Public Health England

Protecting and improving the nation's health

Point of care tests for influenza and other respiratory viruses

Winter 2019 to 2020

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Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

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Contents

About Public Health England 2
Executive summary 4
Point of Care Tests (POCT) 5
Targets 5
Samples 5
CLIA 5
Regulatory requirements 6
Types of POCT 6
Implementation of POC Tests 9
Factors to consider in implementation 9
Clinical governance and quality assurance 13
Clinical governance 13
Quality assurance 13
Internal quality control 13
External quality assessment 13
National surveillance 14
Audit and monitoring effectiveness 14
Examples of current POCT platforms 15
Early adopters of technologies in the UK 18
Implementation checklist 22
Sources of further information 23
Document authors 24
References 25
Appendix 1: Influenza specimen collection table 27

Executive summary

The purpose of this document is to provide written resources for hospital sites considering implementation of rapid Point of Care testing (POCT) for seasonal influenza and other respiratory viruses during winter of 2018/19. Public Health England (PHE) does not endorse nor recommend any of the commercial platforms or devices considered.

The scope of this document is restricted to consideration of platforms with the potential to be used within 20 metres of patients and operated by a wide range of staff, including those without a laboratory background. Time to result may vary from 10 to 90 minutes.

POCTs for influenza have been available since the late 1990s. The earliest versions of such tests depend on immunological detection of viral antigens in a variety of simple formats, such as dipsticks or small hand held cassettes. Whilst the specificity of these devices is generally greater than 90%, overall sensitivity is typically in the range of 40 to 80%. These are defined here as first generation devices.

POCT devices now entering into clinical use are based on nucleic acid amplification technologies (NAAT), defined here as second generation devices. These platforms generally have improved sensitivity, typically in the range of 60 to 90%, compared to first generation POCTs, and require portable instrumentation with a footprint of approximately 30cm x 30cm. Several of these platforms have been used in Early Adopter (EA) locations within the NHS.

Several key factors have been identified for successful implementation of second generation POCT in hospital settings by EA sites. These include clear testing policies, samples taken early during hospital admission, staff training for operating and maintaining the POCT platform, detailed management algorithms including patient movements, linkage to hospital information technology (IT) and surveillance systems.

Successful outcomes reported by EA groups include improved patient triage, better cohorting and use of isolation rooms during periods of winter pressure. Improved clinical outcomes may include more targeted use of antivirals, a reduction in unnecessary antibiotic use and a reduced length of hospital stay.

Detailed health economic analysis and evidence for the cost effectiveness of second generation POCTs in acute settings is currently missing. Several of the perceived advantages of their use in patient triage and Emergency Admissions may also be delivered through reconfiguration of existing hospital laboratory testing services to make the time to result much faster.

Point of Care Tests (POCT)

Definition: A POCT is a medical diagnostic test, performed at or near the site of patient care, undertaken by healthcare professionals who may not be trained laboratory staff. It is a test to support clinical decision making, to help the physician to decide upon the best management options, and for which the results can be available in real time, usually in less than 90 minutes.

Targets

Respiratory viral testing targets in POCT platforms can be single, dual or multiplex. The commonest are influenza A and B (and/or subtypes) alone, or with respiratory syncytial virus (RSV) testing. Other platforms test ‘syndromically’ for a comprehensive range of viral targets including parainfluenza, human metapneumovirus, seasonal coronavirus, and rhinovirus.

Samples

Nose and throat swabs are the most common sample type used, but optimum sample type vary depending on the platform used. Descriptions of different respiratory tract samples are included in Appendix 1.

CLIA

Clinical Laboratory Improvement Amendments (CLIA) of 1988 are the United States federal standards that regulate laboratory testing and require clinical laboratories to be certified by their state, as well as the Centre for Medicare and Medicaid Services before testing human samples can occur. 3 agencies are responsible for CLIA, which are the Food and Drug administration (FDA), the Centre for Medicaid Services (CMS) and the Centres for Disease Control and Prevention (CDC).

