Abbott ID Now analyser for COVID-19 and Influenza A/B testing

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Review Interval	2 years

Changes from last version of this document

Updated template

Update in bleach maintenance procedures

Contents

1 Purpose and Principle

1.1 Purpose

In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus, SARS-CoV-2, causes the associated coronavirus disease COVID-19. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.

The most common symptoms of COVID-19 are fever, loss of taste or sense of smell, and dry cough. These symptoms are usually mild and begin gradually. Some people become infected but remain asymptomatic. The disease can spread through respiratory droplets produced when an infected person coughs or sneezes. These droplets land on objects and surfaces around the person. Other people may acquire SARS-CoV-2 by touching these objects or surfaces, then touching their eyes, nose, or mouth. On March 11, 2020, the COVID-19 outbreak was characterized as a pandemic by the World Health Organization (WHO).

Influenza is a winter respiratory virus which can be detected in a Point of Care Testing (POCT) setting alongside SARS-CoV-2 for COVID-19. It is a highly contagious, acute, viral infection of the respiratory tract. It is a communicable disease that is easily transmitted through the coughing and sneezing of aerolized droplets containing live virus. Influenza outbreaks occur each year during the autumn and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder.

Rapid and reliable detection of influenza A & B allow for immediate, effective treatment decisions. Rapid diagnosis of influenza can lead to reduced hospital stays, reduced secondary complications and allow for effective implementation of infection control measures.

1.2 Principle

The Abbott ID Now Influenza and COVID-19 assays performed on the ID Now instrument are rapid, automated molecular *in vitro* diagnostic tests utilising an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of target RNA in direct nasopharyngeal swabs (or throat swabs for Covid-19) from patients. The system is intended as an aid in the differential diagnosis of Influenza & COVID-19 viral infection in humans in conjunction with clinical and epidemiological risk factors.

The Abbott ID Now automated system is comprised of a Sample Receiver, containing elution buffer, a Test Base, comprising two sealed reaction tubes, each containing a lyophilised pellet, a Transfer cartridge for transfer of the eluted sample to the Test Base, and the ID Now Instrument.

The reaction tubes contain the reagents required for amplification of target nucleic acid, as well as an internal control. The templates are utilized for the specific amplification of the target nucleic

acid and fluorescently-labelled molecular beacons are used to specifically identify each of the amplified RNA targets.

To perform the assay, the sample receiver and test base are inserted into the ID Now instrument. The swab sample is added to the sample receiver and transferred via the transfer cartridge to the test base, initiating target amplification. Heating, mixing and detection are provided by the instrument, with results automatically reported.

2 Patient Preparation & Sample Requirements

- Nasal swab samples collected as dry swab from patient
    - Kit swabs must be labelled and transported in provided transport tubes
    - can be stored in a capped transport tube for **up to 1 hour at room temperature**, 15°C to 30°C. If greater than 1 hour delay occurs, dispose of swab and take a fresh sample.
- DO NOT use viral transport media (VTM) swabs
- Swabs should only be analysed ONCE then discarded as clinical waste as per local policy

3 Tasks, Responsibilities and Authorisations

- These procedures should be carried out by HCPC Registered BMS staff, OR Point of Care Testing operators who have been appropriately trained and whose competence has been established and recorded on Q-Pulse or POCT database.
- Trainee and student BMS/AP staff may carry out these procedures under the direct supervision of a HCPC Registered BMS as above.
- All requests for clinical advice must be referred to a member of the clinical team in the first instance.

Tasks	Responsible	Authorised
Test analysis	Operators – access only given following appropriate training	Trained POCT staff
Maintenance/IQC/EQA	POCT staff	POCT tasks competency

4 Equipment

- Abbott ID Now instrument:

- Universal Printer (*Product code: 55115*)
- Barcode scanner (*Product code: OPR2001ZWU1-201*)
- Abbott ID Now **COVID-19 Test Kit** (*Product code: 191-000*): single use, store at room temperature 2°C to 30°C, provided by POCT and

- Abbott ID Now **Influenza A&B Test Kit** (*Product code: 427-000*): single use, store at room temperature 2°C to 30°C, provided by POCT.
    - BASE **Test Base**: Orange plastic components containing two reaction tubes of lyophilised reagents for the targeted amplification of RNA.

