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**Summary of Significant Changes at this Revision:**

To include Flu testing on the ID Now

**Purpose and Scope**

ID Now Instrument is a rapid molecular *in vitro* diagnostic test utilising an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of Flu A & Flu B or COVID-19 RNA in direct nasal swabs from patients with signs and symptoms of respiratory infection. The system is intended for use as an aid to diagnosis of COVID-19 or Flu A & Flu B viral infections in conjunction with clinical and epidemiological risk factors. Negative results do not preclude COVID-19 or Flu A & Flu B virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. This document is relevant to all trained and competent staff

**Items Required**

Abbott ID Now analyser  
 Box of COVID or Flu Test devices/Swabs/iQC swab  
 Patient details  
 Alcohol wipes  
 ID Now Community Result Record sheet (EXT/POCT/34)  
 Abbott transfer tubes

**Definitions and Abbreviations**

RT-PCR = Reverse transcriptase polymerase chain reaction.  
 DNA = deoxyribose nucleic acid  
 WHO = World Health Organization  
 COVID-19 = Corona virus disease  
 SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2  
 Flu A = influenza A virus  
 Flu B = influenza B virus  
 EQA = External Quality Assurance  
 POCT = Point of Care Testing  
 SOP = Standard Operating Procedure  
 RNA = Ribonucleic Acid  
 PPE = Personal protective equipment  
 MSC = Microbiological Safety Cabinet  
 COSHH = Control of Substances Hazardous to Health  
 QC = Quality Control  
 ISO = International Standards Organisation  
 UKAS = United Kingdom Accreditation Service  
 MHRA = Medicines and Healthcare Products Regulatory Agency  
 VTM = Viral transport media

**Grade / Qualifications**

All staff who have received training and have a personal log in can use the analysers.

**Competencies Required**

Current Version of: FM/POCT/COMP/11

**Risk Assessment:**

Current Version of: RA/POCT/17 & RA/POCT/21 can be found on the POCT web page on the intranet

**Safety Precautions for This Procedure:** Handling potentially COVID or Flu positive samples requires full PPE to be worn including disposable gloves, face visor or goggles, face mask, disposable apron – Follow local donning and doffing procedure for your area.

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## 1 Purpose/Scope/Clinical Relevance

ID Now Instrument is a rapid molecular *in vitro* diagnostic test utilising an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of COVID-19 or Flu A & B RNA in direct nasal swabs from patients with signs and symptoms of respiratory infection. The system is intended for use as an aid to diagnosis of COVID-19 or Flu A & B viral infections in conjunction with clinical and epidemiological risk factors.

Negative results do not preclude COVID-19 or Flu A & B virus infections and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

This document is relevant to all trained and competent staff

## 2 Principle

The ID Now COVID-19 and Flu tests are automated multiplex assays that utilise isothermal nucleic acid amplification technology. The 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 in the Test Base contain the reagents required for amplification of viral RNA, as well as an internal control. In the COVID test base the templates (similar to primers) designed to target SARS-CoV-2 RNA amplify a unique region of the RdRp segment. In the Flu test base templates designed to target Flu A RNA amplify a unique region of the PB2 segment while the templates designed to amplify Flu B RNA target a unique region of the PA segment. 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 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.

## 3 Specimen & Patient Preparation

A nasal swab should **only** be collected with an Abbott ID Now dry swab provided with the test kits. VTM swabs **must not** be processed on the ID Now for COVID testing, VTM samples can only be used in the laboratory for ID Now Flu testing.

- Direct nasal swabs should be placed back into the swab packet then into a sample bag and tested immediately. The sample bag with the swab inside must be labelled with the patient MRN, name, and DOB, the date and time of collection.
- **COVID specimens** that cannot be processed immediately must be placed into a sample transfer tube (applicable for ED testing) instead of the swab packet, where it is stable for up to **1 hour**.
- **COVID specimens** not placed in a transfer tube and not run immediately cannot be analysed as they may produce erroneous results.
- **Flu specimens:** If immediate testing is not possible, the swab can be held in its original package at room temperature (15 – 30°C) for up to **two hours** prior to testing.