Tests are categorised by their complexity (assessed by the FDA) categorised as a score of 1, 2 or 3 representing waived, moderate and highest level of complexity respectively (Centre for Devices and Radiological Health, U.S. Food & Drug Administration (FDA), 2018).

CLIA waived tests are laboratory examinations or procedures that are approved by the FDA for home use, or that are simple enough to have an insignificant risk of an erroneous result including those that:

- employ methodologies that are so simple and accurate as to render the likelihood of erroneous result by the user negligible
- pose no reasonable risk of harm to the patient if performed incorrectly

Regulatory requirements

FDA is responsible for classifying medical devices in Class I, II or III which defines the regulatory requirements. These increase from Class I to III. Most Class I are exempt from Premarket notification 510(k), most Class II require Prenotification Notification 510(k) and most Class III devices require Prenotification Approval.
Premarket Notification: A device cannot be commercially distributed until a letter of substantial equivalence from the FDA authorises this to occur.

Prenotification approval: This is required of Class III devices that are high risk and pose a significant risk of illness or injury, and involves submission of clinical data to support claims made.

CE Marking: Used in the European Union (EU) and given when medical devices comply with European-in-vitro Diagnostic Device Directive (98/79/EC), in order that the device may be legally commercialised in the EU.

New in Vitro Diagnostic Regulations (IVDR) were published in 2017 but most requirements will not fully apply until 26 May 2022: www.ce-mark.com/IVD%20Regulation.pdf.

Types of POCT

Test platforms with varying formats and characteristics are available from a wide range of manufacturers. The following considerations should be used when planning services and selecting the most appropriate platform for the setting.

Technology: Antigen detection tests

Antigen based rapid influenza detection tests, sometimes called Rapid Influenza Detection tests (RIDT), are based on immunological detection of viral antigen. These are typically formatted as dipsticks or small hand held cassettes with a 10- to 15-minute running time. They have sensitivity in the 40% to 80% range with high specificity (>90%), but are unable to provide influenza A subtyping. These are classified as first generation tests.

Digital immunoassay antigen (DIA) tests are antigen detection tests that use fluorescence technology to provide signal amplification and therefore improve sensitivity

to 70% to 80% and typically use a hand held or small ‘reader’. These show incremental improvement over the earliest first generation antigen detection kits.

Manufacturer measurement of performance of antigen detection POCT platforms may differ from that observed in field use. Concern over variability in performance and less than optimal sensitivity of antigen based POCTs, has led the FDA to reclassify them as Class II devices.

Technology: Nucleic Acid Amplication Tests (NAAT)

Rapid POCT molecular assays generate results in 15 to 90 minutes. The technology principle here involves amplification of the viral target prior to detection, generating the conditions for enhanced performance. These POCTs have higher sensitivity and specificity (90 to 95%) than antigen based POCT, when compared to the gold standard laboratory based PCR testing. These are classified as second generation tests.
The format of the POCT platform typically includes a small footprint (~30 x 30cm instrument) which requires a power supply and a closed single or multiple use pre-loaded cassette for sample handling, in which the NAAT biochemical test is performed (see figures below).

NAAT test POCT platforms use Reverse Transcription polymerase chain reaction (RT-PCR) or similar, to detect and discriminate between influenza A and B viruses including specific influenza seasonal A subtypes.

Detection of virus by NAAT does not necessarily indicate viable virus or ongoing replication.

Performance characteristics

	Sensitivity	Specificity
First generation Single Antigen based	50% to 70%	85% to 100%
Second generation NAAT based Single target (influenza A+ B only)	90% to 99%*	95% to 99%
Second generation NAAT based Multiple targets	90% to 99%	95% to 99%

Points to note

Every effort should be made to collect samples which have respiratory tract cellular material and taken early during the course of illness.

Sensitivity and specificity for all tests will vary with timing of the specimen from illness onset to collection, quality of specimen collected, time of transportation of sample to testing source, handling of specimen and sample type (eg throat swab versus nasopharyngeal swab).

