.

As these timelines restricted the ability to mobilise new laboratories at pace with appropriate accreditation assurance to support the national testing effort, a robust assurance process was designed and established that focused on onboarding 11 core LH laboratories to support Pillar 2 testing. These laboratories were Milton Keynes, Glasgow, Alderley Park, Cambridge, Randox, Brants Bridge, Newcastle, IP5 (Newport), Plymouth, HSL and the Rosalind Franklin laboratory. Accreditation assurance processes also applied to surge capacity laboratories, which were contracted for shorter time frames when there was increased demand for PCR testing over and above that available through core LH laboratories. The following sections outline the laboratory processes and governance.

Ensuring the highest quality standards for a world class service has been integral throughout the scale-up of testing. Critical to Pillar 2 testing capacity was having confidence in the quality of results delivered by laboratories and ensuring, for example, their traceability, comparability, and validity. Any laboratory that is designated a national testing laboratory or LH laboratory was required to adhere to UKHSA implementation and quality assurance processes. The quality assurance and governance processes in place supported the maintenance of high quality standards and identification of further process improvements when necessary. Validation and operational readiness checklists for onboarding of testing laboratories in Pillar 2 were created to support this requirement, detailed further in Section 3.2.2. As part of this process, all laboratories were required to demonstrate accreditation, or show evidence that they were working towards achieving the accreditation standard, by UKAS, and adherence to the relevant ISO standards including, for example, ISO 15189:2012 Medical laboratories — requirements for quality and competence.

In 2021 UKHSA became aware of anomalous results at the private Immensa laboratory brought into the testing network. The laboratory was commissioned to provide additional testing capacity for NHS Test and Trace from 2 September 2021. UKHSA suspended testing at the laboratory on 12 October 2021 following reports of inaccurate results.

The cause was the incorrect setting of the threshold levels for reporting positive and negative results of PCR samples for SARS-CoV-2 by staff in Immensa's Wolverhampton laboratory. This means that some PCR tests were reported by the lab as negative which would have been assessed as positive if the threshold had been correctly set.

UKHSA's serious incident investigation concluded that no singular action or process implemented by NHS Test and Trace could have prevented the errors within the Immensa

laboratory arising, but it has also identified a range of ways to enable earlier detection of any similar laboratory errors wherever possible. Improvements subsequently implemented can be found online.

3.2.1 Pillar 2: laboratories and surge testing onboarding audit development

To ensure confidence in the quality of the laboratories onboarded, results validation, and operational readiness, checklists were developed, to be completed prior to onboarding a new laboratory. The validation checklist was created to cover the key elements of the ISO 15189:2012 accreditation standard in relation to delivering a SARS-CoV-2 detecting assay – for example, having a robust quality management system, clinical governance, staff training and competencies, assay validation, standard operating procedures for the end to end testing pathway, and EQA participation. The first 3 LH laboratories received a site visit or input from an NHS Clinical Virologist and a site visit by a member of the Laboratory Validation and Quality Assurance team (or representative) to understand the pathways and processes in place and advise on what was required to meet the checklist requirements. Whilst these visits only happened in March and April 2020 for the first 3 LH laboratories due to resource pressures on the validation team, every additional core LH laboratory still underwent a robust desktop validation assessment alongside an operational readiness checklist, with regular virtual meetings by Microsoft Teams, to ensure the laboratory was operating to the standard required prior to go live. The Laboratory Validation and Quality Assurance team met 2 to 3 times per week, to review progress of the checklists, discuss individual laboratory issues, to ensure consistency across the LH laboratories with respect to quality standards, and assign tasks required for next steps, including ongoing virtual meetings with the Laboratory leads of Laboratories being assessed.

When the LH laboratories were first established in March 2020, a clinical virology lead from the NHS was appointed as part of the LH laboratory staff (due to resourcing constraints, it was not possible to appoint a clinical virologist at each of the 10 LH laboratories, but all labs had access to clinical virologists through regular weekly site directors' meetings). At the start of the pandemic, none of the LH laboratories had accreditation with UKAS, and few of the UKHSA laboratories or NHS laboratories had successfully applied for an extension to scope with UKAS to test for SARS-CoV-2. As the nature and severity of the pandemic required immediate scaling of testing capacity, the first LH laboratories (Milton Keynes, Glasgow, and Alderley Park) were rapidly created with the support of the armed forces and universities (through the provision of RT-PCR testing equipment). Prototyping and protocol development for the laboratories was created in partnership with NHS Clinical Virology leads. Validation tests were run by the laboratories with machines validated and tested prior to subsequent ramp-up. Over time the national team, under the Chief Scientific Officer for England (CSO), ensured these initial LH laboratories worked in parallel to meet the full requirements from the onboarding checklists and worked with UKAS towards accreditation status.

3.2.2 Pillar 2: laboratories and surge testing onboarding and quality assurance

Quality assurance described by CSO

The Laboratory Validation and Quality Assurance Team (reporting to the Chief Scientific Officer for England/ Director Testing Technologies), provided Regulatory, Quality and Assurance, had developed itself since its formation at the start of the national testing programme and assured that sufficient validation was in place to inform the operational readiness of all Pillar 2 and surge laboratories to provide high quality, validated, accurate and safe SARS Cov-2 testing services. This included RT-PCR and E-PCR, and – latterly – reflex tests and sequencing, which were implemented post March 2021. Direct LAMP was deployed into the NHS for asymptomatic staff testing funded by NHS Test and Trace/UKHSA and in general delivered by NHS staff, and these LAMP laboratories were subject to the same Pillar 2 onboarding process.

The team used the laboratory onboarding validation audit checklist developed to align with UKAS, ISO 15189:2012, and ISO 22870:2006 requirements. As part of the process, laboratories were required to provide evidence of registering with UKAS for accreditation. This was not legislative, but it was mandatory, with some exceptions, specifically LAMP Laboratories, and the Sanger for genome sequencing, due to the short contractual nature of their operational delivery.

Potential provider laboratories were requested to provide evidence that they have appropriate standards in place, inclusive of assay validation data. The evidence was then assessed by the team through a formal desktop review. On completion of the review the team made a recommendation to the Testing Operations Team, following which there was another operational onboarding process led by the Laboratory Directorate who then decided whether the provider had sufficiently completed an operational readiness checklist to enable them to go live with testing. Laboratories were requested to submit a change request form providing evidence of any changes including new validation and verification data to show continued quality assurance, prior to becoming UKAS accredited, see below. Oversight of operational readiness for onboarding new labs (both LHL and surge) that were not already part of the core Pillar 2 network was originally the responsibility of the DHSC Design Authority Review (DAR) board (before it was stood down in Q3 of 2020). Validation readiness was subsequently overseen by the CSO for England Testing Oversight Group on formation of NHS Test and Trace in mid-2020. The DAR Board process was replaced by a formal process run by the Lab Directorate, which assessed operational readiness after validation readiness had been confirmed by the CSO for England Testing Oversight Group. Only after completion of this checklist was the operational go ahead for the lab to go live given.

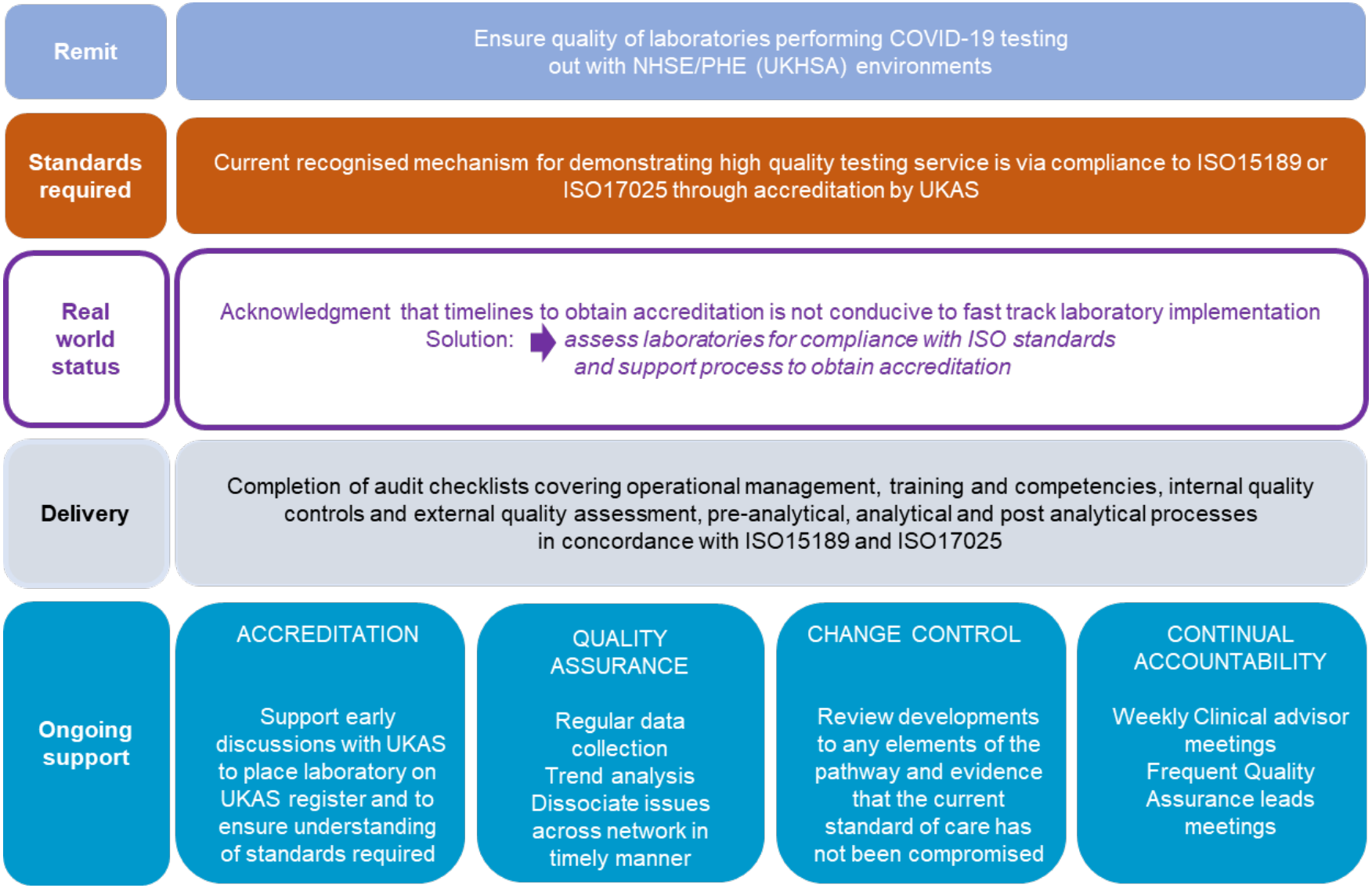
The Laboratory Validation Team provided advice to the laboratories directorate as part of the assessment for operational readiness through desktop reviews of documentation, which changed from the early stage as discussed above. This was submitted by the potential testing provider, with respect to the standards expected at a level of either ISO 17025 (general requirements for the quality and competence of testing and calibration laboratories) or ISO

15189:2012 (general requirements for the quality and competence of medical laboratory testing). The ISO standard to reach was dependent on the level of testing to be provided, that is, diagnostic or surveillance. It was acknowledged that laboratories may not be UKAS accredited at the time of evaluation but must show evidence that they have registered with UKAS to become accredited under one of the 2 schemes as part of the evaluation review. Any omissions in evidence were resolved through a series of virtual meetings with members of the potential testing provider, to support submission of all necessary evidence that would allow the Laboratory Audit Team, a sub-group of the Laboratory Validation Team, to ascertain readiness to go live with testing[5]. This process as described by the CSO is illustrated in Figure 2.

The quality system that was operational across the LH Laboratory network where individual contracted laboratories were ultimately responsible for ensuring they had robust quality management systems (QMS) in place, is detailed in Figure 2. Laboratory Quality Assurance Overview. This process was from an oversight perspective only and that individual contracted laboratories ultimately were responsible for ensuring there were robust Quality Management Systems in place, as referenced in more detail below in Section 3.2.5.

[5] For the Immensa laboratory, there was no evidence of an audit report being completed under the first contract. A subsequent report was completed prior to the laboratory going live with testing under the second contractual term; this was before any issues arose during the second contractual term.

Figure 2. Laboratory Quality Assurance overview



Accessible text version of Figure 2

The chart above shows the Laboratory Quality Assurance overview. It shows 5 aspects of the process and then explains them.

1. Remit: ensuring quality of laboratories performing COVID-19 testing out with NHSE/PHE (UKHSA) environments.

2. Standards required: current recognised mechanism for demonstrating high quality testing service is via compliance to ISO15189 or ISO17025 through accreditation by UKAS.

3. Real-world status: acknowledgement that timelines to obtain accreditation is not conducive to fast-track laboratory implementation. Solution - assess laboratories for compliance with ISO standards and support process to obtain accreditation.

4. Delivery: completion of audit checklists covering operational management, training and competencies, internal quality controls and external quality assessment, pre-analytical, analytical and post analytical processes in concordance with ISO15189 and ISO17025.

5. Ongoing support: Ttis encompasses:

- accreditation- support early discussions with UKAS to place laboratory on UKAS register and to ensure understanding of standards required
- quality assurance - regular data collection, trend analysis and dissociate issues across network in timely manner
- change control - review developments to any elements of the pathway and evidence that the current standard of care has not been compromised
- continual accountability - weekly clinical advisory meetings and frequent quality assurance lead meetings

This team also provided ongoing quality assurance of laboratories through the following activities:

1. Standards Compliance: Oversaw and monitored continued compliance with the above standards with the Laboratory Site Directors and Quality Leads via weekly and fortnightly group meetings: used the principles of quality development and improvement, monitored and reviewed incidents, undertook root cause analysis of incidents, identified trends, put in place corrective and preventative actions, shared best practice, and supported laboratories to work towards full UKAS accreditation to ISO 15189/17025 standards where appropriate.
2. Change Control: Reviewed change control requests when the laboratories submitted them. Reviewed developments to any elements of the pathway ensuring laboratories provided evidence that the current standard of care has not been compromised.
3. Quality Management: Completed technical and quality audits to inform continuous improvement. A two-step onboarding process for laboratories focussed on desktop review followed by a site visit, (limited to a desktop review only after the first 3 laboratories had been assessed due to resourcing challenges within the validation team), with virtual meetings with laboratories subsequently.
4. Commercial: Collaborated with the commercial team who ensured appropriate due diligence and commercial checks were completed for all laboratories and suppliers.
5. External Quality Assurance (EQA): Assurance of laboratories participation in EQA through, for example, the UK National External Quality Assurance Schemes (NEQAS) and the use of National Internal Control standards produced by the National Institute for Biological Standards and Controls (NIBSC).
6. Variants of Concern (VOC): Laboratories were expected to assure their laboratory testing aligned with latest VOC monitoring, advice and validation, outlined in Section 5.5.
7. Ad hoc scientific advice from and to the UKHSA leadership.

Priority was given to laboratory onboarding activities to ensure sufficient testing capacity was available to meet demand, with significant pressure to onboard additional capacity quickly, particularly evident in times of surging demand due to increases in prevalence of Omicron and other new variants. This was exacerbated, given the lack of availability of staff with suitable experience and qualifications.

Quality management systems (QMS) that was operational across the LH Laboratory network

To enable the rapid scale up of the LH Laboratory network to respond to the COVID-19 pandemic, the organisational construct adopted was that of an aggregation of entities, not a single organisation. The entities that were brought together ranged from NHS Trusts, public-private partnerships and private laboratories. The implications of this construct were that each of the entities, whilst contracted to work on the common requirement of UKHSA COVID-19 testing activities, had all operated as independent laboratories with their own QMS defining their approach to quality assurance, monitoring and improvement. The labs' QMS was supported by a site Quality Lead and, often, a nominated Clinical Advisor.

