



Medicines & Healthcare products
Regulatory Agency

Accelerated CTDA Pathway

Step 2: Process for desktop review

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On 10 July 2025, the Government published a response to the consultation on the Common Specification requirements for In vitro Diagnostic Devices. Having considered the views of respondents, the Government intends to remove the Coronavirus Test Device Approvals (CTDA) requirements and introduce Common Specification requirements for high-risk IVD devices, including COVID-19 detection tests. The government will implement this change in the Medical Device Regulations 2002 accordingly, in line with the [Medical Devices Regulatory Reform Roadmap](#). In the interim, the government has agreed to introduce an accelerated CTDA process for COVID-19 devices which are CE-marked under the EU In Vitro Diagnostics Regulations (EU IVDR) and meet the requirements of Common Specifications as set out in Annex I and XIII to Regulation (EU) 2022/1107.

This guidance outlines how the Medicines and Healthcare products Regulatory Agency (MHRA) will undertake the desktop review of COVID-19 detection tests that qualify for the Accelerated CTDA pathway. This pathway is intended for only for coronavirus test devices that are CE-marked under the EU IVDR and compliant with the relevant Common Specifications set out in Annex I and XIII to Regulation (EU) 2022/1107.

Molecular tests detect viral RNA or DNA and include Polymerase Chain Reaction (PCR), Isothermal Amplification and Loop-Mediated Isothermal Amplification (LAMP) tests. Antigen tests directly detect viral proteins or components of the virus other than nucleic acids and include those that require an analyser/reader and lateral flow tests that do not. All COVID-19 molecular and antigen tests are subject to approval in the UK, whether they are designed for use in a laboratory, at point of care, near patient or for home use (self-test). **For multiplex assays with multiple detection targets, only the SARS-CoV-2 component will be assessed to meet the requirements specified in this guidance.**

Overview of the process

The desktop review is a systematic assessment of the evidence submitted by a supplier against a set of requirements. The purpose of this step is to prevent tests that are below the expected standards from progressing to a technical validation in a laboratory. The

information submitted will be reviewed to check for completeness and then passed to a Scientific Advisor who will undertake the assessment. The assessment will be presented to the Desktop Review Assurance Group who will make a recommendation for pass/fail. All decisions will be ratified by the Regulatory Approvals Committee. The main areas of assessment are as follows:

1. Manufacturer and test information
2. Regulatory status
3. Intended Use Case
4. Test performance
5. Biosafety

1: Manufacturer and test information

The applicant must supply a PDF of the Instructions for Use (IFU) for the applicant test and other supporting documents (see table below). This information will be required to demonstrate the submitted test aligns with the intended use and evidence the stated performance characteristics.

The applicant must inform CTDA at CTDA@mhra.gov.uk if they make any changes to submitted information whilst their application is being considered.

| Document | Antigen Assays | Molecular Assays |
|---|--|--|
| Current version of IFU (with date of publication). The IFU must contain all information on the validation and verification studies conducted to demonstrate the analytical and clinical performance of the assay, including target population, sample type and stability claims. The IFU must be written in English language. | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied |
| IFU for all comparator assay(s) that were used to evaluate performance characteristics. The version of the supplied IFU(s) must match the version of the assay(s) used in testing. | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied |
| Biosafety documents (including viral inactivation where a claim of inactivation is stated in the IFU) | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied |
| Completed performance characteristics template (see Section 4. Test performance for full details) | <ul style="list-style-type: none"> • Not required | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied |

| | | |
|--|--|--|
| Clinical Performance Study Report (see Section 4. Test performance for full details) | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied |
| Field safety notices (wherever issued) related to the submitted test issued from 01/01/2020 to date of application, and any pending notices. | <ul style="list-style-type: none"> • Required if applicable | <ul style="list-style-type: none"> • Required if applicable |
| Evidence of regulatory status (see Section 2. Regulatory status for acceptable evidence) | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied | <ul style="list-style-type: none"> • Required • Automatic reject if not supplied |
| Signed declaration of conformity to the applicable Common Specifications (see Section 2. Regulatory status for detailed requirements) | <ul style="list-style-type: none"> • Required • Automatic exclusion from the Accelerated pathway if not supplied | <ul style="list-style-type: none"> • Required • Automatic exclusion from the Accelerated pathway if not supplied |