Predictive values of all tests vary according to the prevalence of disease. The overall performance of any POCT platform will be improved during an influenza epidemic compared to results obtained out of season in sporadic cases.

The gold standard test remains laboratory based RT-PCR testing for influenza or respiratory viral pathogens. This serves as the comparator for sensitivity and specificity.

National and local surveillance information is derived from gold standard laboratory results. Further samples may be required for additional tests. It is important to consider how POCT test results and additional confirmatory samples may be channelled into existing pathways for laboratory testing, and samples are made available for further testing if required.

POCT should ideally be reported via hospital Laboratory Information Management Systems (LIMS) for clinical governance, operational management and surveillance purposes.

Implementation of POC Tests

Factors to consider in implementation

Selection of a POCT Platform

Patient populations: POCTs can be used in children and adults but there may be some notable differences eg preferred sample type may differ; nasopharyngeal aspirates tend to be used in children compared to nose and throat swabs. Children tend to have a higher viral load of respiratory virus and therefore any test may perform better in this patient group.

Sample type: For example nose or throat swabs, nasopharyngeal aspirates, nasal washes and sputum. Every effort should be made to ensure that there is good respiratory tract epithelial cell content in clinical samples.

Range of viruses targeted: Influenza A+B only, influenza A+B plus respiratory syncytial virus (RSV) or a comprehensive panel (influenza, RSV, rhinovirus, parainfluenza, seasonal coronavirus, human metapneumovirus and adenovirus). Consider impact on cost, clinical management of patients and infection control actions of single versus multiple pathogen detection.

Setting in which the test is to be used: Emergency departments (ED), medical admission units, outpatients.

Technology used (antigen detection /NAAT): Ease of use, care and maintenance of equipment, location and space required, power supply and space for recording results and handling samples.

Sensitivity and specificity: The tests may perform differently compared to the manufacturer’s data, dependent on local patient characteristics, time from illness onset to presentation, background influenza rates, location and staff performing test. Careful monitoring of performance compared with the gold standard laboratory test is advised as part of implementation to gain experience in the performance characteristics of the tests in addition to laboratory quality assurance.

Consideration of clinical and operational impact of a low negative predictive value according to the intended use.
Speed and ease of test: Speed varies from around 15 to 90 minutes. Speed and ease of testing will affect how staff organise to run tests and feedback information for real time clinical decision making.

Cost of test, including cost of equipment, parallel testing/laboratory verification testing if appropriate.

Published studies from the UK, Europe and the US where NAAT POCTs have been used in secondary care settings (Davis *et al.*, 2017)(Brendish *et al.*, 2017) (Merckx *et al.*, 2017a) do not report consistent outcomes. Some studies evaluate only the performance characteristics (ie diagnostic accuracy) of the test against another laboratory test, whereas others evaluate the use of the test device with measured health outcomes.

Operational and logistical practicalities

Factors to be considered when introducing point of care testing into clinical practice include:

1. Location of the machine: Machines may be located in clinical areas convenient for clinician use, such as the ED and Medical Admissions Unit. Some hospitals may choose to situate the machines in a dedicated point of care area, or the main laboratory.

2. Test operator: Training is required to ensure appropriate sample collection and disposal, machine use, and recording of results. Consider which staff group is best placed to carry this out locally (clinical, nursing, technical or laboratory staff), with assessment and maintenance of competency.

Clinical pathway considerations

Clinical engagement: The introduction of clinical algorithms may help signpost clinicians to prompt testing. Engagement of departments is crucial including ED, medical assessment unit, microbiology, virology and infection control teams, medical director and management teams. Appointing flu champions in local areas may contribute to successful uptake.