    - RCVR **Sample Receivers**: Blue plastic components containing 2.5mL of elution buffer.

    - CARTRDG **Transfer Cartridge**: White plastic components used to transfer 2x 100µL of sample extract from the Sample Receiver to the Test Base.

    - Foam tipped swab provided as part of the kit

- COVID-19 Swab Transport Tube Accessory pack *(REF: 190-010):* provided by POCT

- Printer paper rolls (*REF: 26333):* provided by POCT
- Qnostics SARS-CoV-2 Q Control 3rd party positive controls (*5060605502021)*

For in-house support:

- POCT York 772 5890
- POCT Scarborough 771 2659

For technical support/advice from Abbott:

- EMEproductsupport@abbott.com
- +44 161 483 9032

5 Chemicals and Reagents

Name	COSHH Ref. No.	Classification & Specific Instructions Summary
ID Now Covid Elution Buffer	**Safety Data Sheet availabl e from Abbott**	**Description:** 2.5mL of elution buffer in plastic Blue Sample Receiver, mixed with patient swab to remove sample from swab. **Preparation:** Use as supplied. **Storage:** Room temperature 2-30C **Supplier:** Abbott ID Now Risk Statement & Control Measures This product is unlikely to cause harmful effects under normal conditions of use. Wear appropriate PPE including eye protection. **Action in the event of Spillage** In the event of spillage of excess liquid from the container, soak up with absorbent material and dispose via clinical waste. Hazard Identification & First Aid Measures **Eye contact:** Rinse immediately with plenty of water. If eye irritation persists, seek medical advice. **Skin contact:** Rinse well with soap and water. I**nhalation:** Move to fresh air. **Ingestion:** Rinse mouth with water. If symptoms persist, seek medical advice. Liquid Waste Disposal Discarded connected to the other test pieces as per the method section to prevent spillage.
PDI Sani-Cloth 70% Alcohol wipes	**SDS availabl e from:** http://me dia. supplych ain. nhs.uk/m edia /docume nts/ VJT164/ COS HH/6331 4_VJ T164.pdf	**Description:** Sani-Cloth. Can be used as terminal sterilization/high level disinfection on any surface that has come in contact with contaminating material, including equipment and broken skin. **Preparation:** Use as supplied. **Storage:** Keep closed and store in upright position in a cool and dry place. Once opened, use within 6 months (label container with use by date) **Supplier:** PDI, Aber Park, Flint, UK Risk Statement & Control Measures This product is unlikely to cause harmful effects under normal conditions of use. **Action in the event of Spillage** In the event of spillage of excess liquid from the container, soak up with absorbent material and dispose via yellow bags. Hazard Identification & First Aid Measures  Flammable.

		Eye contact: Rinse immediately with plenty of water. If eye irritation persists, seek medical advice. **Skin contact:** Rinse well with soap and water. I**nhalation:** Move to fresh air. **Ingestion:** Rinse mouth with water. If symptoms persist, seek medical advice. Liquid Waste Disposal Dispose of via sluice/laboratory drain with plenty of water. Rinsed plastic container can be disposed of as plastic/household waste.
Hospec General Purpose Thin Bleach (0018000017)	**SDS availabl e** from Product Informati on on NHS Supply chain or on request from POCT.	**Description:** 10% bleach solution (1 part bleach and 9 parts water) for general cleaning procedures **Preparation:** Make fresh weekly – eg. add 2 ¼ water to ¼ cup bleach and gently swirl and date solution. Do not mix with other household chemicals particularly those containing acids. **Storage:** Room temperature 2-30C for 1 week **Supplier:** NHS Supply Chain - Hospec Risk Statement & Control Measures This product is unlikely to cause harmful effects under normal conditions of use. **Action in the event of Spillage** In the event of spillage of excess liquid from the container, soak up with absorbent material and dispose via clinical waste. Hazard Identification & First Aid Measures  Warning **Eye contact:** Rinse immediately with plenty of water. If eye irritation persists, seek medical advice. **Skin contact:** Flush skin thoroughly with water. Seek medical attention if irritation persists after washing. I**nhalation:** Move to fresh air. **Ingestion:** Rinse mouth thoroughly with water. DO NOT induce vomiting. If symptoms persist, seek medical advice. Harmful to aquatic life with long lasting effects. Liquid Waste Disposal Dispose of via sluice/laboratory drain with plenty of water. Rinsed plastic container can be disposed of as plastic/household waste.