In addition, the COVID-19 test methods utilised by these entities were not all the same. The operational practices and procedures, including the quality monitoring and improvement activities were, therefore, defined by each lab to reliably deliver the services required by UKHSA, alongside the entities' other activities. This included meeting the requirements of good laboratory practice and the quality and safety standards as set out by the regulators and accreditors. Each of the entities had an independent relationship with the regulatory bodies, for example, MHRA and the HSE, and Accreditation body UKAS, that set the standards for their operations, that is, ISO 15189:2012 / ISO 17025 and were generally accredited, or in the process of gaining accreditation of their compliance, with these standards. The UKHSA Laboratories Directorate had no formal responsibility or relationship with the regulators and accreditors for these entities.

Prior to the commencement of any engagement on UKHSA-contracted COVID-19 activities, the labs had undergone a formal review of their operations and a validation exercise supported by both the Lighthouse Labs Team and NHS England quality specialists. This formal review identified the status of the operational preparedness, the COVID-19 test method capability and suitability of the quality systems in operation. Successful completion of these reviews resulted in a documented readiness assessment and an 'activation meeting' with the Head of the Laboratories Directorate.

A key component of the ongoing internal quality system that ensured ongoing and continuous assessment of the labs' COVID-19 specific method and operational practices, was the use of both positive and negative controls on each sample plate tested. Deviations in the expected responses of these controls required documented assessment, sample retesting and potentially formal Corrective and Preventive Actions (CAPA), logging and follow-up activities depending on the specific instance. The labs also used externally available standards, such as Qnostics standardised panels, to assess their test method performance. Ongoing issues or any material breaches of procedure affecting the UKHSA COVID-19 testing. These were required to be notified to UKHSA SOC, once this was established, for resolution and the implementation of preventative actions.

Daily reviews of lab performance included key quality metrics, such as sample voids and positivity rates were completed by the central Labs Team. Weekly lab performance review meetings were held with each laboratory by the UKHSA Labs Team, LH Laboratories Lead and the UKHSA Relationship Manager. Any subsequent material changes to the COVID-19 testing post this assessment were reviewed and approved by the NHS England quality specialists.
In summary, a robust system of assurance was in place with the fundamental responsibility for the entities' compliance with regulatory and accreditation standards, and the operation of the Laboratory's QMS lying with the laboratory itself. Its capability and compliance was assessed by UKHSA quality specialists upon validation and reviewed by this team if there were any material changes. Ongoing quality assurance and method / practice performance monitoring was provided by the inclusion of controls with all test runs, individual labs' broader QMS requirements and the UKHSA Labs Team monitoring of key quality indicating metrics.

National testing programme ongoing governance of Pillar 2 laboratories

An effective governance system across laboratories operated within the national testing programme was critical to maintain the highest of standards. All laboratories across the network were required to nominate a Quality Assurance Lead for their laboratory. The lead was responsible for promoting good quality practice and reported to laboratory management on the performance of the quality system in place and any non-conformities or requirements for improvement. The lead also supported immediate actions, where required, to resolve or reduce any risks of non-conformity or non-compliance that might arise.

Across the programme, a governance framework had been created for the laboratories to ensure high quality standards were maintained – by the validation team, as detailed in Figure 3, and the one within Laboratories Directorate team that reported directly to SLT, as detailed in Figure 4.

Figure 3. Overview of the laboratory quality assurance for CSO for England Oversight: testing technologies, validation and regulatory compliance

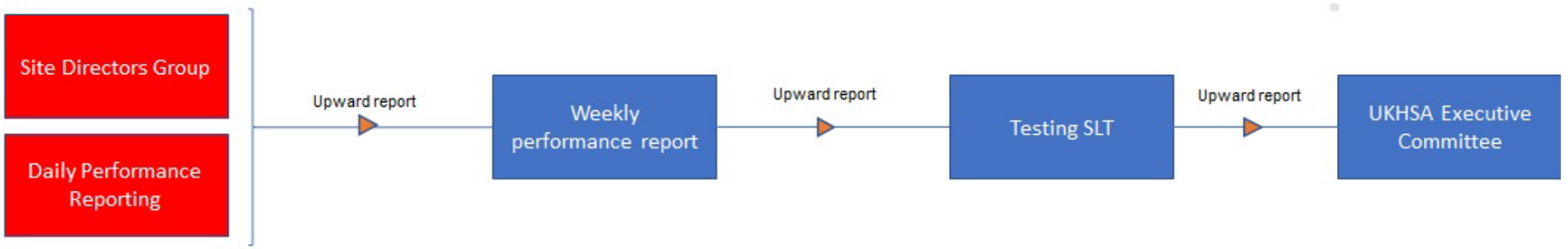
Accessible text version of Figure 3

The chart above gives an overview of the laboratory quality assurance for CSO for England oversight, Testing Technologies, Validation and Regulatory Compliance.

Clinical Advisory Leads Group and the Quality Assurance Leads Group report upwards to the Laboratory Validation and Assurance SMT and the Laboratory Performance Review Group.

They both report to CSO for England Oversight Group, who report to the Testing Operations Board, who report to UKHSA Senior Leadership.

Figure 4. Overview of the quality management system that was operational across the LHL network for England



Accessible text version of Figure 4

The chart above givesn an overview of the quality management system that was operational across the LHL network for England.

Site Directors' Group and Daily Performance Reporting is put into a weekly performance report and reported to the testing SLT, which then reports to the UKHSA executive committee.

At a high level, the initial key committees and governance fora for initial escalation were as follows:

1. Pillar 2 Quality Assurance Leads Group (QAL): This group was attended weekly by the Quality Assurance Leads from the validation team and Clinical Advisors from each laboratory across the network. The QAL was part of the national Testing Capacity Quality Assurance and Development Group and was responsible for assuring the quality and operational development of all Pillar 2 laboratories testing for SARS-CoV-2 within the programme. The QAL assured the standard of service delivered by network laboratories and continual monitoring of the service including oversight of service developments. Quality Leads reviewed and discussed quality issues, Key Performance Indicators (KPI) monitoring, and shared good practice and lessons learnt.
2. Site Directors meeting: All LH Laboratory site directors attended a twice weekly meeting, which was attended by the validation team where possible. This group was chaired by the Director of Laboratories and provided a forum for reporting, status updates, risk, and issues escalation.
3. Daily Performance Reporting: Performance was reviewed throughout the day and detailed views of the networks performance were reviewed by the team. Any identified issues were reviewed with the lab as actions from this meeting. Weekly laboratory performance meetings were held with each laboratory to present only their data and discuss individual performance or issues specific to the laboratory. The meeting was attended by operational leads or laboratory site director.

Oversight and escalation from the laboratory validation governance process was to the weekly Laboratory Validation and Assurance Senior Management Team (SMT) meeting and Laboratory Performance Review Group. Outputs were additionally reported into the Patient Safety Panel (PSP), detailed later in Section 4.2.3. The overall oversight of the Laboratory Performance Review Group including laboratory directors was to the Laboratories Directorate. Laboratory functions related to the Chief Scientific Officer for England/ Director of Testing Technologies, Validation and Regulatory Compliance reported on a weekly basis to the Chief Scientific Officer for England (CSO) Oversight Steering Group with further escalation to UKHSA Senior Leadership.

3.2.4 Pillar 2: laboratory monitoring and performance metrics

As outlined in sections 3.2.2 and 3.2.3, there was a robust governance and quality assurance system in place across the programme and laboratory network. Where risks or issues arose, there was a clear escalation and response process in place to mitigate and immediately action any required responses.

The Laboratories Directorate had oversight of laboratory performance metrics and results were monitored and reported daily. The results provided input to supporting dashboards across the programme. These dashboards supported assurance of quality through monitoring of trends and variation in, for example, positivity rates between laboratories and across the network. An

individual and summary laboratory report was sent to each laboratory with performance and issues discussed regularly. Additionally, laboratory performance reports were generated weekly for each laboratory with follow up discussions covering performance, capacity, incidents, issues, and escalations, if required.

For the positivity rates, the labs had a set of KPIs that were regularly reviewed. These included turnaround times and voids but also utilisation and sample positivity rate. The positivity had always been a feature of the labs' performance review but was restricted to one single data point being reported for all samples.

The UKHSA published a broader report into the improvements that have been made in the UKHSA's systems and processes since the Immensa incident to enable earlier detection of errors to occur. This report was published alongside the SUI report and can be viewed in full online: Improvements to UKHSA's systems and processes implemented since the Immensa incident.

The process of reporting positivity across the lab network was one of the areas that was strengthened and the revised process was fully implemented within weeks as part of the learnings from the Immensa incident. This meant the result could vary significantly due to the sample mix of channels with differing positivity rates. Hence, although monitoring was in place, the metric was not sufficiently sensitive to detect laboratory variances.

Post the Immensa issue, a new channel specific positivity dashboard was introduced that compared each labs daily positivity to the national average and with regional concurrence when more than one lab services a region. This was used to detect deviations from expected performance. This was reviewed daily by the Labs Team and weekly in a formalised review and approval for specific actions with epidemiological colleagues and the weekly Labs Board. Reviews and service improvements from incidents was a crucial aspect of effective governance and quality management. Performance reporting and metrics were adapted and developed as the network has evolved. Specific examples of development are outlined below.

1. Reporting Level Improvements: Changes to the reporting of laboratory performance through inclusion of positivity rates by testing channel and positivity output review within, for example, the organisation's daily programme dashboard. This was reviewed by the laboratory directorate senior leadership team with escalation of issues or risks if identified. Enhanced positivity reporting data is now further included as part of the weekly performance meetings with laboratories to support continuous improvement. The reporting also supported knowledge sharing across the network through analysis of appropriate comparative data on both a regional and cross-network basis.
2. Data Analytics and Strategic Reporting Improvements: Strategic reporting had been developed through the inclusion of an enhanced positivity dashboard including regional comparisons to identify differential trends with outbreak surveillance support. This had supported enhanced Key Performance Indicator (KPI) monitoring by laboratories through inclusion of daily positivity data.

3.2.5 Pillar 2: laboratory quality assurance audit

The Laboratory Quality Assurance Audit review was produced to ensure development and dissemination of quality management and assurance standards, policies and procedures for products and laboratories. For laboratories under review, these provided a minimal level of assurance, as the laboratories may not have been covered by UKAS accreditation. Laboratories were expected to provide evidence of delivery of training as appropriate for the competence of the staff undertaking processes and services provided, and provide assurance that the workforce is able to feed into operational frameworks and activity. For laboratories that were not UKAS accredited, they needed to provide evidence that operating standards, systems and processes were in place to support laboratory accreditation (either assured by the UKAS or on track to be accredited within a given timeframe) for COVID-19 testing and, in due course, wider future health threats. Reviewers of the audit checklists were qualified scientific advisors and were trained to have a particular focus on scientific elements – for example, validation, verification, training and overall operational readiness.

As part of the audit review Scientific Advisors undertook the review work with, and advise, laboratory Quality Managers and Clinical Advisors or Leads on all aspects of the audit checklists, with particular emphasis on providing raw data from validation and verification for their assays and equipment, and to provide support and advice on training and competency assessment. The advisors could also visit laboratories to provide feedback and guidance (as required). Although not routine practice, Scientific Advisors undertaking the review could engage with UKAS regarding a laboratory's registration for accreditation and timeline for accreditation. Through an existing disclosure agreement, UKAS were able to share with Scientific Advisors mutual disclosure of any initial non-conformities arising through UKAS inspections or Scientific Advisor site visits. Laboratories also had to provide progress reports on the laboratory readiness through agreed governance arrangements. Scientific Advisors could also assist with the preparation for audits with the MHRA (for example, Exceptional Use Authorisation or *In Vitro* Diagnostics CE regulations), and provided senior level scientific and quality assurance advice to relevant groups within the UKHSA – for example, onboarding teams and relationship managers.

Ongoing monitoring and reporting of laboratory and product KPIs was facilitated through agreed governance arrangements to identify early warning signals of possible non-conformities, and the review of change control forms that impact service delivery of SARS-COV-2 tests and sequencing providers. The Scientific Advisors informed relevant teams of changes that impacted on existing arrangements (for example, commercial, operational, bioinformatics, assay or lab validation).

In the event of an incident, Scientific Advisors could support the laboratories to determine product and/or laboratory failure root causes, and evaluate risk of failures, review and assist in investigating incidents, customer complaints and quality issues in relation to products and laboratories (qualitative/quantitative via KPIs). They could also interact with products suppliers and MHRA as required, track CAPA activities (for product and laboratories), and establish

meetings with the laboratories and the manufacturing /distribution supply chain to ensure corrective and preventative actions are in place and learnings are shared. They also ensured that reporting of quality incidents ‘from observation to resolution’ was accessible across Pillars, that this was appropriately governed, and the information was disseminated through learning lessons. Finally, they also supported the laboratories in promoting continuous improvement of quality processes through a program of internal auditing and feedback, and provide senior level scientific advice relating to policy, strategy and for the ongoing development or introduction of new standards.

4. Ensuring quality in testing services

The UKHSA Framework document with the Department of Health and Social Care (DHSC) set out the powers, duties and aims of UKHSA. As part of this framework, following merger of NHS Test and Trace under UKHSA, requirements and duties were placed on UKHSA to operate governance arrangements that align with good corporate governance practice and the applicable regulatory requirements and expectations. Good governance provided the key to effective leadership across UKHSA Testing Operations including meaningful challenge and accountability. The governance in place applied across the entire organisation including all testing services provided, or commissioned through, UKHSA.

4.1 National testing programme clinical governance for testing services

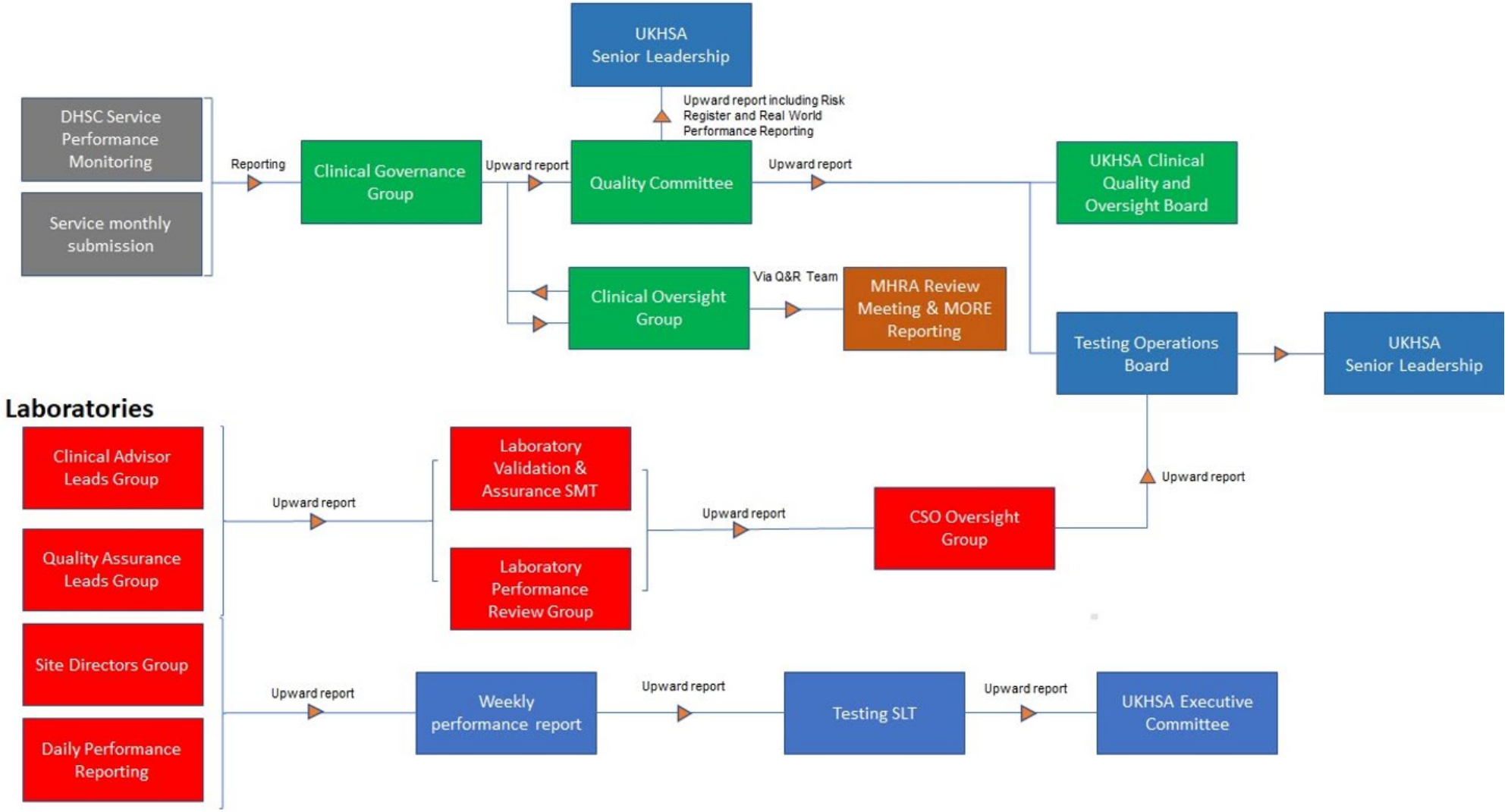
Effective quality assurance and management process with robust clinical governance frameworks were key to assuring quality services and regulatory compliance across the programme. These were established from the outset of the National Testing Programme and developed and evolved over the course of the pandemic. They had to adapt to the evolving requirements and changing landscape in which they operated.