Patient group targeted: This may include all patients presenting to ED or acute medical services with a respiratory illness and/or fever or history of a fever regardless of comorbidities. Some departments may choose to test both adults and children. Additional use of the test should be considered for services with patients vulnerable to severe influenza such as haematology and oncology day units, and maternity services to ensure early isolation and management of affected patients.
Action of the results: Local protocols may be helpful in linking the results of the test to clinical guidelines on antiviral and antibiotic use. The results should assist clinicians, bed managers and infection prevention and control teams in planning appropriate admission, discharge and isolation arrangements in real time.

Role of Infection Control team: Close liaison with the Infection Control team is crucial, including policy setup, facilitating implementation, guidance and support for colleagues and ensuring compliance. Guidelines are recommended to encompass clinical and infection control aspects of respiratory viral illness. Patient leaflets may be useful to answer common questions.

Timely reporting of the results: Robust systems must be in place to ensure that the result is recorded clearly in an appropriate place in each patient's medical records and hospital result systems, and that clinical teams are aware of the result to enable them to take necessary action in real time.

Local and National Regulatory Requirements

POCT platforms should be linked via an interface to the laboratory Information management system (LIMS) and/or the electronic patient record (EPR) to ensure good data quality and clinical governance as with other POCTs, such as arterial blood gas device.

Mandatory Public Health Surveillance: National Hospital mandatory surveillance schemes (UK Severe Influenza Surveillance Scheme USISS) involve weekly reporting of confirmed influenza cases admitted to Critical care. Ensuring holistic integration of influenza POCT results into routine hospital surveillance data underpinning mandatory national schemes is essential to avoid duplication or under reporting of influenza cases.

Training

Personnel are required to support training and maintain competency, ensure regular monitoring and maintenance of supplies and equipment, including trouble shooting any issues with timely repairs, and perform quality assurance assessments. Trusts may appoint a POCT team in order to undertake this function. This should be done in a timely manner in preparation for influenza season

Cost effectiveness

Manufacturers may offer different arrangements concerning POCT platform costs to purchase or hire consumable unit costs, and servicing and maintenance contracts. Local NHS Procurement may have relevant information.

The costs of POCT are often accrued in different budgetary areas to the clinical benefit gained from implementation. Investment in time and resources from laboratory and ED teams may accrue savings in inpatient services, for example, through targeted appropriate antiviral treatment, potential shorter courses of antibiotics and possible earlier discharge, timely isolation of affected patients, and avoidance of unnecessary

use of side rooms, decreased deep cleaning and improved patient flow. This should be considered when building a business case and monitoring effectiveness of the service.

Clinical governance and quality assurance

Clinical governance

Safe and effective delivery of POCT is a clinical governance issue which involves effective organisation and management arrangements and should be fully integrated into overall risk management frameworks.

Choice of instrumentation and POCT should be clearly linked to description of methodology, FDA or European Medicines' Agency (EMA) approval, verification and review of regulatory validation data to ensure that the selected POCT profile matches the specification required.

Laboratory support and a project plan should be in place to manage the introduction of any POCT, and an appropriate senior professional should be identified to be the Lead for the service.

Reporting lines need to be clear and may involve a POCT committee. Lines of accountability should be well defined in local policy guidelines.

Quality assurance

Tests performed away from the laboratory must still have rigorous quality assurance and safeguards which encompasses proper training and overall performance. This consists of 2 elements which are internal quality control (IQC) and external quality assessment (EQA) to ensure reliable results.

Internal quality control

Local teams implementing point of care respiratory virus testing have taken various approaches as to whether to repeat all, selected or random samples through standard laboratory processes as part of the ongoing quality control process. Ensuring that samples are captured for regular respiratory viral surveillance programmes is essential.