### 3.1 Prior to Sampling

- Decontaminate hands per Trust Infection Control hand hygiene procedure (Policy Ref:613), and don gloves, disposable apron, and eye shield (visor or goggles), and face mask.
- Confirm the patient ID.
- Explain and discuss the procedure with the patient.
- Obtain verbal or implied consent

### 3.2 Nasal Swab Procedure (for Adults) – BOTH NOSTRILS

- To collect a nasal swab, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible.
- Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril).
- Rotate the swab several times against the nasal wall then slowly remove from the nostril.
- Using the same swab, repeat sample collection in the other nostril.

**NB: For paediatric patients please follow local protocols if applicable. POCT may be able to provide a suitable swab for paediatric patients.**

### 3.3 Post Sampling Procedure

- If running immediately: Place the swab back inside the original, avoiding swab contact with the inside of the packet as much as possible.
- If not running immediately (applicable for ED testing): Place the swab in a transfer tube where it is stable for up to an hour.
- Ensure that the sample is labelled with the **patient's hospital number, full name and date of birth** at the patient's bedside.
- In ED the ID Now bag insert must also be completed with the name of the person that took the sample, the date and time and the location of the patient. Place sample and insert into the bag and seal for transport to the analyser.
- Provide the patient with a tissue if required.

## 4 Equipment

Abbott ID Now instrument:



## 5 Reagents, Calibrators & IQC Materials

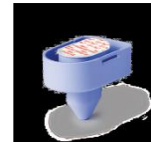
### 5.1 Test Bases **BASE** :

Orange plastic components containing two reaction tubes of lyophilised reagents for the targeted amplification of SARS-CoV-2 RNA or Flu RNA (store at room temperature 15-30°C)



### 5.2 Sample Receivers **RCVR** :

Blue plastic components containing 2.5 mL of elution buffer (store at room temperature 15-30°C)



### 5.3 Transfer Cartridges **CARTRDG** :

White plastic components used to transfer 2 x 100 µL of sample extract from the Sample Receiver to the Test Base (store at room temperature 15-30°C)



**NB:** It is very important when handling the transfer cartridge that the lower section (circled) does not come into contact with any surfaces or hands. The transfer cartridge should remain in its packaging until immediately prior to use.

### 5.4 Nasal Swabs:

Sterile swabs for use with the ID Now COVID-19 Test these are supplied with the test kits (store at Room temperature 15-30°C).

### 5.5 Positive Control Swab

- The positive control swab for influenza is coated with inactivated influenza A and B viruses.
  - For COVID-19 the positive control swab is coated with inactivated SARS-CoV-2 virus
- These swabs must be handled as though they could transmit disease (store at room temperature 15-30°C)

## 5.6 Negative Control Swab:

A sterile sample swab provided in the kit must be used as a negative control for COVID-19 and Flu A & B test kits.

## 5.7 Batch Acceptance Testing

On arrival of the delivery, test devices must be accepted into use by passing iQC, each lot number of test devices must also be accepted into use (see SOP/POCT/70)

## 6 Environmental, Health & Safety Controls

Appropriate PPE consisting of a disposable apron, single use disposable gloves and single use disposable fluid resistant face masks must be worn at all times when handling samples and test kits.

Test kits must be stored between 2 – 30°C. The test kits are stable until the expiration date marked on the outer packaging and containers. All test components must be at room temperature before use.

Please refer to the following documents for COSHH, held in laboratory quality system ref: EXT/POCT/23 for COVID 19:

- ID Now Covid 19 Test Kit insert
- ID Now Covid Positive control swab
- ID Now Covid Elution Buffer

EXT/POCT/33 for influenza A & B:

- ID Now influenza A & B Test Kit insert
- ID Now influenza Positive control swab
- ID Now Elution Buffer

## 7 Calibration & Metrological Traceability

The ID Now Instrument is factory calibrated and does not require any further calibration. However, if the instrument was transported or moved, a performance check using ID Now positive and negative controls is recommended to ensure proper functionality.

## 8 Responsibilities

### 8.1 The Supplier

Abbott are responsible for providing the Trust with the correct equipment and testing kits, reporting any known issues with the kits to the consumer, and providing technical support as required.

**Contact details for Abbott technical support advice line for the ID Now Instrument:**

Tel: (+44) 0161 483 9032

Email: [EMEproductsupport@abbott.com](mailto:EMEproductsupport@abbott.com)

### 8.2 Point of Care Testing

The POCT Team will be monitoring stock levels of test kits and performing acceptance testing.