Testing service settings included regular testing of groups such as health and social care, testing for events, or testing within educational institutions, workplaces, and community settings. The technology used depended on setting and symptom type, with molecular tests and antigen tests, specifically lateral flow devices (LFD), the main testing technologies currently in use.

4.1.1 Clinical governance and quality assurance overview

Clinical governance and quality assurance activity was designed to ensure robust and effective governance structures, systems and processes are in place. This framework provided the necessary safeguards to make sure testing services were operating in an environment where there was clear oversight and an assurance of safe, effective, and appropriate delivery of services. These covered testing activities to receipt of samples by laboratories and the return of results once issued by the laboratory. It did not cover subsequent public health activities, that is, contact tracing, which are under separate governance arrangements outside of the UKHSA testing programme. As part of ongoing assessment of services to ensure they remain fit for purpose within the current COVID-19 response, laboratory governance processes within the clinical governance framework were regularly reviewed. A high level overview of the clinical governance framework for testing is included in Figure 4.

Figure 5. Overview of the clinical governance framework for UKHSA Pillar 1 and Pillar 2 testing



Accessible version of Figure 5

The chart above gives an overview of the clinical governance framework for UKHSA Pillar 1 and Pillar 2 testing.

DHSC service performance monitoring and service monthly submission report to the clinical governance group who report to the quality committee and the clinical oversight group. The Clinical Oversight Group report to MHRA for review meetings and more reporting. The Quality Committee report the risk register and real-world performance to UKHSA senior leadership. The Quality Committee report to UKHSA Clinical Quality And Oversight Board and the Testing Operations Board. The testing operations board also report to UKHSA Senior leadership.

Laboratories - clinical advisor leads group, quality assurance leads group, site directors group and daily performance reporting report to the laboratory validation and assurance SMT and Laboratory Performance Review Group. These report to the CSO Oversight Group who report to the testing operations board who report to UKHSA Senior leadership.

Laboratories - clinical advisor leads Group, Quality Assurance Leads Group, Site Directors Group and the Daily Performance Reporting create a weekly performance report which goes to Testing SLT and is then reported to the UKHSA Executive Committee.

4.1.2 Clinical Governance Group

The Clinical Governance Group (CGG) was a governance safeguard for testing services to support and enhance the work of clinical processes and procedures detailed within the comprehensive standard operating procedures for testing services. The purpose of the group was to provide initial strategic direction and leadership of the clinical governance function of testing services for Pillar 2. This provided assurance to key stakeholders that services were being delivered in a safe, effective, and appropriate manner and to the defined quality standards.

Services followed clinical Standard Operating Procedures (SOP) that were regularly reviewed and updated in alignment with, for example, policy, clinical and public health guidance. Issues were escalated to the group where a systems-based approach was required or where repeat incidents suggest a systemic issue which would benefit from external scrutiny. These issues could include, although not limited to, those matters relating to user satisfaction, safeguarding, adverse clinical outcomes, clinical advice requirements, unwarranted variation in service delivery, and clinical audit programme reports.

The group functions were to review controls and assurances against relevant risks and assure the UKHSA Executive Committee that priority risks are managed. This was supported through the monitoring of external and internal assurance reports and action plans. Service duties towards maintaining Caldicott principles and safeguarding were also reviewed by the group.

4.1.3 Quality Committee

The next level within the Pillar 2 testing services clinical governance framework was the Quality Committee (QC). Membership included key senior stakeholders across public health and clinical oversight, quality service operations and laboratory operations.

The focus of the QC was to provide expert review of clinical governance and quality assurance activity to ensure appropriate governance structures, systems and processes were both in place and deployed effectively across the organisation. The CGG reported upward to the QC including escalation of outstanding matters. In addition to CGG upward report, the QC also received high level incident report notification and escalation. It was positioned to review the testing services quality and safety performance metrics dashboard, infection prevention and control reports, and provide input into the UKHSA Testing Operations organisational risk register for services.

Escalation and upward reported from the QC is to the UKHSA Clinical and Quality Oversight Board. Additionally, the QC reported to UKHSA Senior leadership on the latest organisational risk register for testing services and real-world performance monitoring reports.

4.1.4 Clinical Oversight Group

The purpose of the Clinical Oversight Group (COG) was to provide appropriate public health and clinical input and oversight of internal and external programme responses, including to regulatory agencies under UKHSA's role as IVD manufacturer and testing service provider/ distributor. This included conditions and requirements for the delivery of testing as well as oversight of the development and maintenance of post market surveillance planning, processes, and reporting. The group also input into the manufacturing requirements of UKHSA including, although not limited to, product labelling, instructions for use, and frequently asked questions to ensure they meet the public health and clinical requirements.

Membership of the group was reflective of its aims and purpose with weekly attendance including clinical, regulatory, governance and incident leads from across the programme. The group's aim was to support a continued drive of improvement in user experience, patient safety and public health outcomes. Critical review and appraisal of emerging evidence, for example new technology, was an essential focus area with recommendations made in line with service requirements and safe use. This included commissioning of new evidence generation activities where a gap is found to exist.

4.1.5 UKHSA Clinical Quality and Oversight Board

The UKHSA Clinical Quality and Oversight Board was the final level of escalation for the Executive Committee. The Board included members of the Executive Committee including the Chief Medical Advisor, UKHSA Chief Scientist, and Chief Operating Officer for Testing. It provided strategic oversight, scrutiny and assurance for clinical quality and clinical governance within UKHSA and was established by the Chief Executive of UKHSA. The Board reported directly to the UKHSA Executive Committee after each meeting and via annual reporting. The Board provided assurance on the clinical quality and safety of all services across the organisation and oversees clinical governance activity delivered within UKHSA. This supported assurance of organisation compliance with regulatory standards relating to clinical quality, patient safety, and safeguarding. The Board aimed to provide a supportive environment for incidents to be escalated in addition to any serious concerns identified related to quality and safety of care in the services provided.

As a multi-directorate Board, input was additionally received from across the programme including safeguarding, medicines governance, incident management, clinical audit, patient feedback, public feedback, and professional development.

All aspects of clinical quality, governance, safety, and safeguarding were represented in reporting for the Board and progress on all of these was monitored closely. Where a serious adverse incident or issue was raised, progress to resolution was also monitored. Where a multi-directorate response was required, the Board had the option to appoint an incident manager to lead on these incidents.

4.2 Clinical incident response process for UKHSA Testing Operations services

A robust incident response process was essential to the safe, effective, and appropriate functioning of the programme and testing services. Incidents could manifest in a diverse number of ways requiring a coordinated management process to ensure a timely and effective response. Apparently minor local incidents could have a major impact due to the large number of individuals tested. If a problem was widespread, there could be an impact on the population and testing could do more harm than good. Incidents could affect the whole testing service and may not be localised to a department or provider organisation in which the issue occurs. They may have involved several organisations across geographical boundaries and could affect public confidence in testing services.

It should be noted that the processes and mechanisms outlined for incident management and reporting, whilst accurate at time of writing, are subject to ongoing review and evolution.

4.2.1 Scope and responsibilities of the clinical incident response process

The incident response process was designed to ensure actions initiated were proportional to the risk of harm based on accurate and prompt investigation. The primary objective was to provide a consistent process to managing incidents to ensure clinical incidents were recorded accurately, prioritised and handled in an appropriate sequence and timescale, mitigating activities put in place, and a post-mitigation risk assessment completed to determine the residual risk and ensure high standards of safety are maintained throughout.

An incident could be raised by anyone working in the programme, providing support, or otherwise indirectly involved. Incidents may also have been raised through service and device feedback mechanisms including citizen complaints (including the 119 service), device complaints, and regular survey (including Qualtrics survey).

Individuals had a responsibility to report any clinical safety incidents that they become aware of and was done with the support of a qualified clinician or other appropriate health care professional. Incidents raised could include, but were not limited to, clinical safety incidents that the individual has been involved in, incidents that they may have witnessed, incidents that caused no harm (a ‘near miss’), or incidents with a more serious outcome.

Table 1 provides a high-level outline of the functional areas and assigned responsibilities once an incident has been reported into the programme.

Table 1. Clinical incident response roles and responsibilities

Role	Responsibilities
Incident Reporter	This was the individual who reported the incident through any of the designated channels.
Service channels	Service channels were required to have a dedicated function to be able to respond to incidents with clear accountabilities for ensuring incident reporting occurs. The team was required to assign roles and implement mechanisms to monitor and investigate incidents occurring within the service and ensure steps taken to resolve an incident follow correct procedure. Services were responsible for escalating incidents to key stakeholders and programme leads.
Control Tower	This team was assigned to monitor and investigate incidents occurring within Test supply and logistics. The Control Tower ensures steps taken to resolve incidents follow correct procedure. They are also responsible for recording incidents, initiating investigations, documenting outcomes, and monitoring agreed remediation activities. The team was responsible for escalating incidents with key stakeholders and programme leads.
The Integrator	The Integrator was a cross-cutting team ensuring transparent communication, appropriate triage, escalation, and co-ordination of routine and non-routine incidents across Pillar 2 testing. The Integrator reported upwards on incidents through the integrator report to key stakeholders and committees within quality and clinical governance.
Patient Safety Panel (PSP)	The PSP was embedded as a function of the Integrator. The panel directly oversaw and coordinated aspects of patient safety and clinical governance activity relating to incident management. The panel had a responsibility to minimise patient safety incidents and drive improvements in safety and quality across the programme.
Security Operations Centre (SOC)	SOC coordinated and managed immediate incident response where an incident was categorised as either a P1 or P2 incident and requires cross-directorate input.
Quality and Regulatory	Incident dependent regulatory and quality assurance support and input.
Clinical Leads	Ensured that all clinical impact was considered and highlighted any clinical risks as part of the clinical incident investigation. They advised the Clinical Safety Officer.
Subject Matter Experts	Subject Matter Experts (SME) ensured investigation and impact analysis were carried out correctly. If actions were assigned to these individuals, they ensured that these were completed within the required timeframe.

4.2.2 Assessing and managing clinical incidents

The clinical safety incident management process incorporated a framework and procedure to ensure all incidents were managed appropriately and in a timely manner. The service identified the incident was required to seek advice and consider whether the incident met the definition of a clinical incident and/ or serious incident. Isolated minor events, with little or no safety risk, which will not reoccur locally, were resolved by the service provider and channel lead through the service incident management teams. Supply and logistics incidents were managed through the Control Tower. The clinical incident management process was followed whether the incident relates to, for example, a device, manufacture and supply, or service delivery. Device incidents were reported to the MHRA via the Regulatory and Quality team.

The Integrator team oversaw and managed incidents across Pillar 2 testing. This included triage, escalation, and co-ordination of routine and non-routine incidents. Escalation was dependent on the priority category of an incident with P4 the lowest priority category and P1 the highest category requiring immediate action and response, as outlined in Table 2.

Table 2. Triage and prioritisation categories for incidents raised and examples

Category	Type of incident	Examples of incidents
P1	Risk to life Serious physical assault on Staff and/or Public Complete cessation of testing service Catastrophic disruption to user experience High risk of reputational damage, financial or legal issues	Death G.B.H. or serious injury Programme halted Booking portal unavailable Results voided Missing MedDx box Swab stuck in throat
P2	Actual physical assault on Staff and/or Public Major testing service disruption (7 people or more) Major disruption to user experience Serious property damage	A.B.H. or physical violence Service standards may be compromised Serious property damage Users re-directed for test
P3	Threat of physical assault on staff and/or public Minor testing service disruption (6 people or less) Potential risk to user experience Minor operational or technical issue affecting part of service Actual or perceived protest	Credible or perceived threat to harm staff, public or property Theft or vandalism Minor property damage Protest Programme can continue but workaround is needed Partial site closure

Category	Type of incident	Examples of incidents
		Anything related to protests, actual or perceived
P4	Verbal assault or anti- Social Behaviour to staff and/or public Recurring minor issues Minimal risk to user experience Negligible risk of reputational damage, financial or legal issues	Verbal abuse, uncooperative behaviour Drug dealing Minor issues usually fixable – escalate if multiple incidents Suspicious courier activity
Risk Factor (RF)	An event that may affect the service in the future	Positive case at site
Non-Incident (NI)	There is no effect on the service	Suspected positive case at site – monitor Low stock but replenished in time

The incident management process was designed to achieve the following outcomes:

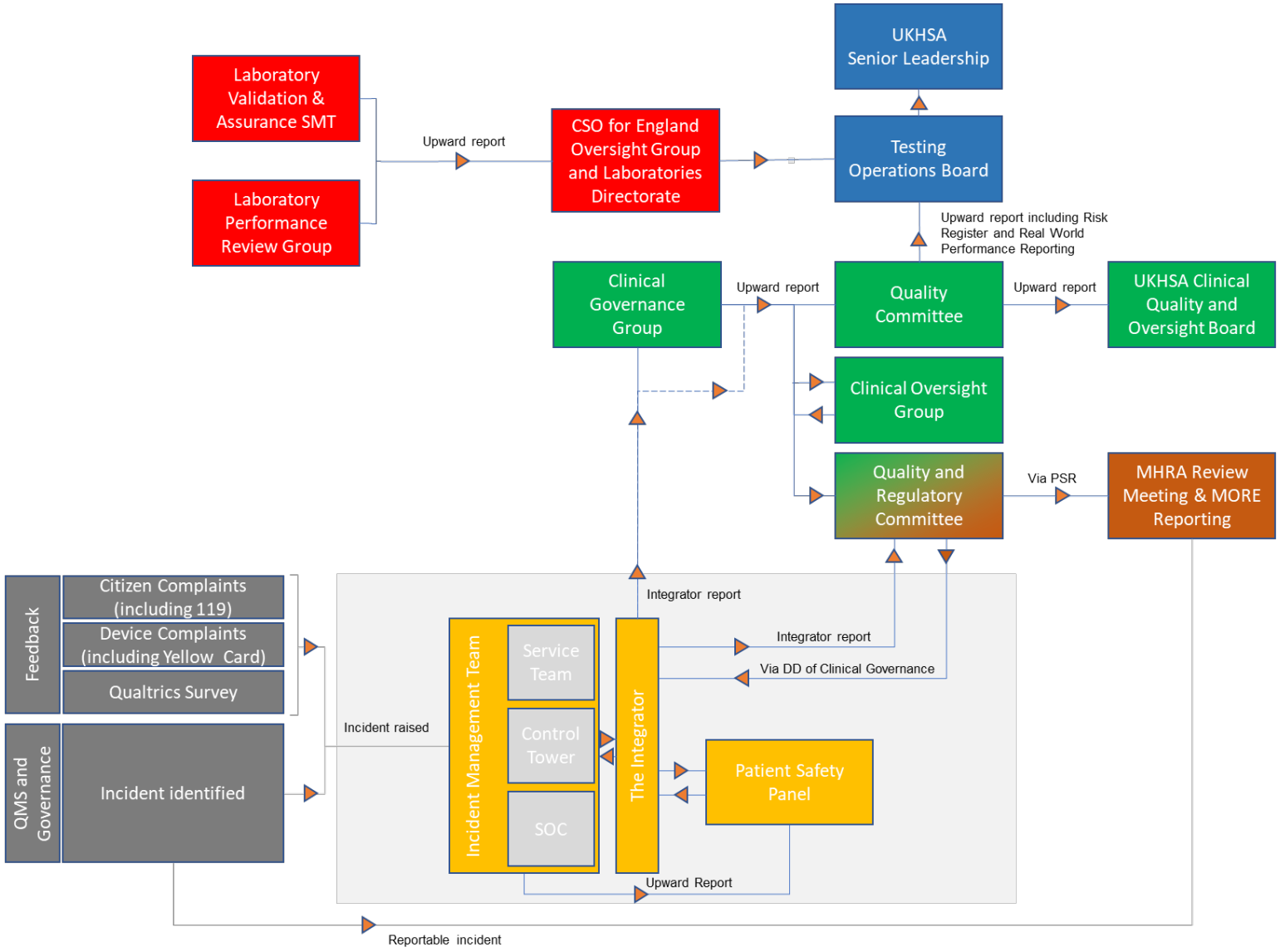
- to take immediate action, where required, to make the testing service safe
- produce and implement an action plan to manage the consequences of a problem or incident, including its impact on members of the public, services and staff
- establish the root causes of the incident
- oversee the progress of the recovery actions
- agree timescales for closure of the incident
- identify lessons to be learnt from the incident and its handling

The Security Operations Centre (SOC) supported an immediate management response with cross-directorate communication for serious incidents categorised as P1 (or P2 in certain circumstances). The purpose of SOC was to provide additional support to service incident teams or the control tower for these incidents to ensure swift and immediate actions to prevent or mitigate harm. SOC does not apply to Pillar 1 testing, where incidents supported and coordinated within the UKHSA laboratory or within NHS laboratories. Where required and appropriate, incidents were escalated to the incident management process.
Once an investigation was complete, an investigation report was produced and signed off by key stakeholders. The report was reviewed, and any actions and recommendations monitored by channel governance processes detailed in Section 4.2.3.

4.2.3 Governance framework for clinical incident management

As outlined in Section 4.2.2, the incident management process was coordinated by the Integrator team. Incidents raised from across Pillar 2 were reviewed by the Integrator team to ensure appropriate response with cross-directorate escalation and involvement where required. An overview of the framework is included in Figure 6.

Figure 6. Overview of the clinical incident management framework for testing services, supply chain, and device manufacturing under Pillar 2



Accessible text version of Figure 7

The flowchart above shows the overview of the clinical incident management framework for testing services, supply chain, and device manufacturing under Pillar 2.

Laboratory Validation And Assurance SMT and Laboratory Performance Review Group report to CSO for England Oversight Group And Laboratories Directorate, who report to testing operations board who report to UKHSA Senior leadership.

Feedback - citizen complaints including 119, device complaints including yellow card and Qualtrics survey incidents are raised to the Incident Management Team, which includes the Service Team, Control Tower and SOC. The Incident Management Team report to the Patient Safety Panel but also between the integrator.

QMS and Governance – Incident is identified and raised to the Incident Management Team which includes the Service Team, Control Tower and SOC. The Incident Management Team reports to the patient safety panel but also between the Integrator. Reportable incidents are reported to MHRA review meeting and MORE reporting.

The Integrator reports to the Clinical Governance Group, the Quality Committee, the Clinical Oversight Group and the Quality And Regulatory Committee. The Quality And Regulatory Committee reports via PSR to the MHRA Review Meeting and MORE reporting. The Quality Committee reports to the UKHSA Clinical and Oversight Board and the Testing Operations Board who report to UKHSA senior leadership.

The Integrator Team reported directly into the CGG, Quality Committee, and the Patient Safety Panel (PSP). The PSP was established to oversee and coordinate aspects of patient safety and clinical governance activity related to incident management, minimising patient safety incidents and driving improvements in safety and quality across the programme.

The PSP met weekly and received escalations from the Integrator team related to patient safety risks, themes, trends, and closure of serious incident action plans. The panel was responsible for review of the clinical risks and to ensure appropriate actions, mitigations and assurance is in place. The panel also oversaw the development and implementation of patient safety and quality assurance strategies to ensure sound systems for clinical governance were in place.

The panel was accountable to the Clinical Governance Group (CGG) and Quality Committee (QC) with responsibility to escalate any issues which may have a potential impact on service delivery to the QC. The QC would also feedback into ongoing incident management process through this panel.

4.3 Quality assurance audit of national testing programme test sites

Testing sites were commissioned to provide testing services nationally and ensure assisted testing is available and accessible to all. Sites may have been located within any service setting (for example, schools and workplaces) or provided as part of the national testing service for the public. Sites were categorised according to their size and operating model. The main types of testing site were:

- regional testing site (RTS)
- local testing site (LTS)
- mobile testing unit (MTU)
- asymptomatic testing site (ATS)

UKHSA had a responsibility to ensure that these services and sites were compliant with current legislation, relevant assessment of necessary standards, guidance, and best practice. The assurance for this was through the robust clinical governance system in place across the organisation, as detailed in Section 4.1. Additionally, for testing sites, regular audit was performed as part of clinical governance. The audit assessed compliance and understanding across a range of processes in place, as detailed in Table 3. These national audits did not replace local audit already performed at sites.

Table 3. Areas of focus during audit of national programme testing sites

Category	Description
Effectiveness	To ensure there was a designated staff member to oversee quality and clinical governance processes, measures to assess compliance with Standard Operating Procedures (SOP), clear escalation and decision processes, and internal quality assurance (including learning from incidents).
Experience	Audit and review of the test site experience from site staff and the public.
Training	To provide assurance training was performed to a high standard, professional development and currency of training maintained, and appropriate feedback mechanisms were in place.
Safeguarding	All sites were required to have safeguarding training and reporting procedures in place to ensure relevant concerns are dealt with appropriately. This included Disclosure and Barring Service (DBS) check for staff members.
Safety	Assurance that appropriate incident management policies, escalation, training and learning mechanisms were in place. Assurance that appropriate infection control, hygiene and waste facilities were in place and correct processes followed.

The testing site audit process included review of site evidence to assess compliance with relevant Standard Operating Procedures (SOP), legislation, infection prevention and control, training, and safety requirements. This was conducted through observational audit, interviews, service user commentary, and review of available compliance evidence. The overall aim was to review actions, governance and assurance processes that had been implemented and acknowledge risks and any gaps in the management to facilitate organisational learning and future planning and mitigation.

Following review, a report was compiled inclusive of the assessment scores and recommendations for improvement and future learning. Reports were reviewed at the Clinical Governance Group, detailed in Section 4.1.2.

4.4 Evaluation and monitoring of testing initiatives and services

Evaluation was an essential and integral component of planning and operating testing services across UKHSA. This programme of evaluation ensured appropriate insight, scrutiny, and service improvement at all stages.

4.4.1 Pilot initiatives and enduring testing service evaluation

Pilots were initially created for proposed services with evaluation a key component of these. Areas of evaluation included assessment of impact, areas that work well, and areas where improvements could be made. Planned evaluation outputs from pilots were confirmed at the Implementation Readiness Working Group (previously known as the Pilot Review Board) – following prior ratification of clinical and public health outcomes. Ongoing evaluation was embedded within the pilots if they moved to an enduring service operating model to ensure continuous understanding of performance and to provide the appropriate level of quality assurance. Areas of evaluation were grouped into 5 key themes, outlined in Table 4.

Table 4. Testing initiatives evaluation framework for pilot initiatives and enduring service operating models

Evaluation theme		Example topic areas
	1. Operational feasibility	Are we able to establish and safely run testing in this setting? Is it acceptable to users? Is there potential to scale up?
	2. Scientific knowledge	Does the application of this technology and/or intervention give the outcomes we were expecting in a real-life setting?
	3. Public health effectiveness	Does this testing service help us to find and contain infection, keeping the population healthier?
	4. Behavioural factors	Why do people agree or decline to be tested? How do people respond to a positive/negative test result?
	5. Broader societal impact	Is there an associated benefit for businesses, institutions, public services, the local community, the national economy? Does this testing service allow us to keep people at work or in education, support commerce, reduce support requirements?

All pilots and services were required to plan and execute this programme of evaluation as a core aspect of delivery according to programme management disciplines. Internal analysis and quality management, with wider peer-to-peer learning and knowledge sharing across the scientific and academic community, were fundamental to this.

4.4.2 Governance of evaluation across the national testing programme

There was a system in place to support evaluation and generation of evidence across testing services, as detailed in Section 4.4.1. Governance and oversight of this system was essential to ensure evidence generated is of high quality and achieves the objectives set.

The Testing Initiatives and Evaluation Board (TIEB) was formed to oversee and scrutinise evaluation methods and outputs from pilots and services. The Board convened on a fortnightly basis and was attended by 3 main groups:

1. Senior management leads from across UKHSA Testing Operations and cross-cutting programme and policy teams.
2. External academic specialists from across public health, infectious disease, virology, microbiology, epidemiology, biostatistics, and behavioural science. This group also includes nominated local Directors of Public Health.
3. Data, analytics, and relevant service teams when required.

The TIEB provided clear quality assurance for the evaluation process including evidence methodology, analysis, and outcomes. It enabled board members to have visibility on protocols and pilot design and to provided the appropriate specialist advice and approvals on end evaluation outputs. The board supported shaping of evaluation across the programme and aided alignment of design with outcome expectations.

Outcomes of testing initiative evaluations were published on a regular basis by both internal and external stakeholders. Published materials are accessible online through GOV.UK, KnowledgeHub and from associated partners including University of Liverpool and University of Oxford.

4.4.3 Ongoing performance monitoring and real-world data evaluation

UKHSA Testing Operations operated a routine programme of post-market surveillance (PMS) to monitor the ongoing performance of products used in each setting and respective populations. This was inclusive of LFD devices and RT-PCR, EPCR, LAMP sample collection kits where UKHSA was a manufacturer. This programme supported assurance of quality standards across service settings and was a component of the broader clinical governance service requirements. Outputs additionally formed part of UKHSA regulatory reporting responsibilities, as detailed later in Section 5.4.

Ongoing performance evaluation comprised retrospective monitoring of performance by product and setting, using ‘real-world’ data[6], and prospective ongoing clinical evaluation. It was carried out alongside UKHSA *in vitro* validation, as detailed later in Section 5.5, and was comprised of the analysis streams detailed in Table 5.

[6] Real world data refers to data that is captured through retrospective analysis of all testing outcomes within test services. This data is not gathered under specific prospective evaluation protocols or under paired testing regime conditions.

Table 5. Analysis streams for ongoing performance monitoring and real-world data evaluation

Analysis stream	Description
Routine monitoring of performance using real-world data from asymptomatic testing services.	Weekly analysis of real-world data captured through analysis of testing within test services. This was to monitor key indicators including, for example, positive test result rates, test void rates and the rate at which RT-PCR testing confirmed an initial positive LFD result[7]. All analysis is segmented by test device, service setting and location. Reported results were used within UKHSA governance structures to identify early any areas of reduced performance requiring further investigation.
Prospective 'Ongoing Evaluation' of device performance in comparison to RT-PCR.	This was an ongoing prospective study of device performance in test service settings. Participants were consented and recruited through the asymptomatic testing services. They were asked to provide 2 samples, one for RT-PCR testing and one for LFD testing, 'paired testing'. Paired tests results were compared at set intervals to provide an ongoing estimate of device performance for each test service.
Retrospective analysis of routinely collected paired LFD and RT-PCR testing regime data.	Certain UKHSA testing services, including Adult Social Care (ASC), used a 'paired test' testing regime on a routine basis. Each individual performed both a RT-PCR and an LFD test on the same day. Data from these services was compared to estimate device performance in relation to RT-PCR. A large number of these samples were genomically sequenced which allowed for monitoring of device performance against new variants.
Prospective service evaluation.	When required, UKHSA commissioned prospective service evaluations in defined locations to address specific outstanding questions.

Through continually monitoring performance outcomes in the real-world setting, comparison could be made to initial estimates on which decisions for device deployment were made and to detect any early signals of a change in performance and quality of service.

[7] In England, from 11 January 2022, confirmatory RT-PCR tests for positive lateral flow device (LFD) test results were temporarily suspended. Individuals who had received a positive LFD test result for coronavirus were required to self-isolate immediately and not required to take a confirmatory RT-PCR test from this date.

4.5 UKHSA Testing Operations digital content and process assurance

UKHSA worked with a number of teams, NHS organisations, and public bodies to ensure digital content and the end-to-end digital processes are current, safe, effective and ultimately fulfil the high quality standards required.

1. Digital processes comprised the end-to-end journey from initial guidance, registering and ordering a COVID-19 test, processing and data management, through to an individual's receipt of their result.
2. Digital content assurance supported public health, clinical and policy review of guidance and messaging provided through digital channels inclusive of results messaging.

4.5.1 Digital process assurance for the end-to-end digital journey

The end-to-end digital journey for the public and UKHSA testing service teams was critical for the successful operation of the service. UKHSA worked in partnership with NHS Digital (NHSD) to ensure hazards and risks associated with the service were continuously monitored, logged, and mitigated – inclusive of new systems or processes. Assessments were subject orientated and included all interactions an individual may have with the relevant systems.

A Health IT System was defined as a product used to provide electronic information for health or social care purposes. The product may have included hardware, software or a combination of both. There were 2 main standards requiring compliance by UKHSA under Section 250 of the Health and Social Care Act 2012:

1. DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems. This standard was designed to help manufacturers of health IT software evidence the clinical safety of their products, it provided a set of requirements suitably structured to promote and ensure the effective application of clinical risk management by those organisations that are responsible for the development and maintenance of Health IT Systems for use within the health and care environment.

2. DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems. This standard provided a set of requirements suitably structured to promote and ensure the effective application of clinical risk management by those health organisations that are responsible for the deployment, use, maintenance or decommissioning of Health IT Systems within the health and care environment.

The DCB0129 and DCB0160 standards contain 7 key components:

- general requirements for clinical risk management
- project safety documentation and depositories

- clinical risk analysis
- clinical risk evaluation
- clinical risk control
- current position
- delivery, monitoring and modification

NHSD provided a digital service on behalf of the UKHSA national testing programme. This included working with partners and third parties to oversee the design, delivery, deployment and maintenance of the testing platforms, including the website members of the public use if they wish to book a test. They also worked with a broad range of system suppliers and service providers across the end-to-end journey for testing, from booking a test through to communicating test results.

NHSD employed accredited Clinical Safety Officers (also known as a CSO) who led the multidisciplinary team with regard to the requirements of the regulatory standards on behalf of the UKHSA testing programme. Public Health and Clinical Oversight (PHCO), UKHSA, maintained the role with regard to the acceptance of risks of these standards for those systems delivering testing, on behalf of UKHSA Testing Operations. PHCO worked with NHSD to understand prospective and current hazards within current or planned clinical digital systems, identifying any mitigating actions required to reduce the risks to an acceptable level. The hazards were reviewed on a fortnightly basis and monitored through the clinical governance framework. A fortnightly risk register to the UKHSA Testing Executive Committee was submitted routinely. A routine update was provided to the Clinical Governance Group (Section 4.1.2) with escalations made to the Quality Committee (Section 4.1.3).