External quality assessment

This allows testing of a sample of unknown value to be circulated to a number of users of a similar device. This may be organised on a local or national level. Consideration to EQA should be given, although it is noted that this is not available for every analyte which is measured in a point of care test

The MHRA have produced guidance on the processes and systems required in the management of in vitro point of care test devices, available at: www.gov.uk/government/publications/in-vitro-diagnostic-point-of-care-test-devices

National surveillance

National monitoring of respiratory virus prevalence and testing of vaccine effectiveness may be affected if the use of POCT technologies results in the submission of fewer samples to the laboratory. PHE influenza guidelines covering a range of clinical scenarios are updated every autumn in preparation for the winter season, 2018 to 2019 guidance can be found here: www.gov.uk/government/publications/influenza-treatment-and-prophylaxis-using-anti- viral-agents

Audit and monitoring effectiveness

Clinical audit is an important tool to ensure quality is comparable to the gold standard and to monitor the effectiveness of implementation.

Information that may be included in clinical audit includes:

- characteristics of the population sampled (eg patient age groups, nature of symptoms such as acute respiratory illness, fever, comorbidities)
- number of detected positive and negative cases; comparison with laboratory results
- time from presentation to test result
- time from specimen collection to test result
- time to initiation of antiviral treatment where indicated
- appropriateness of antiviral treatment – for example, percentage of neuroaminidase inhibitor (NAI) treated patients with and without flu, duration of NAI treatment in influenza negative patients.
- impact on antibiotic use for patients testing positive – for example length of antibiotic course, percentage of influenza positive patients treated with antibiotics
- length of stay.
- impact on isolation practices – side room use, ward closure, cohorting, side rooms requiring deep clean
- appropriate use of the algorithm by clinical staff, for example correct patient groups tested – factors identified where this was not the case
- cost effectiveness analyses incorporating the above

Audit parameters should be identified prior to POCT implementation, with clear methods to collect, store and collate data at certain time points. This should be under the responsibility of a designated lead, with presentation and dissemination of results to the trust.

Examples of current molecular POCT platforms

Name	Targets detected	Duration of test	Regulatory status	Performance Characteristics
Alere TM Influenza 	Flu A + B	15 minutes	CLIA waived for direct nasal swabs CLIA complexity moderate for nasal or nasopharyngeal swabs in viral transport media	Sample type: Nasal swab direct in viral transport medium or nasal or nasopharyngeal swabs in VTM Report from manufacturer: Flu A Sensitivity 97.9% (95% CI 92.6 to 99.4%) Specificity 86.2% (95% CI 82.8 to 89%) Flu B Sensitivity 92.5% (95% CI 84.6 to 96.5%) Specificity 96.5% (95% CI 94.5 to 97.8%) UK study Multicentre (4 hospitals). 827 participants, 589 analysed Sample type: nose swab Sensitivity 75.8% (95% CI 72.9 to 89.5%), Specificity 96.8% (95% CI 95.2 to 98.3%) (Davis et al., 2017) Meta-analysis (Merckx et al., 2017b) Flu A Sensitivity 85% (95% CI 75.3 to 90.9%) Specificity 98.9% (95% CI 97.7 to 99.6%) Flu B Sensitivity 86.6% (95% CI 69.0 to 95.3%) Specificity 99.1% (95% CI 98.1 to 99.7%)
Cobas LiatTM influenza A+B Assay Roche	Flu A + B or Flu A + B & RSV	20 minutes per test	CLIA waiver	Sample type: Nasopharyngeal swabs (Kingston NHS Hospital used throat swabs) Used by Kingston:

Name	Targets detected	Duration of test	Regulatory status	Performance Characteristics
				99% specificity but too few samples 100% sensitivity Study of 197 swabs showed: Sensitivity 99.2% Specificity 100% (Binnicker *et al.*, 2015) A 12 site study showed similar sensitivities and specificities (Gibson *et al.*, 2017) Meta-analysis (Merckx *et al.*, 2017b) (also stratifies results by industry sponsored or not) *Flu A* Sensitivity 97% (95% CI 92.9 to 98.9%) Specificity 99.4% (95% CI 98.4 to 99.8%) *Flu B* Sensitivity 98.7% (95% CI 95.6 to 99.7%) Specificity 99.5% (95% CI 98.7 to 99.9%)
GeneXpert Flu Assay Flu A+B and Flu A+B & RSV(Cepheid, Sunnyvale CA, USA)	Flu A + B or Flu A + B & RSV Up to 16 test at a time depending on number of ports	60 minutes	Flu A+B CE marked FDA approval Flu A+B & RSV CLIA waiver	Sample type: Nasopharyngeal swab GeneXpert Flu Assay A+B also accepts nasal swabs Study showed: *Flu A* PPA 100% (95% CI 98.7 to 100%), NPA 99.27% (95% CI 98.76 to 99.57%)
				Flu B PPA 100% (95% CI 97.38 to 99.95%) NPA 99.85% (95% CI 99.55 to 99.95%) RSV PPA 98.01% (95% CI 94.32 to 99.32%) NPA 99.95% (95% CI 99.71 to 99.99%)