6 Risk Assessment (Environmental and Safety Controls)

Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be followed at all times during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.
- See table in 'chemicals and reagents' section for specific COSHH assessment.
- Refer to PC-HSR-IDNOWCOV for risk assessment – available in QPulse and available on request form POCT

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This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk; where possible is mitigated and or monitored with health surveillance to ensure health and safety for all those affected by this procedure

7 Calibration

- The ID now Instrument is factory calibrated and does not require further calibration.
- If the instrument is moved or transported, a performance check using ID Now positive and negative IQC is recommended to ensure proper functionality.

8 Quality Control and weekly maintenance

1. **Weekly bleach clean** – clean the ID Now instrument and surrounding bench using a lint free cloth dampened with a 10% bleach solution (made fresh weekly as per guidance in section 5 Chemicals and Reagents) followed by 70% alcohol wipes. Try to leave the bleach solution soaking for 10 minutes to ensure break down of any RNA sequence remnants. Do not spray or pour liquid directly onto the analyser as excess liquid will damage the instrument. An alcohol-soaked swab can be used to clean the inside holes of the sample receiver and test base.

2. **Weekly environmental testing** - performed by POCT/laboratory staff by swabbing the following areas:
   - Set-up bench
   - ID Now analyser internal and external parts, barcode scanner and printer

   Swab should be analysed as a patient test using 'Environmental' as the patient ID.

   If any environmental swabs yield a positive result, the area must be thoroughly cleaned as per step 1. at least 3x times, emphasizing the minimum 10-minute soak time. Consider following the cleaning procedure for all other touch points, surfaces and items in the testing room. Remember to routinely change gloves and wash hands during cleaning procedures and remove any waste from the room. Environmental swabs should be repeated and acceptable before the ID Now is used to test patient samples again. Report any environmental failures to the POCT senior for review.

3. **Weekly IQC testing** - performed by POCT/laboratory staff using the 'Run QC Test' button from analyser home screen:
   i) Positive QC using 3rd party Qnostics SARS-CoV-2 Q Control
   ii) Negative QC using a blank kit swab
   In case of any QC failure inform a senior member of staff within POCT Team, the analysers should not be used for patient testing until acceptable QCs obtained.

4. **As required batch acceptance** – positive and negative IQC is performed on all reagent lot numbers for batch acceptance and results scanned and stored on X-drive-POCT-Abbott ID Now-Lot verification. If it is suspected that results are invalid due to a particular lot of reagents, a different lot will be used and details of the affected lot will be relayed to the manufacturer, whilst the affected lot is taken out of use. Each Abbott ID Now kit includes a positive control, the negative control can be a blank swab.

9 External Quality Assurance (EQA)

- The laboratory participates in the UK NEQAS 'Molecular Detection of SARS-CoV-2' external quality assurance scheme.
- Refer to PC-SOP-EQA for detailed POCT EQA procedures

10 Procedural Steps

Infection prevention and good laboratory practice are essential. Change gloves periodically and between clean and dirty tasks. Clean analyser thoroughly between use. Keep the analyser room clean and tidy. Report all spills and breakages to POCT

One swab can be collected for both COVID-19 and Influenza A/B testing, if both are required, test for COVID-19 first, then follow guidance below for **sequential Flu A&B testing** (10.3).

10.1 Sample Collection and Pre-Analysis

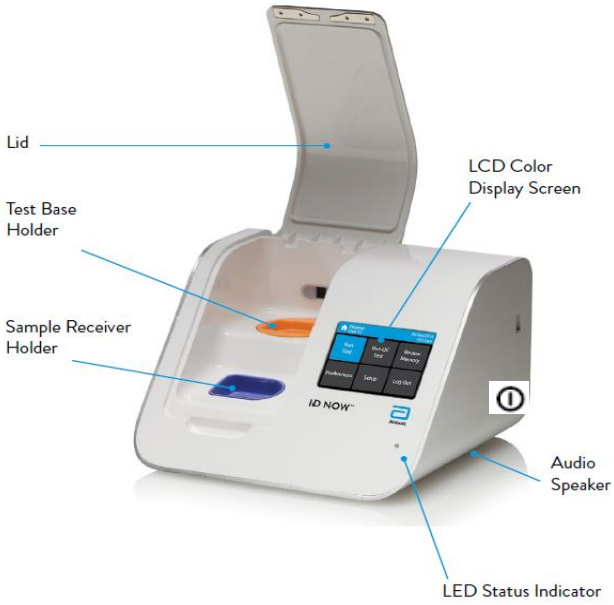
Patient swabs and transport tubes are provided as part of the test kit, please do not use VTM swabs. Samples should be tested as soon as possible (within 1 hour).