Initiation and development of new digital journeys, or a change to a digital journey, in UKHSA Testing Operations required a robust assurance process to ensure, for example, anticipated public health outcomes are maximised, risks reduced, consistency across the programme and a positive user experience. Digital journeys that this applied to were broad and inclusive of ordering tests, user sourcing of clinical and policy guidance, and reporting and receiving results through predominantly the UKHSA, GOV.UK, NHSD and NHS.UK content delivery channels.

Public health and policy teams were critical to the successful delivery and optimisation of public health outcomes. New policy was defined, and user journey language was reviewed to ensure alignment. Behavioural insight teams conducted user research and evaluation on the optimum user journey and content language. Throughout this process, clinical, public health and policy teams were involved in addition to legal, communications, and design teams. Through this multidisciplinary approach, digital user journeys were assured to be both consistent and in alignment with public health requirements and policy. The consistency supported reduction in risk and optimisation of public health outcomes.

4.5.2 Digital assurance for content channels

Guidance and content available through digital channels was subject to a comprehensive process of robust review and quality assurance. This was inclusive of new content, changes to content, archive and cessation of guidance where new content is to be made available. Key areas of content include UKHSA, GOV.UK, NHSD, and NHS.UK provided guidance and information for COVID-19 testing and policy. Content was reviewed by all areas of the multi-disciplinary team to ensure policy and public health adherence. This included policy, legal, clinical, communications, and design teams. Weekly meetings with UKHSA, NHSD, and NHS.UK teams had been established to review content and met more frequently when required. Through the digital content governance and assurance process the content provided by digital channels was assured to be consistent and optimised for public health and policy requirements. This had the impact of reducing risk and optimising the user experience and understanding of requirements.

The way an individual's result was communicated could impact their response and understanding. It was imperative for public health objectives, and the prevention of transmission, to ensure robust clinical and policy review of communications prior to deployment. Additionally, NHSD content and results messaging was supported by the behavioural insights team. The team was commissioned to identify optimal communication methods and terminology to support understanding to ensure the highest impact which could include additional areas such as nudge communication research and user insights.

5. Ensuring quality in testing devices

UKHSA operated and commissioned testing services across a variety of settings for both asymptomatic and symptomatic individuals within Pillar 1 and 2 testing with test kits additionally supplied to organisations and NHS bodies. This required validation and quality assurance of a range of technologies and devices to support testing at scale. The main technologies used across the programme are molecular detection, such as RT-PCR, EPCR, and LAMP performed in either a laboratory setting or at point of care, and antigen detection, such as LFD, performed outside the laboratory setting in a designated test setting or at home. Whilst Coronavirus Test Device Approvals (CTDA) was not used as a means of selecting tests for use in UKHSA laboratories and services, it could be in the future once there are a range of approved tests. If the selection for future procurement aligns with CTDA requirements, it can alternatively be ensured that tests are procured can be approved under CTDA.

The testing programme operated at scale to provide a service that was available for all individuals to access. In its role, UKHSA, through the Department of Health and Social Care (DHSC), was also IVD manufacturer for specific products including sample collection kits for RT-PCR, EPCR, and LAMP and antigen detecting devices, for example LFD. If a testing service takes on the role of legal manufacturer, then the regulations that cover manufacturing become obligations.

Maintaining a documented quality management system and assurance programme was an essential requirement of UKHSA. The purpose of these was to ensure all aspects of validation, design and manufacture of products is planned, performed, and monitored in a well-defined and controlled environment with capable processes in place for the verification and assurance of product quality and performance.

5.1 Pre-deployment evaluation process

Pre-deployment validation of technologies and test kits used in the national testing programme was a core requirement to ensure quality across the network. The systems and processes in place were designed to assure the programme that all products and technologies comply with regulatory requirements and standards set by UKHSA. These standards included minimum performance requirements (for example, sensitivity and specificity) and, if relevant, comparison of candidate assays prior to selection for procurement and deployment.

5.1.1 Validation of testing technologies, molecular assays and process overview

In March 2020, testing technologies and molecular assays for SARS-CoV-2 were limited and in development. Initially, for molecular assays as part of laboratory testing, PHE provided guidance on preferred commercial kits which were CE marked. Laboratories had to ensure in-

house assays that were to be used had met locally agreed acceptance criteria, according to local quality management systems for validation, prior to deployment and patient use. As testing capacity for SARS-CoV-2 needed to scale, and new technologies were developed, the New Technologies Assessment Group (NTAG) and the Virus Detection Technology Assessment Group (VTAG) were formed. NTAG focused on assessment of serology tests (for example, coronavirus antibodies) and VTAG focused on assessment of technology for the detection of SARS-CoV-2. In the summer of 2020, the Technology Validation Group (TVG) was formed and incorporated the roles and remit previously performed under VTAG and NTAG. The exception to this was assessment and review of Lateral Flow Devices for detection of SARS-CoV-2 which was maintained under the remit of NHS Test and Trace and Public Health England (PHE) overseen by the Lateral Flow Oversight Group, see Section 5.1.3 for further details.

With the creation of UKHSA in October 2021, TVG moved under the new Testing Technology Validation Team (TTV) within UKHSA, a subgroup of the Chief Scientific Office for England (CSO), having previously reported into NHS Test and Trace under DHSC. The TTV programme was responsible for the expansion of the UK's COVID-19 and SARS-CoV-2 testing abilities and was made up of Scientific Advisors and Project and Service Delivery Professionals, split into the following teams:

- Coronavirus Testing Devices Approval team (CTDA)
- Technologies Validation Group (TVG)
- Business Unit

Technologies Validation Group (TVG)

A range of testing technologies were considered for use across the national testing programme. As part of this assessment process, it was imperative that there was adequate and scientifically robust data to support these assessment activities prior to procurement and deployment to ensure technologies were fit for purpose for the specific applications required.

The TVG was brought together as a representative group of the 4 nations with the specific objective of reviewing all testing technologies considered for the programme, working closely with the Medicines and Regulatory Healthcare products Regulatory Authority (MHRA). TVG provided a central mechanism for an informed, pragmatic review of available scientific, clinical and operational data on testing solutions proposed for use across the testing programme (for Lateral Flow Devices, see Section 5.1.3). The work incorporated a scientific advisory subgroup (Expert Panel), with representation across the 4 nations, to undertake detailed assessment of information on solutions and technologies submitted. For example, this reviewing evidence that a molecular assay performance evidence is in line with use case testing standards and meets the requirements of the target product profile or reviewing evidence on the reproducibility of assay performance. This mechanism facilitated agreement if the available data met agreed standards to allow the solution to be adopted for a required use case and, if not, what further data was necessary. The group was able to then recommend on the suitability of a testing option for deployment, based on accuracy and validation of the data, and advise on the

potential use cases for the testing options that could be deployed. Quality assurance on solutions deployed was maintained through a process of revisiting evaluations within agreed timescales.

As part of the validation process, TVG were able to identify where further validation or studies (including usability studies) were needed. This could include, for example, further validation evidence on cross-reactivity with other coronaviruses and other pathogens or non-specific reactivity of oligonucleotides that may cause artificial signals. The TVG construct would agree on the nature of the validation required and outline next steps and timelines for delivery and accountability in the context of the priorities for the overall programme. As such, TVG was additionally placed to provide a supportive interface between groups developing novel testing technologies and the broader national testing programme.

As new technologies and testing solutions were developed, a Target Product Profile was required to support standardisation of requirements. TVG worked with the MHRA on potential Target Product Profiles (TPPs) requiring development, including for molecular assays. MHRA meetings were also established through the Quality and Regulatory team with the formalisation of weekly A and B meetings in the latter half of 2020.

Coronavirus Testing Devices Approval team (CTDA)

Experience from the Technologies Validation Group (TVG) showed that approximately 75% of tests evaluated failed an initial desktop review, due to poor quality evidence supporting the performance claims. To protect the public from the market deployment of poorly performing tests, the Coronavirus Test Devices Approvals (CTDA) amendment was made under Section 15 of the Medicines and Medical Devices Act 2021. CTDA is a UK wide regulation that came into force on 28 July 2021, requiring antigen and molecular detection SARS-CoV-2 tests to reach minimum performance requirements through a thorough assessment of evidence by UKHSA scientists before sale on the UK Market. The regulation ensured all tests sold on the market are fit for purpose with successful tests published publicly on an approved device register on GOV.UK for consumers to consult.

CTDA applied to all molecular diagnostic or antigen tests, irrespective of the detection technology used, the sample type or the environment in which the test is carried out (the use of algorithms to analyse the data is also in scope). The SARS-CoV-2 component of tests that include detection of multiple pathogens was also within scope, while the detection of the other pathogens was out of scope. Tests that rely on a host response, for example, the measurement of volatile organic compounds in breath or cytokines in blood, were out of scope.

CTDA set minimum standards in specificity and sensitivity that a test must achieve for each of 3 technology types: extracted molecular, direct molecular, and antigen test. The thresholds for passing CTDA had been calculated assuming comparison to a suitable comparator RT-PCR assay and inclusion of samples covering the full range of viral loads.

These thresholds were:

- an antigen test (for example, lateral flow) must be at least 60% accurate in identifying positive samples, and at least 93% accurate in identifying negative samples
- a direct molecular test (for example, point-of-care PCR) must be at least 70% accurate in identifying positive samples, and at least 93% accurate in identifying negative samples
- an extracted molecular test (for example, RT-PCR) must be at least 93% accurate in identifying positive samples, and at least 97% accurate in identifying negative samples

The CTDA evaluation, in the form of a desktop review, required suppliers to provide specific information about their test. In particular, data on the sensitivity and specificity of the test when used in accordance with the device Instructions For Use (IFU) – that is, using the correct clinical samples listed, including self-test samples for self-test devices. Guidance on the information required for the desktop review is published on GOV.UK and covers:

- manufacturer and test information
- regulatory status
- intended use case
- test performance
- biosafety

The guidance also gives details of acceptable comparator assays and evidence must include samples across a wide range of viral loads, including samples with low viral loads. Only true clinical samples are accepted (CTDA does not accept contrived samples). The assessment was done in 3 steps:

1. Review of performance data by a scientific adviser, with peer review by a second scientific advisor, against the minimum required data set.
2. Quality assurance group assessment of the submission.
3. Consideration by the regulatory approvals committee.

The result of the evaluation was signed off by an oversight group that included representatives from DHSC and MHRA, and approved tests added to a register on GOV.UK. Any test that had not been approved was not permitted to be sold in the UK, unless there was an allowable exemption – exemptions included it only being sold to DHSC, or the Devolved Administrations, or being procured under a contract that pre-dated 28 July 2021. As this is a goods regulation, a valid CE/UKCA mark was required for CTDA approval

As of 14 March 2022, a total of 219 applications had been received, with 33 test devices approved; 21 approvals were extracted molecular, 9 direct molecular and 3 antigen devices.

5.1.2 Molecular assay sample collection kit validation process for procurement into the national testing programme

Molecular assay sample collection kits were sourced and procured from a number of suppliers to provide the capacity required and to ensure supply resilience across the programme. All new supplier leads that have passed initial specification and compatibility checks were progressed through a robust assessment review process to ensure conformity to the expected standards and regulatory requirements. The MHRA provided further regulatory review where issues had been raised as part of this process.

Where a supplier had passed verification and compatibility assessment, the product was progressed according to priority onto the next stage. For sample collection kits, these would be procured as either a complete kit or may require a combination of product parts from different suppliers. Where a kit was formed from multiple constituent parts, UKHSA assumes the role of manufacturer as the product is a new device. Once compatibility had been assured, either through a complete kit or combination kit, the product progresses to the next stage of validation according to priority.

The next stage of validation was a multi-step process with the aim of ensuring sample collection kits are appropriate for use in the settings where they are used. Since the start of the pandemic, UKHSA had streamlined this process to allow for efficient and controlled roll-out of any new test kit product. Once the product had met specification, compatibility, regulatory, and due diligence requirements, a decision could be made to progress the product through to the next stage. UKHSA ran a series of validation stages in collaboration with the UKHSA Lighthouse Laboratories. The stages were Scientific Validation, Operational Validation, Clinical Validation, and Assay Verification.

1. Scientific Validation: This stage assessed whether, under controlled laboratory conditions, the test kit can function against set criteria including viral RNA survival time in the test kit, detection level verification as per specifications, and requirements for sterility of the product.
2. Operational Validation: The operational specifications and requirements of the product were assessed. Included in this stage was a detailed review of the safety and performance requirements, specifications for the operational end-to-end journey, and any evidence of failure along this journey including evidence of leaks, robotic failure with the swab, or failure of compatibility with equipment in the laboratories.
3. Assay Verification: The assay verification stage ensured prospective testing kits met the requirements of the molecular assay equipment used within the national testing programme. This also included verification of result including sample control assessment.
4. Clinical Validation: Assessment of the test kits to ensure they performed as expected for the detection of coronavirus within a clinical setting. At this stage, participants with known infection were consented to use the test kit in a clinical setting. Areas assessed

included whether the sample collected is sufficient for processing, viral RNA survival time when using the kit, specification, and sterility requirements of the kit.

Following validation, a decision was made on whether further evaluation was required prior to deployment. If required, there may have been a subsequent usability study or service evaluation of the test kit to ensure it is acceptable for use from an operational or large scale real-life clinical perspective.

5.1.3 LFD evaluation process for procurement and use in the national testing programme

LFD test kits were widely used across the national testing programme. Assisted tests were used towards the start of the program in the latter half of 2020, with a migration to predominantly ‘self-tests’ occurring in 2021. This allowed a significant increase in the number of tests being performed. In some settings, for example care homes, schools and hospitals, assisted testing continued to be used.

There was a robust multiphase process in place to ensure the performance of all LFDs used within the national testing programme had been evaluated and found to be of a sufficient standard prior to deployment. This process operated only within the national testing programme with separate requirements under CTDA for LFDs used by external private providers.

The evaluation process for all LFD antigen tests was commissioned by Ministers, involving UKHSA and Oxford University, to ensure minimum standards for LFDs used within the national testing programme. The LFD Oversight Group was in place to oversee this work and scrutinise results from a scientific perspective. It was comprised of members from across the academic community and UKHSA Officials.

The main decision steps in the LFD antigen test evaluation process are shown below.

Phase 1: A desktop assessment of product viability performed by UKHSA. This included detailed supplier questionnaires and an in-depth review of technical and commercial aspects of the device, this was combined with supplier call for successful applicants to confirm details.

Phase 2: Laboratory evaluation at UKHSA Porton Down using laboratory grown virus with approximately 100 tests.

* Variant of Concern (VOC) – Laboratory evaluation at UKHSA Porton Down for all current VOC.

Phase 3: Laboratory evaluation at UKHSA Porton Down using clinical samples with approximately 1,200 tests.

* When a new VOC was identified, tests that have previously passed Phase 3 may also be tested against this new variant and in-use tests are always tested as a priority.

Tests that pass Phase 3, and subsequent VOC testing, were eligible for the dynamic purchasing system (DPS) which was a prerequisite for an LFD to be procured into the national testing program.

As outlined, the validation protocol was delivered in multiple phases:

Phase 1: A desktop review performed to ensure LFDs that progress to laboratory testing had the key features that were required for deployment. This could include, for example, able to be used by asymptomatic individuals.

The prioritisation criteria step required suppliers to apply for evaluation of their LFD, submitting key information about their test and company. The initial submission was reviewed against published prioritisation criteria based on the usability, sustainability, and performance of the device as set out on the GOV.UK website.