Name	Targets detected	Duration of test	Regulatory status	Performance Characteristics
				(Cohen et al. 2017)
FilmArray (biofire Diagnostics Inc) RP amd RP 2 	RP; Multiplex nested PCR 20 targets including Flu A, B, RSV & a number of viral and bacterial pathogens. RP 2; as above plus 2 extra targets - MERScoV and Bordetella parapertussis	RP: 60 minutes RP 2: 45 minutes	CE marked, FDA approved	Sample type: nasopharyngeal swabs Multicentre evaluation of 33,843 analysable FilmArray RP2 organism results for 1,612 specimens (Leber et al., 2018) Overall PPA 97.1% (1,105/ 1,138) Overall NPA 99.3% (32, 481/ 32, 705) 91.7% or greater for detection of all but 3 analytes: Coronavirus (CoV) OC43, Bordetella parapertussis, and Bordetella pertussis 9 of 22 analytes had demonstrated a PPA of 100% (CoV-HKU1, CoV-NL63, Flu A, Flu A H1-2009, Flu A H3, Flu B, Parainfluenza 1 & 4 and Chlamydia pneumoniae) Overall negative percent agreement of ≥93.8% for all analytes (Leber et al., 2018)

Early adopters of technologies in the UK

Several UK centres have already integrated POCT for influenza testing during the winter season (October to April). This provides a framework for implementation, and highlights potential areas that may require further work.

These centres have kindly offered their local experience of POCT testing below and are happy to be contacted. Their experience raises helpful points that may benefit other centres, but we acknowledge may not be applicable to all.

Name of location	Experiences	Contacts
University Hospital Southampton Foundation NHS Trust	Randomised controlled trials of routine POCT (using a comprehensive multiplex respiratory panel) in patients with acute respiratory illness or unexplained fever was associated with: improved detection of influenza more appropriate use of antivirals more appropriate use of isolation rooms reduced use of unnecessary antibiotics shorter length of stay Additional analysis showed that these clinical benefits were dependent on a turnaround time for POCT < 2 hours. Lancet Respiratory Medicine www.thelancet.com/journals/lanres/article/PIIS2213- 2600(17)30120-0/abstract?code=lancet-site European Respiratory Journal erj.ersjournals.com/content/52/2/1800555.long	Dr Tristan Clark Associate Professor and Honorary Consultant in Infectious Diseases NIHR post-Doctoral Fellow T.W.Clark@soton.ac.uk
Kingston Hospital NHS Foundation Trust	Introduced POCT influenza to avoid unnecessary isolation of patients whilst waiting for results, which impacted on patient flow and available beds during winter. In winter 2017 and 2018 POCT was introduced with:	Fran Brooke-Pearce CNS Infection Prevention and Control Fran.brooke-pearce@nhs.net Dr Elli Demertzi