The POCT team will manage access to the analysers and hold records of training.

The POCT Team will be managing IQC, EQA, stock, troubleshooting and breakdowns, audits, reporting COVID tests and consumable number reporting.

## Contact details

POCT Team: ext: 6044

Email: [ruh-tr.biochempoc@nhs.net](mailto:ruh-tr.biochempoc@nhs.net)

POCT Coordinator (Nicola Hodges):

Phone: 07500050655

Email: [nicolahodges@nhs.net](mailto:nicolahodges@nhs.net)

## 8.3 Ward/Community Staff







Only trained staff are permitted to use the equipment and access is given on an individual basis and must not be shared to other staff. Trained staff should use the equipment as outlined in this SOP and report breakdowns to the POCT department.

## 9 Patient Test Procedure

The ID Now analyser benefits from detailed visual instructions displayed on the screen, these instructions should be followed closely. Each of the steps has been described in detail below.

Running a patient test involves several steps which have a time limit to complete. If the time limit (displayed on screen) is exceeded all test pieces will need to be removed, discarded and the test started from step 1. The patient will require a repeat swab to be collected.

### 9.1 Step 1 - Sign in and Enter Test Details

- Put on a fresh pair of gloves and turn on the ID Now Instrument (if it is switched off) – press the power button  on the side of the instrument
- **Enter User ID** – Press  after entry
- Touch **'Run Test'** – This will begin the test process
- Touch **'COVID-19'** – This starts a COVID-19 test.
- Touch **'Influenza A&B'** – This will start the flu test
- **Enter Patient MRN** – using on screen keyboard or barcode scanner.
- Touch .
- Touch 'edit patient' and enter the first and second name
- Touch .
- Verify that the ID was entered correctly, and then touch  to confirm entry.
- If they have not been entered correctly touch 'edit patient' again to edit name or the  button to start again if the MRN is incorrect.

**NOTE:** If the instrument is unattended for one hour, the instrument will go to a black screen power save mode. Touch the screen to return the unit to active display operation

### 9.2 Step 2 - Loading the Test base

- Open the lid and Insert Orange Test Base into Orange Test Base holder (foil pack 1)
- Confirm that the correct test is displayed on the screen – Touch 'OK' to proceed.
- You will have **10 minutes** from now to confirm the test and complete all steps pre analysis



**⚠ Caution:** Do not apply excessive force (this could damage the instrument)

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### 9.3 Step 3 - Loading the Sample Receiver and Adding Sample

- Open foil pack 2 and remove just the blue base
- Insert Blue Sample Receiver into the Blue Sample Receiver holder



**⚠ Caution:** Do not apply excessive force (this could damage the instrument).

- Wait for the Sample Receiver to Warm Up (3 min) before moving to **Step 4**.
  - **Do not** remove the Sample Receiver from the instrument once Warm Up begins.
  - **Do not** remove the foil seal until prompted by the instrument.
  - **Do not** close the lid or insert the sample until prompted by the instrument

**Note:** Once the Sample Receiver has been placed in the holder, the user will have 10 minutes to start the test (Steps 4).

### 9.4 Step 4 - Removal of the foil seal and addition of the patient swab to the Sample receiver.

- When prompted (after 3 min) place two fingers along the outer edge of the Sample Receiver to hold it in place then peel off the foil seal.
- Remove the swab from its packaging and vigorously mix the swab in the elution buffer for 10 seconds.
- Press the swab head against the side of the Sample Receiver as you mix it. This helps remove the sample from the swab.
- Once the swab is removed, touch '**OK**' to proceed. Be careful not to cause any splashing of the elution buffer in the sample receiver
- Discard the swab in a yellow Burn-bin or sharps bin.

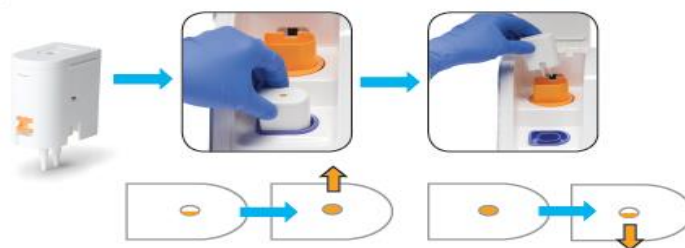


**Note:** If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test pieces (Sample Receiver and Test Base) and clean the instrument. Press 'Run Test' to start a new test using a new Test Base and Sample Receiver.