1. Positively identify your patient and obtain verbal consent for testing if appropriate.
2. Request a POCT COVID-9/ Influenza test for your patient from CPD and print out the OrderComms form.
3. Follow best practice for taking nasal swabs ensuring:
    - ✓ Clean hands and appropriate PPE
    - ✓ Tilt patients head back and swab the back of the nose rotating the swab 6 times (or counting 10 seconds of contact)
4. **You must** place the swab in a LIDDED TRANSPORT TUBE labelled with the OrderComms label clearly showing patients' NHS number, full name and Date of Birth.

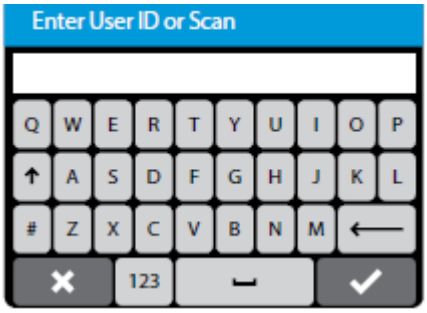
NB: DO NOT put the patient swab back in the paper packaging as this will invalidate your results

PLEASE ENSURE YOU ARE USING THE CORRECT KIT FOR THE TEST REQUESTED.

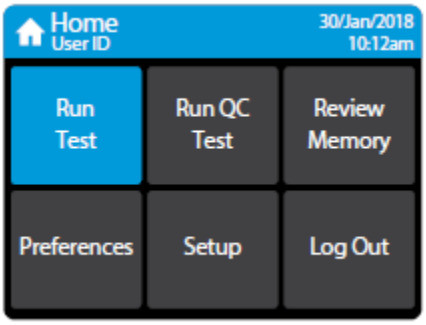
10.2 Running a test on the ID Now



1. With a fresh pair of gloves touch the screen to return the unit to active display operation. *(If the unit is switched off, press the power button on the side of the instrument).*

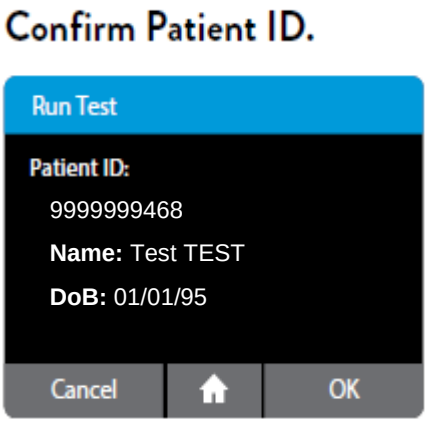


2. Enter your own **Operator ID and password** – press ✓ after entry



3. The instrument will run a 'self test' after which the home screen is displayed.

4. Touch '**Run Test',** then touch '**Influenza A & B** or **COVID-19'** this will begin the test process.



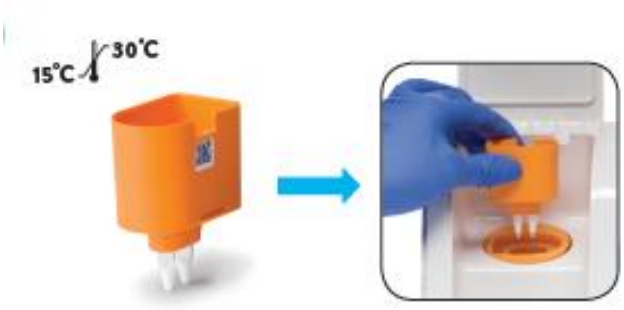
5. Enter your **patients' NHS number in Patient ID** – press ✓ to confirm entry

6. Your patient's details should appear on screen, verify they are correct - press ✓ to confirm entry

   *(If no patients name/DOB do not apper use **'Edit Info'** to add details using the on screen keyboard – press ✓ after entry)*

Step by step instructions will be shown on screen as below:

7. Open the lid of the ID Now and insert the **Orange Test Base** into the orange Test Base Holder. Confirm the test required displayed on screen and press 'OK' to proceed.