2: Regulatory status

The following evidence is required:

- CE Declaration of conformity and EU-type examination certificate from a Notified Body
- Signed declaration of conformity to the applicable Common Specifications set out in Regulation (EU) 2022/1107. The statement must outline:
 - Whether the applicant assay meets the criteria for each and all performance characteristics outlined in Annex I of Regulation (EU) 2022/1107
 - The Table(s) in Annex XIII of Regulation (EU) 2022/1107 that apply to the applicant assay
 - Whether the applicant assay meets the criteria for each and all performance characteristics outlined the applicable Tables

3: Intended Use Case

The IFU must outline the following information in the intended use statement.

| Criteria | Response | Guidance Notes |
|---|----------------------------------|---|
| Intended use | Automatic reject if not supplied | Please describe the intended use case |
| Intended use population | Automatic reject if not supplied | Please describe if the submitted test is intended for symptomatic and/or asymptomatic cases (i.e. people that are infected but do not display symptoms) |
| Specimen type and sample collection device specifications | Automatic reject if not supplied | Please state the specifications and product reference numbers for collection devices (including swabs, media and containers) that have been validated for use with the submitted test |
| Intended use setting | Automatic reject if not supplied | Please state if the submitted test is intended for use at point of care, near patient testing and/or laboratory based |
| Intended user | Automatic reject if not supplied | Please state if the submitted test can be used by a trained healthcare professional; member of the allied health professions; layperson and/or self-test |

4: Test performance

The performance characteristics (analytical and clinical) stated in the IFU must match raw data in other documents (such as clinical performance study report) submitted for CTDA application.

4.1 Clinical Performance

Clinical performance data must be derived from clinical samples only. No result from contrived or diluted samples will be accepted.

4.1.1. For antigen assays: The IFU and Clinical performance study report will be assessed for:

| Performance metric | Diagnostic Sensitivity | Diagnostic Specificity |
|---------------------------------|---|--|
| Specimen numbers, features, use | ≥100 positive clinical specimens as determined by an acceptable comparator assay: <ul style="list-style-type: none">- NAT-positive specimens from early infection within the first 7 days after symptom onset- represent the full dynamic range of naturally occurring viral loads- consideration of genetic variants, variations in specimen collection and/or specimen handling | ≥400 negative clinical specimens as determined by an acceptable comparator assay, of which: <ul style="list-style-type: none">- ≥300 from non-infected individuals- ≥100 from hospitalised patients |
| Acceptance criteria | 95% confidence interval entirely above 60% | 95% confidence interval entirely above 93% |

Acceptable comparator assay: The comparator assay must be a CE-marked extracted molecular assay, tested using nasopharyngeal swab specimens.

If the device is intended to be used for more than one specimen type, the above requirements apply to each unique combination of specimen type and collection media (e.g., nasal in UTM, throat in UTM, nasal in VTM, throat in VTM etc), and must not be aggregated. If this is not possible in exceptional circumstances (e.g. if specimen collection is very invasive), the manufacturer shall provide a justification and evidence of matrix equivalence.

Matrix equivalence studies shall be assessed in line with relevant standards such as CLSI EP35. Approval will be limited to sample types with sufficient data demonstrating performance above the specific thresholds for the applicable technology type.

4.1.2. For molecular assays: The IFU, Performance characteristics template and Clinical performance study report will be assessed for:

| Performance metric | Diagnostic Sensitivity | Diagnostic Specificity |
|---------------------------------|--|---|
| Specimen numbers, features, use | ≥100 positive clinical specimens as determined by an acceptable comparator assay: <ul style="list-style-type: none"> - represent the full dynamic range of naturally occurring viral loads. It is expected that positive samples should span viral loads approximate to CT values <25, 25 to 30, >30-35, >35; with no less than 10% of samples in any one category and no more than 40% in the CT<25 category) and represent the target population that the test is intended to be used in (e.g. symptomatic only). | ≥500 negative clinical specimens as determined by an acceptable comparator assay |
| Acceptance criteria | Direct molecular test: 95% confidence interval entirely above 70% Extracted molecular test: 95% confidence interval entirely above 93% | Direct molecular test: 95% confidence interval entirely above 93% Extracted molecular test: 95% confidence interval entirely above 97% |

If the device is intended to be used for more than one specimen type, the above requirements apply to each unique combination of specimen type and collection media (e.g., nasal in UTM, throat in UTM, nasal in VTM, throat in VTM etc), and must not be aggregated. If this is not possible in exceptional circumstances (e.g. if specimen collection is very invasive), the manufacturer shall provide a justification and evidence of matrix equivalence.