Following a successful application, the LFD was then progressed to the lab evaluation team at UKHSA Porton Down. Porton Down was chosen for this work due to its world class expertise and facilities in the assessments and handling of dangerous pathogens, working with live cultures of SARS-CoV-2 requires CL3 facilities.

Phase 2: A laboratory-based futility test at Porton Down to prioritise products for further assessment by identifying:

- Kit failure rate: percentage (%) of tests that do not give a control (C) line
- Specificity: percentage (%) of False Positive results from a panel of known negative samples
- Sensitivity: percentage (%) of False Negative results against a panel of known positive samples that have been serially diluted to a defined viral concentration
- Cross reactivity against 3 common human respiratory coronaviruses (229E, OC43 and NL63)

Results of Phase 2 were reviewed by the LFD Oversight Group and the New Technologies Governance Group (NTG) before being released to the supplier – the NTG is a UKHSA governance forum comprising commercial, legal, and operational specialist expertise.

Variant of Concern (VOC) laboratory-based testing was performed to determine the sensitivity of LFDs to a VOC. This included tests that had just passed Phase 2 or have previously passed Phase 3 and subsequently a new VOC had been identified.

Phase 3: Evaluation of each LFD antigen test against a larger clinical reference panel.

- specificity against a panel of 1,000 True Negative samples
- sensitivity against a panel of 200 True Positive samples

Results of Phase 3 are reviewed by both the LFD Oversight Group and the NTG before being released to the supplier.

Upon successful completion and approval from the UKHSA Porton Down evaluation process, the test becomes eligible to bid under the DPS.

Since August 2020, over 500 products have been assessed at Phase 1 of which 172 LFDs entered lab evaluation at UKHSA Porton Down. As of March 2022, 44 LFDs have passed all phases.

For those LFD antigen tests successful in the bidding process, the next stage was regulatory review and evaluation. The UKHSA LFD product team works with the MHRA to ensure that the LFD could be used in the United Kingdom and had the necessary regulatory approvals.

Relevant documentation and approvals were collated and checked with detailed review to ensure compliance. In parallel, LFD product fact packs were assessed by operational teams to ensure suitability from an operational perspective.

The evaluation steps detailed assured the programme that any LFD being procured were suitable (including usability, sustainability, and performance) and appropriate for deployment.

The CTDA process and UKHSA Porton Down LFD evaluation processes were initially separate; it should be noted that the CTDA process does not currently incorporate a wet testing element. A temporary protocol for CTDA was approved in October 2021 allowing LFD antigen tests that have a current pass for Phase 3 evaluation at UKHSA Porton Down to be sold on the Private market under CTDA regulations providing they have registered for the CTDA process.

The temporary protocol had 2 lists, one for professional use tests (of which some are LFD antigen tests) and one for self-tests (comprised of only LFD antigen tests). An LFD that had passed Phase 3 but has not registered for the CTDA process would not be included in the protocol. Additionally, an LFD could pass the CTDA evaluation without having entered the UKHSA Porton Down evaluation process. An LFD could also pass the CTDA evaluation process in principle if the LFD had failed at UKHSA Porton Down providing the information provided by the manufacturers met the CTDA requirements. Additionally, a test could pass at UKHSA Porton Down but fail the CTDA process if the information provided by the manufacturers did not meet the CTDA requirements. The test must only be sold for the use cases stipulated on the CTDA application and Instructions for Use.

Tests were taken off the temporary protocol in the following circumstances: they were approved under CTDA (they were added to the register of approved tests and able to remain on the market), they had failed under CTDA (in which case the test must be removed from the market within 10 days), or if the Porton Down evaluation process Phase 3 pass was rescinded secondary to failure during new VOC detection evaluation.

5.1.4 Peri- and post- procurement LFD validation process for procurement and use in the national testing programme

UKHSA key principles were usability, accessibility and sustainability for LFD products procured through the national testing programme. UKHSA required customisation of products to be procured based on these principles and meant specific product variants were required. Areas of customisation could include pack size, packaging, instructions for use, digital considerations, and technical specifications including buffer solution. Sustainability was important with suppliers required to, for example, minimise materials used, ensure the packaging and components are easily recyclable where possible, and kit contents are non-toxic and can be disposed through the normal domestic waste streams. As UKHSA required a customised product version, suppliers were required to provide a unique product code for UKHSA products and obtain updates to their regulatory approval to include any customised variant. If the legal manufacturer was based outside of the UK, they were also required to appoint a UK Responsible Person (UKRP) to represent this product variant and register the device with the MHRA and comply with UK requirements where applicable.

All prospective suppliers of LFDs were subject to validation checks following a satisfactory pass from Porton Down. Due diligence including satisfactory audits, to provide assurance of supplier capability and product quality, and regulatory checks were completed. UKHSA worked collaboratively with the MHRA to support verification and assurance of prospective supplier regulatory checks.

The LFD variant was then reviewed from a clinical performance and operational point of view as per the process for molecular assay sample collection. Where required, service evaluation and useability studies may have been performed at this stage to ensure it is acceptable for large scale deployment.

Once procured through a competitive tender process, LFD products were subject to further review and quality control of areas including the product's fact pack, standard operating procedures, confirmation of operational and digital logistics, and instructions for use (IFU) to ensure these are appropriate for use nationally and easily accessible. Review was further made to ensure appropriate Post Market Surveillance plans (PMS), real-world performance monitoring plans, and reporting and quality requirements were in place prior to deployment. Finally, to proceed to deployment nationally, approvals must have been obtained from leads within the UKHSA LFD Product Team, Public Health and Clinical Oversight (PHCO) Directorate, Regulatory, Supply Chain and Logistics, and the Commercial Team. There was ongoing validation and assurance on Variants of Concern (VOC) throughout the process and post-deployment – further information on this process is included in section 5.5.

5.2 Supply chain evaluation process

5.2.1 Maintain quality throughout supplier onboarding

As part of the procurement process, and supplier onboarding, due diligence, including audits and confirmation of regulatory requirements was obtained. This process supported assessment of potential suppliers for factors including financial stability, satisfactory audits to provide assurance of supplier capability and product quality, ability to deliver the material when required, in the quantities required, and material cost. UKHSA collaborated closely with the MHRA as part of this process and to support verification supplier regulatory requirements have been met, where applicable.

Once a supplier was to be onboarded, they were required to complete a detailed supplier questionnaire and Quality Technical Agreement to ensure appropriate standards and quality management systems were in place, for example, ISO 13485 and ISO 9001. Dependent on these results, and the outcome of all audits, a supplier would be placed into either the low, medium, or high-risk supplier categories which determine the frequency of subsequent review and inspection.

- High Risk Supplier: Supplies material that directly impacts product function and/or quality and does not have ISO 13485 and/or ISO 9001 accreditation
- Medium Risk Supplier: Supplies material that directly impacts product function and/or quality but has ISO 13485 and/or ISO 9001 accreditation
- Low Risk Supplier: Supplies material that does not directly impact product function and/or quality

Where a supplier had been assessed as high or medium risk, an initial supplier audit is conducted including an ISO 13485 and ISO 9001 review (if applicable), supplier capability, latex audit (if applicable), and traceability tests. For suppliers based outside the UK, they were audited by an external third party and, where relevant, a human rights audit.

Once the onboarding and evaluation process had been successfully completed, Quality Technical Agreements could be signed between the UKHSA and supplier. Further, as part of this monitoring of performance, all medium and high-risk suppliers were re-evaluated annually with any concerns arising discussed promptly with the supplier and actions raised where necessary.

5.2.2 Quality throughout the supply chain process

Quality was assured at each stage of the UKHSA supply chain process as part of a robust quality management system and through systems in place to comply with relevant standards and regulations. All suppliers to UKHSA were subject to quality control mechanisms and audit as detailed in Section 5.2.1.

For lateral flow devices (LFD), following manufacture of the product, test devices were inspected to Acceptable Quality Limit (AQL) standards for the assurance of overall product quality. Basic parameters included are: size, weight, quantity, packaging requirements, liquid leakage, carton drop tests. In addition, a smaller subset (10%) of samples will be examined for function, QR code legibility and barcode checks. Additionally, a small subset of samples were ring-fenced and expedited to the UK for validation. UKHSA employed third party quality control service providers to conduct the inspection. This validation process encompassed the following:

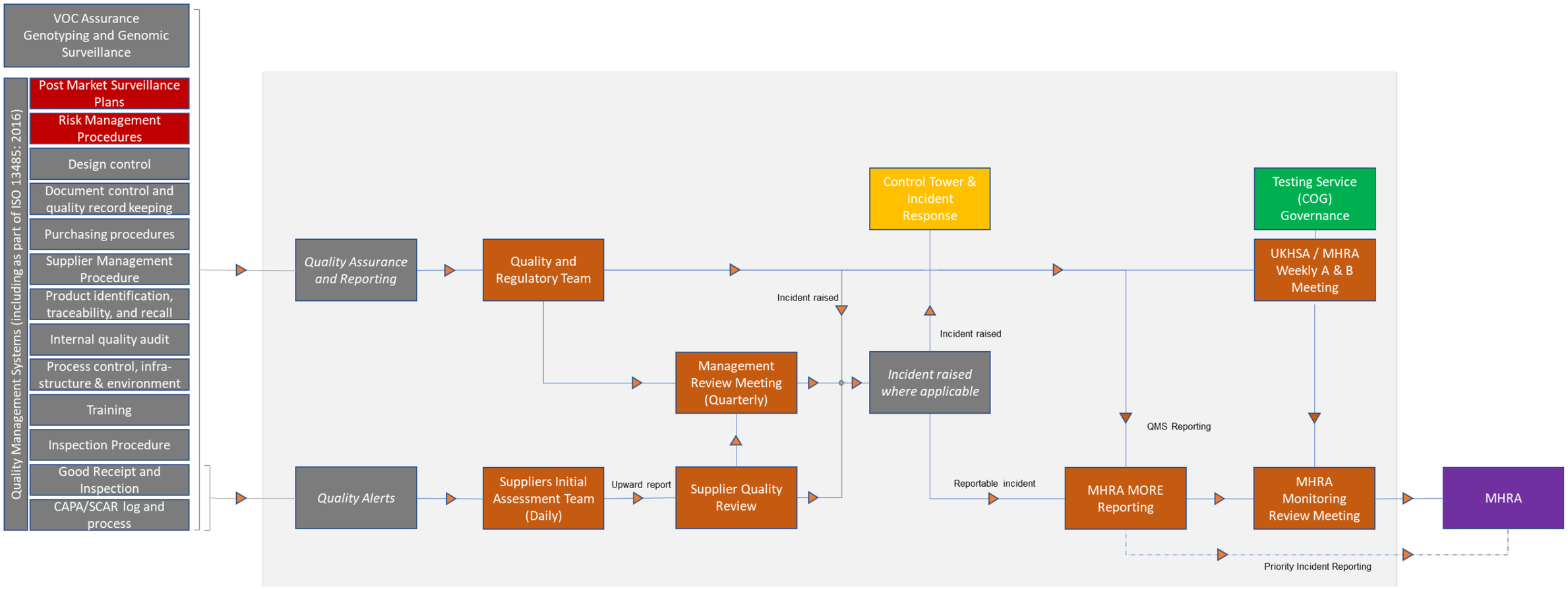
- 5% of samples were inoculated with a positive control solution[8] for presence of test line
- 5% of samples were treated with a negative control solution[9] for absence of test line
- the remainder of the samples were tested for control line function with extraction buffer solution for presence of the control line. This was typically performed on a larger sample size than the initial function checks performed as part of 'At-Origin' inspection
- bioburden sterility tests were also performed on swabs provided in validation test kits to ISO 11737:1 standards with results calculated in colony forming units (cfu) per test

As part of the process, quality alerts may have been raised through the quality management system as a Corrective and Preventive Actions request (CAPA) or, where applicable, a Supplier Corrective Action Request (SCAR). The quality management system was reviewed in more detail in Section 5.3.

As outlined in Figure 6, supplier quality alerts raised were reviewed at the daily Suppliers Initial Assessment Team meeting. If applicable, and where required, these were escalated to the Supplier Quality Review Committee for review. Depending on the risk and severity outcome of the quality alert, this could result in escalation and notification to the UKHSA incident response Control Tower in the first instance (as detailed in Section 4.2) and through the MHRA MORE reporting portal for reportable incidents. All escalations and outcomes were further reviewed during the quarterly Management Review Meeting.

[8] Containing either recombinant nucleocapsid protein or heat inactivated viral culture.
[9] Simple phosphate buffered saline (PBS) media.

Figure 8. Overview of the quality management systems and governance framework throughout the manufacturing and supply chain for testing devices used within the national testing programme



Accessible text version of Figure 9

The chart above gives an overview of the quality management systems and governance framework throughout the manufacturing and supply chain for testing devices used within the national testing programme. VOC assurance genotyping and genomic surveillance. Quality management systems (including as part of ISO 13485: 2016). Post market surveillance plans, Risk management procedures, Design control, Document control and quality record keeping, Purchasing procedures, Supplier management procedure, Product identification, traceability and recall, Internal quality audit, Process control infrastructure and environment, Training, Inspection procedure, Good receipt and inspection, CAPA/SCAR log and process, complete quality assurance and reporting these are reported to quality and regulatory team who report to management review meetings (quarterly), UKHSA / MHRA Weekly A&B meeting, Testing Service (COG) governance, MHRA MORE reporting, MHRA monitoring review meeting then into MHRA. If at the (quarterly) management review meetings incidents are raised (where applicable) these are then reported to Control Tower And Incident Response, incidents are reported to MHRA MORE Reporting, the MHRA Monitoring Review Meeting and MHRA.

Good receipt and inspection and CAPA/SCAR log and process, and produce quality alerts. These are reported to Suppliers Initial Assessment Team (daily) and Supplier Quality Review. Iincidents are raised (where applicable). These are then reported to MHRA MORE reporting, the MHRA Monitoring Review Meeting and MHRA.

Actions from the UKHSA incident response Control Tower as a result of a quality alert may have led to, for example in the event of a serious incident, issue of safety notice and/ or a recall of the product. This highlights the importance of the robust traceability and recall processes included as part of the UKHSA quality management system. Traceability was maintained at each stage of the supply process. All suppliers were required to establish and maintain procedures for identifying each unit, lot, or batch of finished devices and, where appropriate, components. This also included logistics partners, shipping, and distribution. From quality records maintained by suppliers, it must also have been possible to establish all other products sharing any common factor or component with the relevant product and these must also have been traceable. In the case of LFD test kits, suppliers were also required to directly print unique barcode identifiers onto the test cassettes. The prefixes were supplier specific and were provided by the UKHSA digital team. Suppliers were required to provide succinct traceability data to define which lot numbers contain which range of barcode numbers, enabling UKHSA to be able to track a device from point of origin (manufacturing factory) up to the end user.

In the event of an investigation into a product, the product was quarantined until the outcome is known. Where a recall of the product was required this triggered the established Recall process and key responsible parties were informed of the requirement. Assurance of this process was achieved through periodic mock recalls to test the effectiveness of both the traceability and recall procedures.

5.3 Quality and regulation process as an IVD manufacturer

Due to the nature and severity of the pandemic, testing capacity was required to scale significantly to achieve policy and public health objectives. As part of this scale up of testing, there was an increased demand for sample collection kits for molecular based testing, including RT-PCR and EPCR. The national testing programme, through DHSC, established the validation and quality assurance process of testing kits outlined in Section 5.1 to support increased supply. As available suppliers at the time were unable to match testing demands of the programme, DHSC, working with the MHRA, developed and became legal manufacturer of new sample collection kit configurations from different suppliers. Towards the end of 2020, there was an increasing requirement for self-test LFD (LFD were already widely used in an assisted-test capacity). As there were no available LFD available for self-test at scale, DHSC successfully submitted an Exceptional Use Authorisation (EUA) for the COVID-19 Self-Test (Rapid Antigen Test) and assumed responsibility as legal manufacturer.