*(**NB:** if the test is not confirmed within the **10 minutes** given the instrument will time out and the kit must be discarded).*

8. Insert the **Blue Sample Receiver** into the Blue Sample Receiver holder with the <u>foil still attached</u> as shown here. The Sample Receiver will warm up for 3 minutes.

*(**NB:** stay while the analyser warms up -patient details have already been entered).*

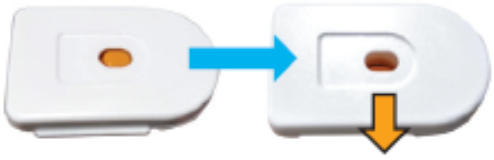
9. When prompted, <u>remove the foil seal</u> from the **Blue Sample Receiver** using 2 fingers to secure the receiver in place. Carefully but thoroughly, <u>mix the patient swab</u> into the buffer liquid, pushing the swab against the sides of the Sample Receiver for **10 seconds.**

*(**NB:** If the test is not started within the 7 minutes the instrument will time out and the kit must be discarded).*

10. After **10 seconds** of mixing, remove the swab and press 'OK' to proceed. <u>The swab and transport tube can be discarded as clinical waste as per local guidance.</u>

11. Firmly press the **White Transfer Cartridge** into the **Blue Sample Receiver** at the front of the analyser until it 'clicks'. The orange indicator will pop up to the top of the White Transfer Cartridge.

12. Lift the **White Transfer Cartridge** out again and push it firmly into the **Orange test Base** at the back of the analyser to connect them**.** The orange indicator will depress to the bottom to dispense the sample.

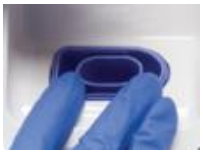


13. Close the lid when prompted**.** The test will run for 8.5 minutes for COVID-19 or 10 minutes for Influenza A/B.

*(**NB.** Do NOT open the lid while the test is in progress, this will cancel the test).*

14. If no further testing required skip to '10.4 Completing Test' for guidance on safely disposing used test cartridges and ensuring the analyser is safe for the next test. If sequential Flu A&B testing required see '10.3 Sequential Testing' below.

10.3 Sequential testing



1. To continue with Influenza A&B following COVID-19 testing **DO NOT DISCARD SAMPLE RECEIVER**
2. Select: Actions > COMBO COVID-19 & Flu A&B
3. Open Flu A&B kit. Connect UNUSED Flu A&B **blue** sample receiver to USED COVID-19 **test base** and **transfer cartridge** and safely dispose in clinical waste

4. Follow steps in **11.2: 7, 9-12** using the Flu A&B **test base** and **transfer cartridge**, and the USED **blue** sample receiver still inside the analyser.
5. Gently close lid, test will complete in ≤10 minutes

10.4 Completing a test on the ID Now

1. **'Test results'** screen which will display one of the following:

ID Now displayed result	Result Interpretation
Negative	*Influenza A &/or B/*Covid-19 was **not detected**
Positive	*Influenza A &/or B/*Covid-19 was **detected**
Invalid	Repeat testing with new kit* and fresh swab (check your technique at step 11 & 12)

If 2x 'Invalid' results obtained, please send a fresh VTM swab to the laboratory as per laboratory protocol.

2. One report will print automatically, **manually print another copy of results**:
   - **Stick one copy into your patient notes** and escalate the result as appropriate.
   - **Stick the other copy to the OrderComms** form and return this to microbiology for reporting to Public Health England.

To safely dispose of kit and clean analyser:

3. Press **'New Test'** to run another patient test, or **'Home'** to return to the home screen – this will prompt to open the lid and discard the used test pieces.

4. Lift out the **White Transfer Cartridge** attached to the **Orange Test Base** and Click these firmly back into the **Blue Sample Receiver** – ensure the test pieces are connected.

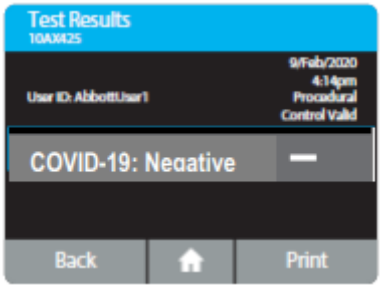
5. Connected pieces can now be removed from the instrument safely without risk of spillage. Wrap the test pieces inside a disposable glove as it is removed from the hand and dispose safely in clinical waste as per local guidelines.