	• the creation of criteria and algorithms for adult flu testing and management • laboratory and clinical verification • training and ensuring quality control A total of 1,526 POC tests were done; 35% of patients were positive of which 33% were discharged on the same day from ED. 65% were negative not requiring isolation, once other risks have been ruled out. Flu POCT had a positive impact on: bed management targeted antiviral treatment antimicrobial stewardship infection control – 9% hospital acquired flu cases compared to 30% the previous year	Consultant Microbiologist and Infection Control Doctor Elli.demertzi@nhs.net
Sheffield Teaching Hospitals NHS Trust Department of Infectious Diseases	Used POCT for influenza for over 5 years in ED, medical assessment, medical admissions unit, frailty unit and Infectious Diseases department. This involved: creating an algorithm for management of suspected cases training and competency for clinical staff champions in each area, supporting staff guidance for testing, post test results, PPE use, antivirals, admission to hospital and critical care criteria IT support with intranet information, creation of electronic infectious diseases referral, real time influenza graphs Outcomes: influenza POCT is now standard of care enhanced infection control practices reduced length of hospital inpatient stay empowers clinicians to make discharge decisions promptly improved patient flow and operational pressures	Dr Mohammad Raza Consultant Virologist Mohammad.Raza2@nhs.net Dr Cariad Evans Consultant Virologist Cariad.Evans1@nhs.net

	Published a prospective multicentre study on diagnostic accuracy and cost analysis of POCT(Davis *et al.*, 2017). Detailed local documents/algorithms are available at: www.sheffieldvirology.co.uk (from an NHS computer). Cariad Evans has described local experience in the Royal College of Pathologists Bulletin October 2018: www.rcpath.org/profession/publications/college-bulletin/october-2018.html	
Public Health Wales	Network of labs covering 6 health boards. In winter 2017/2018, 1400 samples were tested by 1 of 3 POC tests (Cepheid influenza A/B and RSV, BioMerieux Biofire filmarray RP2 and GenMark ePlex respiratory screen). The testing was delivered in the laboratories (not ward based) with a guaranteed turnaround time from receipt of 2 hours. Clinical verbal feedback showed that there was: prompt diagnosis aided early discharge early cohorting of patient to prevent hospital transmissions more effective use of isolation rooms Challenges included difficulty collecting outcome measures, clinical impact and cost benefit. Further expansion of the rapid service is currently underway for the network in time for the 2018/2019 respiratory season.	Dr Catherine Moore Consultant Clinical Scientist Catherine.moore2@wales.nhs.uk Dr Rachel Jones Consultant Virologist Rachel.jones11@wales.nhs.uk

Scottish Health Protection Network (SHPN)	Scottish guidance published November 2018: www.smvn.scot.nhs.uk/poct SBAR: Joint SMVN/SHPN Public Health Microbiology advisory Statement for Influenza Point of Care Tests: www.hps.scot.nhs.uk/resp/resourcedetail.aspx?id=362 0	

Implementation checklist

POCT platform	Clinical pathway and staff training	Result reporting
Which platform chosen? Rationale for choice Location of platform Test operator	Clinical algorithm provided? Methods to disseminate algorithm How will a test be ordered? Who will train staff to use POCT? How will they be assessed? Who is responsible for training and maintaining competency Will you appoint a POCT team? When will the roll out of training begin?	Where is result reported for real time action? Is this integrated into the LIMS? If not, how will the result be available to clinicians? Does the result link to clinical protocols for management of flu? How are results flagged to the infection control team? How does this affect patient workflow in real time (isolation, cohorting)?
Clinical governance	**Costs**	**Monitoring of effectiveness**
Who is responsible for the machine? Is there a clear line of accountability for any issue? Who is responsible for stock supply? Do you intend to do lab/clinical verification? Quality assurances considerations: EQA, IQC	Estimated number of tests over the winter period? Estimated cost per test, initial costs for platform etc. Estimated savings	Components to be assessed (eg length of stay, proportion of NAI treated patients with or without flu, proportion of flu positive patients given inappropriate antibiotics)? Where will the Information be stored? When will this be reviewed? Who will be responsible for this?