Matrix equivalence studies shall be assessed in line with relevant standards such as CLSI EP35. Approval will be limited to sample types with sufficient data demonstrating performance above the specific thresholds for the applicable technology type.

If frozen clinical samples were used for clinical performance evaluation, sufficient data demonstrating specimen stability (freeze-thaw study) must be provided. Specimen stability testing using spiked samples (negative clinical samples spiked with a known concentration of the target analyte) will be accepted. The storage duration at frozen conditions used in freeze-thaw study should be proportionate to the storage duration of clinical samples used in clinical performance study.

The Ct values for each SARS-CoV-2 gene target(s) must be provided as raw data in the Performance characteristics template.

Acceptable comparator assay:

A list of MHRA-cleared acceptable comparator assays intended for use with different specimen types is available, and it is recommended that the comparator assay is selected from this list.

Where an assay outside of this list is used in an application, the comparator assay will be assessed and must satisfy the following requirements:

- Extracted molecular assay
- CE-marked under EU IVDR
- Have a clinical sensitivity of 97% or above with the lower 95% confidence interval at 93% or above, and a clinical specificity of 99% or above with the lower 95% confidence interval at 97% or above for the specimen type used (as indicated on the IFU).
- If the comparator assay includes the E-gene as a target among other targets for SARS-CoV-2, the data for the E-gene must be able to be discriminated or separated from the Ct values of the other targets. An assay that only detects the E-gene for SARS-CoV-2 will not be acceptable.

4.2 Analytical Performance

The IFU will be assessed for:

| Criteria | Response | Requirement |
|--|--|---|
| Analytical sensitivity Please state the Limit of Detection (LOD) of your submitted test, preferably in copies per ml. Where IFU states another unit e.g. copies/reaction please translate to copies/ml where possible. For some tests other units may be applicable e.g. TCID ₅₀ /ml | Automatic rejection if don't state a LOD | Please also include the materials and method used to determine the LOD (e.g., running a quantified standard against the comparator RT-qPCR) |
| For molecular assays: Please confirm <i>in silico</i> (and where appropriate <i>in vitro</i>) testing exclusivity of the submitted test | Automatic rejection if not supplied | Please provide details of <i>in silico</i> tests for primer and probe sequences and any subsequent <i>in vitro</i> testing resulting from organisms with identified <i>in silico</i> homology |

| | | |
|---|---|--|
| <p>For molecular tests the applicant must provide evidence of regular <i>in silico</i> analysis against SARS-CoV-2 Variants of concern or under investigation data as published on gov.uk. During the period the application is being considered, the applicant must inform CTDA at CTDA@mhra.gov.uk within 48 hours of confirmation that a variant of concern (VOC) affects the assay target region/s by <i>in silico</i> analysis</p> | <p>For information only</p> | <p>Please provide details of <i>in silico</i> tests for primer and probe sequences against variants of concern. These data are not a requirement but will aid the assessment of your test. Please note this is a requirement from the MHRA for all COVID-19 tests</p> |
| <p>For antigen assays: Please state the protein target(s) and region(s)</p> | <p>Automatically reject if not supplied</p> | <p>Please provide details of your test design and target region(s) e.g. monoclonal, polyclonal, terminus and target protein</p> |
| <p><i>In vitro</i> or <i>in silico</i> cross reactivity with common respiratory targets</p> | <p>Automatic rejection if not supplied</p> | <p>Please provide details of <i>in silico</i> or <i>in vitro</i> studies with clinical or contrived samples known to contain other respiratory viruses. Examples include commercial EQA and control panels</p> |
| <p><i>In vitro</i> effect of common interferants</p> | <p>Automatic rejection if not supplied</p> | <p>Please provide details of any interfering substances and their concentration, that have been tested in combination with the submitted test. Please see the relevant MHRA Target Product Profile for the submitted test for the required checklist of interfering substances</p> |
| <p>Precision</p> | <p>Automatic rejection if not supplied</p> | <p>Please provide details of reproducibility and repeatability studies demonstrating precision</p> |

Technology performance thresholds for approval under CTDA

The [Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021](#) outlines the regulatory requirement for sensitivity and specificity level for each test type. Please refer to the regulation for definitions of sensitivity and specificity in relation to a coronavirus test device.