As an IVD legal manufacturer of sample collection kits and a self-test LFD, there was a legal responsibility placed on UKHSA to operate a robust Quality Management System (QMS) to meet the relevant regulatory standards. These were detailed in The Medical Devices Regulations 2002, UK statutory Instruments 2002 No. 618 Part IV In Vitro Diagnostic Medical Devices (Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices).

Technologies covered within the scope of responsibility include:

- PCR sample collection kits compliance demonstrated following the conformity route for general IVD as per Directive 98/79/EC Annex III sections 1 to 5
- LFD Self-testing kits compliance demonstrated following the conformity route for self-testing IVDs excluding those which appear in annex II (As per Annex III Directive 98/79/EC Annex III sections 1 to 6)
- LAMP sample collection kits

UKHSA, as a defined legal manufacturer, was committed to the provision of quality products and services with a QMS that fully conformed to the requirements of the ISO 13485-2016 standard, ISO 9001, and all other applicable legislation and best practice. By consistently providing products and services that met and exceeded these expectations, UKHSA could promote higher levels of satisfaction across the programme and in turn achieve overall organisational success.

The main objectives of UKHSA through the QMS were to:

- ensure UKHSA got things right, first time, every time.
- continually improved the overall quality of all our products and services.
- maintain good working relationships with consumers of the products and all suppliers and relevant third parties.
- maintain organisation-wide (including all relevant third party) understanding regarding implementation, operation, and continuous improvement of the quality management system.
- promote an environment of continual improvement in all aspects of the organisation.

To achieve these objectives, UKHSA adopted procedures throughout the organisation that were focused on meeting each department's quality specific requirements. A documented QMS was maintained, and quality assurance program designed and implemented, to fulfil regulatory obligations. The overall purpose of the quality system was to ensure that the design and manufacture of products were planned and performed in a well-defined and controlled environment. A quality plan was developed for verifying and testing new medical and IVD devices, for assuring capable processes, assessing risk and for assuring and verifying product quality and performance. An overview of these systems is outlined below.

Design control

The QMS ensured design processes were planned, activities identified, qualified personnel were assigned to specific design responsibilities, and organisational interfaces were defined and controlled. Design input was formally documented and reviewed, designs were verified and, when applicable, validated with prototype testing or by other means. All design outputs were documented and checked before being released for production through first article inspection. In addition, design changes were controlled via change control processes and purchasing was controlled via purchasing control processes and supplier management activities.

Post-market surveillance (PMS) planning

A Post Market Surveillance (PMS) plan was created for each product and ensured they were continually monitored following initial deployment and outcome reports provided to key stakeholders and regulatory agencies. PMS included systematic collection of data for all new and existing products and the creation or revision of clinical performance and evaluation reports where required. UKHSA included Real World Performance Monitoring (RWPM) as part of the PMS. Further detailed review of UKHSA PMS plans are included in Section 5.4.

Document control and quality record keeping

An essential overarching component of the QMS was to ensure the purpose and scope of quality system documents were defined. All documents were reviewed and approved prior to issue and good documentation practices maintained. Where quality records were generated, these should have demonstrated achievement of required product quality and effective operation of the quality system. Production and product verification records should have provided evidence of product conformance and, when required, material and process traceability.

Purchasing procedures

These procedures ensured all purchases from suppliers were only from those that can satisfy quality requirements. Quality performance of suppliers was monitored and evaluated as detailed in sections 5.1 and 5.2.

Product identification and traceability

As detailed in Section 5.2, identification and traceability was essential to ensure quality. Materials, components, parts, subassemblies, and finished products were identified by a part number correlated to corresponding specifications and other technical documents. When required by design specification, or regulatory requirements, traceability of materials and processes were maintained and recorded.

Process control, work environment, infrastructure, and environmental awareness

Inclusion of process control within the QMS ensures production processes and operations were planned, documented, and monitored. Production work orders, control plans, process operator instructions, and other similar work instructions were issued to personnel where required.

QMS further included process and procedures to ensure work environments foster safety, a positive atmosphere, and conformity to product requirements with buildings and workplaces maintained to provide a clean and safe environment.

Inspection, testing, and control of non-conforming product

As detailed in Section 5.2.2, the QMS ensured inspection was conducted on receiving shipment of finished products. UKHSA testing was conducted by an outsourced party following an AQL set by supplier quality with an emphasis placed on defect prevention rather than detection. Materials, components, subassemblies, and finished products were prevented from use, assembly, and shipment until the required inspections were complete. Inspection records were established and maintained to demonstrate products conform to specified requirements. Non-

conforming product was identified, documented, evaluated, and prevented from being used or shipped with responsibility for disposition clearly defined.

Corrective and Preventative Action (CAPA) log and processes

The QMS included policy and procedures to identify causes of actual and potential non-conformances with investigation and preventive and corrective actions implemented to eliminate them. Controls were applied to ensure that corrective and preventive actions were implemented and were effective. This also included for all customer complaints to be recorded and investigated. Further detail is provided in Sections 4.2 and 5.2.2.

Training procedures

Personnel training needs were identified, and provision was made for the required training. A QMS training matrix had been created by UKHSA. Personnel assigned to perform specific tasks, operations and processes were qualified based on appropriate education, experience, or training with records of personnel qualifications and training maintained.

Internal quality audit

Audit was essential and the QMS incorporated comprehensive, planned, and documented quality system audits carried out against requirements as defined by the QMS. Audits were scheduled based on the status and importance of the activity. Internal auditors were independent of those having direct responsibility for the audited activity. Identified nonconforming conditions, process risks and opportunities for improvement were brought to the highlighted and corrections or corrective actions were implemented in response to these findings.

Regulatory inspections

As a final part of the QMS, there were policy and procedures in place to ensure quality when receiving a regulatory inspection. Inspections were a regular part of a regulatory body's responsibility and these policies and procedures ensured quality and effective cooperation to require by the regulations.

5.4 Post Market Surveillance (PMS) as an IVD manufacturer

A critical component of the Quality Management System (QMS) was the Post Market Surveillance (PMS) plan produced for each of the products where UKHSA was a distributer or manufacturer. UKHSA was manufacturer of a coronavirus LFD self-swab and self-test IVD device as well as RT-PCR, EPCR, and LAMP testing sample collection kits. This was in addition to the role of UKHSA as distributor of a number of LFD self-swab and self-test IVD devices.

Activities within the PMS plans were designed primarily to support and ensure delivery of high quality and safe services by the programme. The plans ensured appropriate information was gathered where required to support reporting processes on the effectiveness of products in the

marketplace and to conform with the relevant standards and regulatory requirements – including IVD Directive 98/79/ EEC, ISO 13485:2016 (Clause 8) and ISO 14971:2019 (Clause 10).

The PMS plans defined activities undertaken by UKHSA to support this continuous data generation and assessment of product performance post market. This ensured the performance and safety of products, within the scope of their intended purpose, distributed or legally manufactured by UKHSA throughout their life cycle. The plans defined these processes and the frequency of activities for gathering of both production and post-production data to input into the evaluation process and relevant risk management processes.

The PMS plans, outlined in Table 6, covered both reactive and proactive systematic processes to collect the required data and information. In parallel, suitable indicators and threshold values were in place for the continuous reassessment with effective tools to trace and identify devices for which corrective actions might be necessary.

Table 6. Post Market Surveillance plan and associated items as part of the Quality Management System

Type	Item	Description
Reactive	Complaints, incidents, and feedback	Complaints, incidents, and feedback data amalgamated from all sources (for example: Yellow Card, incident reports, surveys, governance committees including patient safety panel). These were reviewed as part of the PMS with a decision made on further escalation and if, for example, there are any missed reportable incidents.
Reactive	Manufacturing process performance	Provided information on inspection and validation reports - this included numbers of lots made and rejected. Supported the organisation to determine manufacturing problems which might lead to safety risks for users or new risks for requiring risk management.
Reactive	CAPA and supplier performance	Review of CAPA and SCAR reports to determine if CAPAs were effective or if new CAPAs needed to be raised and to determine if there were any manufacturing problems which might lead to safety risks for users or new risks for risk management.
Proactive	Device performance and Real-World Performance Monitoring (RWPM)	Real world performance monitoring (RWPM) refers to data captured through analysis of testing within the wider programme. Real-world data was captured routinely as part of asymptomatic and symptomatic testing services. This data was segmented by device, service team and site, and incorporates positivity rate, void rates, and confirmatory PCR rates for positive LFD tests, alongside a summary of any variants detected. As part of RWPM, device performance specification (acceptance criteria) for the indication in which the product was used is agreed upon. The trend of actual performance versus acceptance criteria was carefully monitored with regular reporting and escalation when required – for example to the Patient Safety Panel. As part of the PMS plan, a summary of issues and actions for the reporting period is included.
Proactive	Risk management	The PMS plan aimed to identify any new hazards or risks as part of the process. Weekly review meetings were held to discuss any identified hazards, triggers, and risk scores. Mitigating actions for hazards and risk were allocated an owner and a determination is made if the device performance remains acceptable considering the current risk-benefit analysis.

Type	Item	Description
Proactive	State of the art	As part of the PMS plan, information about similar new devices on the market or changes in the clinical environment were proactively reviewed on a regular basis through, for example, literature and regulatory review.
Proactive	Post Market Performance Follow Up (PMPF)	For LFD products where UKHSA is lead manufacturer, proactive performance assessment was conducted in settings where the device was used as part of the PMS plan. Participants in each setting were requested to provide a RT-PCR test as well as perform their LFD test. This paired testing regime allowed for ongoing performance assessment of the device in comparison to the current 'gold-standard' of a RT-PCR test. This provided assurance the device functions at an appropriate standard and performance level for all settings in which it is used. It also supported identification of performance trends, drops in performance, or issues requiring investigation in a setting specific context. PMPF was not conducted where UKHSA is lead manufacturer for RT-PCR, E-PCR and LAMP sample collection kits. In contrast to LFD, the sample collection kits were used to collect samples and transport to the laboratories where they were then processed.
Proactive	Distribution data and roll out plan	A clear identification of distribution of test kits by setting and areas used was provided as part of the PMS plan. This provided visibility of traceability and a comparison of tests distributed and tests registered (as a proxy for utilisation).
Proactive	PMS report	A PMS report was created after all individual reports have been compiled and independently reviewed. This contains a high-level summary of data reported to MHRA for regulatory oversight and to fulfil all applicable EUA conditions, where these exist. The report also contained any relevant changes or information relating to device safety not covered under other sections and, where these have occurred, product and packaging design changes.

* For products where UKHSA is distributor, only complaints and incidents were included as part of PMS plans.

As part of ensuring quality, the conclusion of each summary report received from each of the PMS plan inputs state if a recommendation was required based upon the inputs or if it is acceptable to continue to gather data without generating a periodic report. Any new risks, changes to risks or changes to frequency of occurrences were noted and triggered an update to either the Clinical and Public Health evaluation reports, risk analysis, or both.

5.5 Ongoing monitoring for performance against variants

There was always the risk of new variants of coronavirus developing. Of these new variants, if considered to have concerning epidemiological, immunological, or pathogenic properties a formal investigation was raised where they are designated a Variant Under Investigation (VUI). Following a risk assessment with the relevant expert committee, they may have then been designated a Variant of Concern (VOC).

All testing technology had been validated on VOC present at the time of validation. This meant that where a new VOC is identified, this would need to be monitored with subsequent validation to ensure tests utilised within the national testing programme were appropriate. Where a new VOC is designated, a sample source material was obtained by UKHSA Porton Down public health laboratory and a live culture of the virus is grown and lysates, purified RNA and irradiated stocks were generated for onward evaluation testing of diagnostic tests and vaccines.

VOC were assessed against all gene targets used in testing technologies. All designated VOC were assessed if the change to the virus has affected specific regions of its genome known including the N-gene, S-gene, ORF1ab/E-gene, and non-structural genes. These 2 areas represented a common target for testing technologies. It was therefore vital to assess if any mutation has affected these areas as this will have the potential to impact validity of a test.

The VOC Assurance Working Group was established December 2020 with the remit to provide an assurance framework for the performance of SARS-COV-2 test devices. The group monitored the performance of assays through *in silico* monitoring (based on computer modelling), laboratory test performance quality monitoring and in vitro testing (where indicated by the *in silico* and quality monitoring processes).

Members of the group have developed assurance processes, guidance and standards to guide manufacturers. The VOC Assurance Working Group comprised of members from both UKHSA and MHRA. MHRA expect manufacturers to be responsible for the safety and performance of their devices whilst they are available on the UK market. This includes having a Post Market Surveillance plan in place to continuously monitor, investigate and assess newly emerging variants of SARS-CoV-2.

In line with the UK Medical Devices Regulations 2002, the MHRA considered reports relating to variants to be serious public health threats, therefore significant safety issues should have been

reported within 48 hours. The MHRA regularly engaged with suppliers/manufacturers to review their post-market assurance processes for the most recently published variants in circulation in the UK.

Manufacturers/suppliers were expected to provide a monthly report to MHRA, detailing their monitoring activities. The monthly reports were reviewed by UKHSA scientific advisors to assess scientific robustness and to ensure assays are evaluated against all circulating variants. Issues were flagged to the MHRA. When a test product was impacted by a variant, the MHRA worked with manufacturers to take mitigating actions and inform testing service providers and end users.

The VOC Assurance Working group also evaluated quality concerns of diagnostic tests throughout NHS England and UKHSA testing laboratories. This was achieved through end users reporting issues through a quality form that was circulated to quality leads and the VOC Assurance Working Group. Where an issue was indicative of a possible result of a variant, the VOC Assurance Working Group conducted and investigation to get to the root cause of the issue. When a diagnostic test was shown to be impacted by a variant, the issue was escalated through UKHSA's incident management system. Where deemed necessary, the issue was escalated to Ministers, UKHSA leads, NHS England and the MHRA to ensure mitigating actions were taken to prevent further impact on public health.

The VOC Assurance Working Group also coordinated wet lab testing of diagnostic assays within UKHSA and NHS England laboratories as and when a variant arises and is deemed as potentially impacting diagnostic tests. The VOC assurance working group evaluated the results and identified whether discordant results were a cause for concern. Where discordant results were indicative of a diagnostic assay being impact by a variant the issue was escalated in the same manner as described above through the incident management system.

Lastly, the VOC Assurance Working Group regularly provided assurance against variant genotyping assays that are utilized within Pillar 1 and Pillar 2 laboratories. This was done by overseeing new variant target selection and validation of new assay targets. Discordant results awere monitored on a weekly basis to ensure new assays were performing as expected against variants. In addition to this, *in silico* monitoring of variant selected targets were carried out by evaluating the mutation specificity on a weekly basis against all genomes uploaded in the last 28 days to the COVID-19 Genomics UK Consortium (COG-UK).

5.5.1 Lateral flow device validation against emerging variants

For lateral flow device (LFD) technology, serial testing was performed on each LFD that has passed Phase 3 of the UKHSA Porton Down evaluation process. The LFD were subjected to repeat assessment with live cultured SARS-CoV-2 virus identified as the VOC. During this process, there was a priority focus on tests that are actively deployed nationally. The live virus culture was serially diluted and used to assess device performance.

Alongside serial dilution validation, UKHSA Testing Operations operated a programme of post-market surveillance comprising clinical evaluation via routine monitoring of performance using 'real-world' data (that is, data collected on a routine basis as part of the testing programme). This operated in parallel and was essential to detect early signals of changes in performance with emerging VOC in LFD used as nationally as part of the testing programme. Further information about this programme is detailed in Section 5.4.

If there was a signal of reduced performance from either of the aforementioned validation steps, then the LFD was subject to further investigation through a service evaluation study. Service evaluation paired test studies were performed at Regional and Local Testing Sites (RTS/LTS). Individuals attending one of these sites were asked if they would like to participate in the study. If they consented, an LFD test was performed at the same time as the RT-PCR test. Positive RT-PCR samples undergo genomic sequencing and those positive for the VOC were used to assess and validate LFD performance.