Sources of further information

The MHRA have published their ‘Top 10 Tips’ on POC Testing
assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/403711/Top_10_tips_for_point_of_care_testing.pdf

The MHRA’s full guidance on the management point of care devices is available
www.gov.uk/government/publications/in-vitro-diagnostic-point-of-care-test- devices

New EU in Vitro Diagnostic Medical Device Regulations (IVDR)
www.ce-mark.com/IVD%20Regulation.pdf

The ResPOC trial published in The Lancet Respiratory Medicine in 2017 evaluated the impact of routine molecular point of care testing for respiratory viruses at University Hospital Southampton NHS Foundation Trust as part of a RCT,
www.thelancet.com/journals/lanres/article/PIIS2213-2600(17)30120-0/abstract?code=lancet-site

CDC website on Seasonal influenza which provides guidance for clinicians
www.cdc.gov/flu/professionals/diagnosis/index.htm

U.S FDA Centre for Devices and Radiological Health: Overview of medical device regulation
www.fda.gov/medicaldevices/deviceregulationandguidance/overview/default.ht m

Pathology in Practice: UK NEQAS; coordinating point of care testing. An article regarding point of care testing and NEAS standards
www.pathologyinpractice.com/story/26291/uk-neqas-coordinating-point-of-care- testing

The Royal College of Pathologists Bulletin October 2018; C. Evans; Influenza Point of Care testing: a Sheffield Teaching Hospital experience
www.rcpath.org/profession/publications/college-bulletin.html

Scottish Health Protection Network (SHPN) Scottish guidance published November 2018 www.smvn.scot.nhs.uk/poct

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To make sure this document meets your needs we welcome feedback. Please email your comments to: phe.enquiries@phe.gov.uk

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Appendix 1: Influenza specimen collection table

(Based on CDC guidelines: www.cdc.gov/flu/pdf/freeresources/healthcare/flu-specimen-collection-guide.pdf)

	Nasopharyngeal Swab	Nasopharyngeal /nasal Aspirate	Nasopharyngeal/nasal wash	Deep Nasal Swab	Combined Nasal and Throat swab
Materials	General purpose flocked swab suitable for viral swabbing Viral transport media tube (contains 1 to 2mls of viral transport medium)	Sterile suction catheter/suction device Viral transport media tube (contains 1 to 2mls of viral transport medium)	Sterile suction catheter/ suction device Sterile normal saline	General purpose flocked swab Viral transport media (contains 1 to 2mls of viral transport medium)	Adult – general purpose flocked swab Paediatric – fine tipped swab Viral transport media tube (contains 1 to 2mls of viral transport medium)
Procedure	Tilt patient's head back Insert swab into nostril aiming straight backwards, NOT upwards, (swab should reach depth equal to distance from nostris to outer opening of the ear)	Attach catheter to suction apparatus Tilt patient's head back Insert catheter into nostril. (Catheter should reach depth equal to distance from nostrils to outer opening of ear)	Attach catheter to suction apparatus Tilt patient's head back Insert several drops of sterile normal saline into each nostril Insert catheter into nostril. (Catheter should reach depth equal to distance from nostrils to	Tilt patient's head back Insert swab less than one inch into nostril (until resistance is met at turbinates). Rotate the swab several times against nasal wall and repeat in other nostril	Tilt patient's head back Insert swab less than one inch into nostril (until resistance is met at turbinates) Rotate the swab several times against nasal wall and repeat in other nostril using the same swab Place tip of the swab into sterile viral transport media tube and cut off the applicator stick.

	Rotate swab several times and withdraw Place tip of swab into sterile viral transport media tube and snap off the applicator stick.	Suction and rotate gently. Remove catheter Place specimen in sterile viral transport media tube. Note: NP aspirate may not be possible to conduct in infants	outer opening of ear). Suction and rotate gently. Remove catheter. Place specimen in sterile viral transport media tube. Note: NP aspirate may not be possible to conduct in infants	using the same swab Place tip of swab into sterile viral transport media tube and snap off the applicator stick	For throat swab, take a second dry polyester swab, insert into mouth, and swab the posterior pharynx and tonsillar areas (avoid the tongue). Place tip of swab into the same tub and cut off the application tip