True positive results are those that have a positive result on both the test device and the comparator assay. False negative results are those that have a negative result on the test device and positive on the comparator assay.

True negative results are those that have a negative result on both the test device and the comparator assay. False positive results are those that have a positive result on the test device and a negative result on the comparator assay.

We will use the following formula¹ for calculating 95% confidence intervals:

| | |
|---|---|
| $\text{Lower 95\% CI} = \frac{A - B}{C} \times 100$ | $\text{Upper 95\% CI} = \frac{A + B}{C} \times 100$ |
| <p>where</p> $A = 2r + 1.96^2 \quad B = 1.96\sqrt{1.96^2 + 4r(1 - p)} \quad C = 2(n + 1.96^2)$ | |
| <p>r = number of true positives (for sensitivity) or number of true negatives (for specificity)</p> <p>n = number of positives on comparator RT-PCR (for sensitivity) or number of negatives on the comparator RT-PCR (for specificity)</p> <p>$p = r/n$ (i.e. sensitivity or specificity as a proportion)</p> | |

When calculating the percentage sensitivity and specificity and 95% confidence intervals, we will round to the nearest 0.1% for comparison with the thresholds. For example, a test with a lower 95% confidence interval that rounds to 92.9% or 93.0% would fail against a threshold of 93%, as the requirement is that the lower 95% CI is entirely above 93%. For examples, see the table below.

| Lower 95% CI | Rounded to the nearest 0.1% | If compared to a threshold of | Pass / Fail |
|--------------|-----------------------------|-------------------------------|-------------|
| 92.85% | 92.9% | 93% | Fail |
| 92.95% | 93.0% | 93% | Fail |
| 93.03% | 93.0% | 93% | Fail |
| 93.05% | 93.1% | 93% | Pass |
| 93.15% | 93.2% | 93% | Pass |

¹ Wilson E.B. (1927) Probable inference, the law of succession, and statistical inference. *Journal of the American Statistical Association* **22**: 209–212 <https://doi.org/10.2307/2276774>. As described in Altman D.G., Machin D., Bryant T.N. & Gardner M.J. (2000) *Statistics with Confidence*, 2nd edition. BMJ Books, London

5: Biosafety

Applicant must state the biosafety requirements of their submitted test.

Where the submitted assay includes the use of a reagent that claims to inactivate the virus, the manufacturer must be able to evidence effective inactivation according to the BSI safety standards and/or Public Health England [Position statement on inactivation of SARS-Cov-2: Implications for laboratory testing](#).

The IFU and any supporting documents will be assessed for the following areas as evidence of biosafety:

| Criteria | Documentation | Response | Requirement |
|--|---|--|--|
| Please state the biosafety containment requirements for the submitted test | Please attach and highlight relevant reference in IFU | Automatic reject if not supplied | The biosafety of the submitted test will impact the use-case scenario in which the submitted test can be utilised |
| Does the submitted test include a viral inactivation step? | Please attach and highlight relevant reference in IFU | Automatic reject if not supplied | Please highlight where this is claimed within the IFU |
| If yes, the applicant must provide documented efficacy evidence according to BSI standards | Please attach and highlight relevant reference in IFU | Automatic reject if not supplied and answer above is yes | Viral inactivation claims must be demonstrated with raw data. Evaluation of the inactivation claims will be conducted against the BSI safety standards and/or position statement on the inactivation of SARS-CoV-2. This requires that an inactivation protocol demonstrates, at a minimum, a reduction of the initial viral titre of at least 4 log (to base 10). Equivalence to similar products is not acceptable. See Position statement on inactivation of SARS-Cov-2: Implications for laboratory testing And COVID-19: safe handling and processing for samples in laboratories |
| If your submission does not include inactivation of clinical samples, please confirm whether the | Please attach and highlight relevant reference in IFU | Automatic reject if not supplied | Please provide evidence of sample preparation and processing method, e.g. non-aerosol creating, need for full PPE |

| | | | |
|--|--|--|--|
| submitted test can be used outside of a laboratory setting | | | |
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