6. With a fresh pair of gloves, wipe down the bench, external and internal areas of the ID Now thoroughly with **70% ethanol wipes**. Close the lid.

11 Reporting of Results

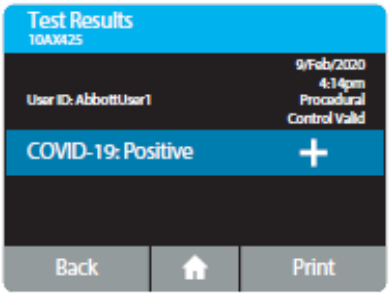
- **Influenza A & B/ COVID-19 Negative:**

  Target virus not detected. Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay. A negative result does not rule out co-infections with other pathogens.

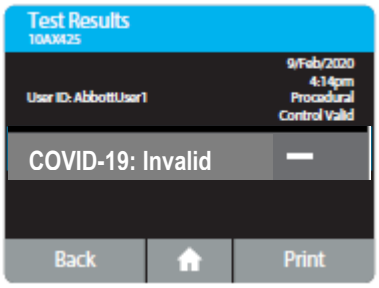


- **Influenza A & B/ COVID-19 Positive:**

  Target virus was detected. Positive results do not rule out bacterial infection or co-infection with other viruses.



- **Influenza A & B/ COVID-19 Invalid: The presence or absence of Viral RNAs cannot be determined.**
  - Repeat testing with a fresh swab sample using new test components.
  - **Where repeated tests lead to Invalid results, or if results do not agree with the clinical picture of the patient, send the patient's VTM to the laboratory for analysis as per the microbiology protocol.**



In the event of analyser breakdown, please report to POCT during routine hours, or leave a voicemail message to be actioned as soon as possible.
If the analyser cannot be used for whatever reason, please send swabs to the lab as per the microbiology protocol.

For clinical assistance, please contact the consultant microbiologist.
For access and training, please contact POCT.

12 Reference Intervals

N/A

13 Performance Characteristics

- **One analyser giving only positive results = possible contamination.**
  If contamination is suspected **do not use the analyser** and report this to POCT and microbiology.
  See Appendix 1 for suggested audit sheet to help pick up possible contamination at Abbott ID Now analysers.

- **Due to the nature of the test, any contamination will falsely affect the results**.
- Contamination is avoided by good laboratory practice and strict adherence to procedures and cleaning described in this SOP and manufacturer 'Instructions For Use'. Report any splashes or spillages of used kit to POCT.

- See Kit insert for additional details and performance characteristics.
- Please see in-house verification data (available from Laboratory Medicine – Microbiology).

14 Known Limitations

- **Viral Transport Media (VTM) swabs are not appropriate for use on the Abbott ID Now, they have not been verified and should not be used**.
- False negative results may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate levels of viruses are present in the specimen. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with Influenza/COVID-19

- Please see the kit inserts (available from POCT, Laboratory Medicine) for details of all possible test limitations.
- Positive and negative predictive values are highly dependent on prevalence and population tested.
- Limit of Detection (LOD):
    - COVID-19: 500 copies/swab
    - Influenza A & B: 6.60 x 10^3 (minimum) in Genome Equivalents/Ml

15 Related Forms/Templates and Documents

PC-INF-IDNOW – user guide

PC-INF-COVFLU QUICKGUIDE

PC-SOP-STOCKCTRL

PC-SOP-EQA

16 References

- Guidance and standard operating procedure - COVID-19 virus testing in NHS laboratories. Version 1.0 VIRUS TESTING 16 March 2020
- ID Now Instrument User Manual (REF: INNAT-000 Rev.11 2020/01)
- ID Now COVID-19 2.0 product Insert (REF: IN193000, Rev. 1 2022/05)
- Department of Health & Social Care Technical Validation of Abbott ID Now (V1.0 Jan 2021)

17 Appendix

Appendix 1 – Suggested audit sheet to help pick up possible contamination at Abbott ID Now analysers

Date & Time	**Operator ID**	**From Ward**	**Test** (Covid/Flu)	**Result**