LFD manufacturers were requested by the MHRA to confirm monthly that their LFD performs to the required standards for variants of SARS-CoV-2. MHRA reports consisted both of *in-silico* predictions and wet laboratory testing. Results of which were disclosed to a panel of scientific advisors within the VOC Assurance Working Group of UKHSA for review of the scientific robustness and assessment of the performance of the assay in question. The MHRA was notified if any assay was either predicted to be impacted or shown to be impacted in wet lab testing so that they could ensure the manufacturer submits a field safety notice. The issue was escalated within UKHSA if the impacted test was used either in UKHSA or NHS laboratories. The VOC Assurance Working Group also then instigated further testing of the device with the VOC.

In addition to MHRA monthly reports requested from manufacturers, whenever there is VOC, an extraordinary request from MHRA was sent to manufacturers for assurance of their test against the new variant. Extraordinary requests were instigated from the VOC Assurance Working Group within UKHSA. These were again reviewed by the VOC Assurance Working Group to identify any tests that may have been impacted. This was then followed up by the VOC Assurance Working Group who then arrange for these tests to be tested against the new VOC to evaluate the performance of the test. Any negatively impacted tests were alerted to the MHRA and escalated within UKHSA.

5.5.2 Molecular diagnostic technology validation against emerging variants

For molecular diagnostic technology used as part of the national testing programme, namely RT-PCR, EPCR, and genotyping, there was a process in place to ensure molecular assays used remain valid. This was in addition to the monitoring of discordant results as detailed in Section 3. Where a new VOC affected the genomic target areas of the molecular assays, PCR assay manufacturers were requested to confirm if there was concern or issue presented by this change. Molecular assay manufacturers also received both monthly VOC assurance reports to

MHRA and were subject to extraordinary requests when there was a new VOC. Additionally, there was a quality form system in place where any issues were alerted to quality assurance leads and the VOC Assurance Working Group to support initiation of investigation into potential issues with a variant.

5.5.3 Governance for ongoing monitoring of performance against new variants

UKHSA operated a robust governance framework to ensure the quality of monitoring of test performance against new variants was maintained and assured. Governance was formed by the VOC Assurance Working Group and LFD Oversight Group and included decisions on assess priorities. The VOC Technical Group and the genomics board then reviewed and decided on a final outcome following assessment. These groups comprised of key internal and external stakeholders including quality and regulatory specialists, MHRA, NHS providers, academic, biotechnology, and molecular specialists.

Appendix A. Overview of testing technology deployed

Extracted molecular tests

Extracted molecular tests were the standard used for testing individuals with symptoms. They used RNA extracted from the sample and concentrated before adding to the test. It could therefore detect very small amounts of the viral material and may have given an indication of how much of it is present, if at all. Examples of extracted molecular tests included Reverse Transcriptase-PCR (RT-PCR), Loop-Mediated isothermal Amplification (LAMP) and End-point PCR (EPCR). Genomic sequencing and genotyping was an additional process performed by the Sanger Institute and UKHSA and reported into the Second Generation Surveillance System (SGSS). The genetic code of SARS-CoV-2 positive samples was analysed as part of surveillance and for the early identification of new variants.

1. RT-PCR (often referred to as ‘PCR’) was the standard used for testing individuals with symptoms. RT-PCR had an upfront step to convert viral RNA to DNA then used replicate cycles of heating and cooling to exponentially amplify the amount of DNA in the sample until it reaches a level that can be detected by a sequence-specific probe. It may have given an indication of how much RNA was in the original sample.

2. End-point PCR (EPCR) was a similar technology to PCR but only identifies if the genetic material is present and detected, there is no quantitation.

3. Loop-Mediated Isothermal Amplification (LAMP) was like PCR but targets multiple areas of the viral genetic material and creates DNA copies with ‘loops’ at the end through an isothermal (one temperature, not cycles of heating and cooling) reaction. These loops became a target of further amplification until they reach a level where they can be detected.

Direct molecular tests

Direct molecular tests did not have an upfront concentration step and are therefore not able to detect as small amounts of viral RNA in samples as extracted molecular tests. Direct molecular assays include direct-PCR, and direct-LAMP. Direct-LAMP was widely used for screening asymptomatic healthcare staff in the NHS as the level of detection better correlates with identifying individuals with a current infection, but not those who have been previously infected but are no longer infectious. Many direct-PCR devices were placed at Point-of-Care (POC) within NHS settings, such as Emergency Departments (ED).

Antigen tests

Antigen tests detected either part of or the whole virus with surface proteins commonly the target. Examples of antigen tests include, Enzyme ImmunoAssay (EIA) automated tests requiring an instrument, or Lateral Flow devices (LFD). In reality, for SARS-CoV-2 detection, the N-antigen is a target for all LFD tests and in some EIA tests.

Automated EIA devices used direct samples, such as nasal swabs, added to a test buffer. The buffer was added to either a well or strip in a device, antigen in the samples binds with antibody in the test, which was also bound to a fluorophore, which produced a reaction that could be measured by the instrument. These devices were placed in Emergency Departments and other NHS areas of hospitals to assess patient status and allow better patient flow according to likelihood of spreading infection.

Lateral flow devices (LFD) were point of care tests based on an immunochromatography assay. For the test, a sample was applied directly to the test strip. If there was SARS-CoV-2 antigen in the sample, this would bind to an antibody and move along the test strip. When passing the test line, the complex was captured by another antibody resulting in a coloured line for a positive result. Within the national testing programme, LFD antigen tests were used across a wide range of use cases and delivery channels, including schools, colleges, public and private industry. The national testing programe used different LFD antigen test devices authorised for use in either assisted test settings (professional use) or as a self-test.

Appendix B. Case study of quality management and assurance processes in the Lighthouse Laboratories, Alderley Park

Alderley Park Lighthouse (LH) Laboratory was one of the original laboratories testing RT-PCR samples for coronavirus as part of the LH laboratory network. It started receiving and processing samples in April 2020 and represents an example of laboratory best practice within the network. The LH laboratory was accredited by UKAS in January 2021 and reinspected in March 2022. The enthusiasm of the staff and standards set were positively commented on at time of inspection.

The LH laboratory followed the External Quality Assessment (EQA) programme through the Quality Control for Molecular Diagnostics (QCMD) organisation. Quality was maintained, for example, through assessing assays against other laboratories and organisations both nationally and internationally to ensure the highest of standards were maintained and the reliability of results. Verification and validation of results meant laboratories could evaluate practice with these external peer laboratories. Participation in the EQA programme also supported maintenance of accreditation through ISO 15189:2012 and high-quality standards.

Suitable controls throughout the process were imperative to ensure standards were maintained and quality of service. Machine learning software was used to assess baseline and developing amplification curves during analysis, a function of RT-PCR testing, to ensure only genuine amplification results were reported. Within the laboratory process there were 3 types of control used:

1. Positive and negative control samples. These samples, produced by Qnostics, were included on every assay plate tested. They were run through the same end to end process that the clinical samples were run through to ensure validity of the control. Any plate with an issue identified from the control could then be flagged rapidly with an immediate response and review. This immediacy of response supported, for example, rapid review and correction of any issues, where feasible, identification of inter-batch reagent variation, or potential signal identification of changes associated with a new variant.

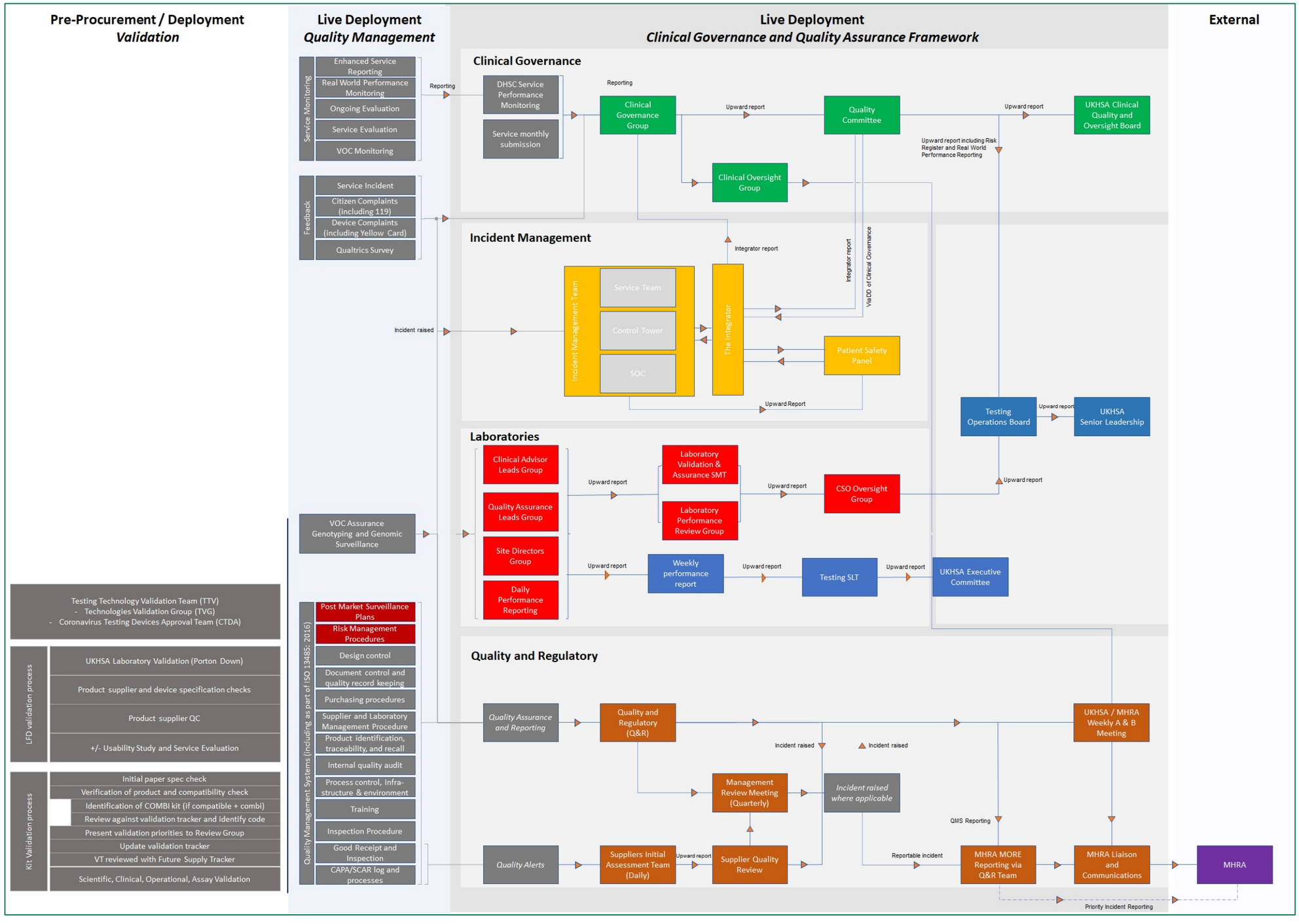
2. Assay-run control. This control sample, manufactured by NIBSC, was run up to 3 times per day and is of a higher concentration than the positive and negative control samples used on each assay plate tested. As a higher concentration sample, the control did not trigger an alert as frequently as found for the assay plate positive and negative controls. This supported a more robust and manageable monitoring mechanism for the occurrence of variations and trends over time in the process.

3. Bacteriophahge-MS2 internal control. As an internal control added to every sample tested, this ensured the sample is free from potential inhibitors of the process. A level was expected in all samples tested. The internal control was ‘sacrificial’ to the viral RNA and it was expected, and seen, for levels to be higher in low viral load concentration samples and lower in higher viral load concentration samples.

Process changes had the potential to affect quality output within the laboratories. An example of mitigation to prevent this from occurring and assure quality were the linearity panels run within the laboratory – provided assurance laboratory results were directly proportional to the concentration of virus present in a sample. For major changes, such as new equipment or technology, a full linearity panel was run to ensure the sensitivity and linearity of the assay is re-evaluated. Outside of major changes, for example personnel or reagent changes, a subset of the linearity panel was run.

The aforementioned key areas were examples of how the laboratory maintains quality and ensures the laboratory conforms to regulatory requirements and maintains high standards of quality at every stage.

Appendix C. Overview of clinical and quality governance frameworks across Pillar 2



Accessible text version of the ‘Overview of clinical and quality governance frameworks across Pillar 2’ flowchart

The flowchart above is an overview of clinical and quality governance frameworks across Pillar 2.

On the left it outlines the process of pre-procurement and deployment validation. Testing Technology Validation Team (TTV), Technologies Validation Group (TVG), Coronavirus Testing Devices Approval team (CTDA).

The LFD validation process is also outlined - UKHSA Laboratory validation (Porton Down); product supplier and device specification checks, product supplier QC, +/- usability study and service evaluation.

The Kit validation process - initial paper spec check, verification of product and compatibility check, identification of COMBI kit (if compatible + combi), review against validation tracker and identify code, present validation priorities to review group, update validation tracker, VT reviewed with future supply tracker, scientific, clinical, operational and assay verification.

In the next column, the live deployment quality management process is outlined. Service monitoring includes enhanced service reporting, real-world performance monitoring, ongoing evaluation, service evaluation, VOC monitoring.

This section reports to clinical governance, DHSC service performance monitoring and service monthly submission. This reports to the clinical oversight group and the quality committee which then report to the UKHSA clinical quality and oversight board.

Next in the live deployment quality management column is the types of feedback, including service incident, citizen complaints (including 119), device complaints (including yellow card), qualtrics survey. These also report to the sections within clinical governance and incident management. The incident management team consists of the Service Team, Control Tower and SOC.

The Incident Management Team report to the Integrator and the Patient Safety Panel which also reports into the Quality Committee and Clinical Governance Group.

The feedback also reports to Quality And Regulatory (Q and R), then onto UKHSA/MHRA weekly A and B Meeting, Management Review Meeting (quarterly). An incident raised where applicable is reported to MHRA MORE reporting via the Q and R team, MHRA Liaison and communications and to MHRA.

The VOC Assurance Genotyping And Genomic Surveillance report to laboratories - Clinical Advisor Group, Quality Assurance Leads Group, Site Directors Group and daily performance report.

The group report to the laboratory validation assurance SMT and the Laboratory Performance Review Group. These then report upwards to the CSO Oversight Group, the Testing Operations Board and lastly to UKHSA senior leadership.

The group produce daily performance reporting and create a weekly performance report which is sent to Testing SLT. This is reported upwards to the UKHSA executive committee.

At the bottom of the live deployment quality management column it shows the quality management systems (including as part of ISO13485: 2016), Post market surveillance plans, risk management procedures, design control, document control and quality record keeping, purchasing procedures, supplier and laboratory management procedure, product identification, traceability and recall, internal quality audit, process control, infrastructure and environment, training inspection procedure, good receipt and inspection, CAPA/SCAR log and processes.

These feed into the quality and regulatory section then into the UKHSA/MHRA weekly A and B meeting which reports to the MHRA Liaison and communications and lastly onto the MHRA.

From the quality and regulatory section it also feeds into the (quarterly) management review meeting, where applicable, if an incident is raised. Once reported, this is sent to the MHRA MORE reporting via Q and R team, which goes into the MHRA liaison and communications and then onto the MHRA – unless it is a priority incident that has been raised, in which case this bypasses the MHRA liaison and communications and goes straight into MHRA.

The bottom 2 on the list of quality management systems are good receipt and inspection CAPA/SCAR logs and processes. Both of these feed into the quality alerts which report to the Suppliers Initial Assessment Team (daily), who upward report to the Supplier Quality Review and then to the Management Review Meeting (quarterly).

An incident is raised where applicable and reported to the MHRA MORE Reporting via the Q and R team, then onto the MHRA liaison and communications and finally to the MHRA.

About the UK Health Security Agency

UKHSA is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. We provide intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation health secure.

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