### 9.5 Step 5 – Transfer of Sample into the Test Base

- Remove the white transfer cartridge from foil pack 2
- Press the White Transfer Cartridge into the Blue Sample Receiver - listen for a click.
- The orange indicator on the Transfer Cartridge will then be in the rise position.
- If the orange indicator does not rise, continue pushing onto the Sample Receiver until it does.
- Lift the white transfer cartridge onto the orange test base.
- Push the transfer cartridge firmly until the orange indicator descends (several clicks).
- If the orange indicator does not descend, continue pushing onto the Test Base until it does.

- Close the lid within **30 Sec**



**Note:** If the orange indicator does not fully rise or descend, insufficient sample will be taken up or dispensed. This may potentially result in invalid or false negative results.

**9.6 Step 6 – Starting the Analysis**

- The lid must be closed within **30 sec** of the transfer cartridge being detected to start the analysis.

- Analysis runs for up to 10 minutes.

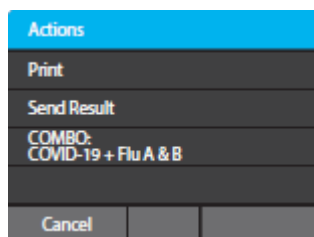


- When amplification and detection is complete, the instrument will automatically save the data before advancing to the results screen for COVID testing.
- Flu testing yields two results if one (either Flu A or B) is positive it will display before the analysis of the second is complete.
- **Note:** Do not open the lid until **all** the results are displayed or the test will be cancelled
- The **Test Results** screen displays either a Negative or Positive result for a successfully completed test.
- If a test error occurs, the result will read 'Invalid'.
- Refer to the Result Interpretation section (14) for interpretation of results (page 12).

**9.7 Step 7 – Finishing the Test and Removal of Test Pieces**

- From the results screen Press **New Test** to run another test, or Press **Home** to return to the Home screen.

**NOTE:** Press '**Actions**' to print or send test results or to initiate an ID NOW flu A & B (post COVID test) combo test utilising the same Blue Sample Receiver (this is only possible where both tests are active on the analyser) follow on screen instruction.



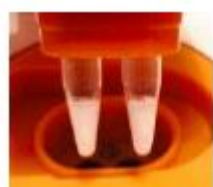
- You will be prompted to open the lid and discard the test pieces (the blue sample receiver must be left in place for combo testing).

- Remove test pieces by lifting the Transfer Cartridge attached to the Test Base, and click it into the Sample Receiver; this may require a gentle rock to clip both edges of the orange into the blue.

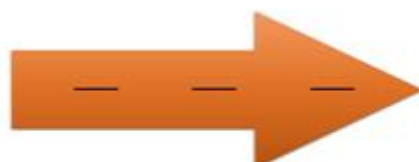


- All test pieces will be connected and can now be removed from the instrument, wrapped inside a disposable glove as it is removed from the hand and disposed of in the yellow Burn bin or sharp bin.
- Don a fresh pair of gloves and wipe the inside areas of the instrument with a 70% alcohol wipe
- Close the lid.
- The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on which previously selected
- Wipe the external areas of the device with a 70% alcohol wipe
- Remove gloves and discard them in clinical waste
- Wash hands as per hand hygiene procedure

**Note:** when the test is finished on removal of the pieces the orange test cartridge base should now have liquid as appose to powder (see below). This may not have happened if the result is invalid.



**Pre-test**



**Post-test**

**Caution: DO NOT** disassemble the pieces or remove the sample receiver by any other method as there is a risk of spilling the elution buffer containing the patient sample.

## 10 Reporting of Results

### 10.1 For connected locations

Results are automatically sent from the ID Now to the middleware system POCcelerator, from here the results are matched to a patient via the MRN number and transmitted to the laboratory information system (Ultra). The test is automatically requested against the patient, resulted and validated and sent down to millennium and ICE.

Ultra requesting codes are:

- COVID 19 = ICV
- Influenza A & B has a panel: IDF and items: ifa & ifb

## 10.2 For non-connected locations

Currently the community hospital locations are not connected to our network and thus results are obtained by the print out and held in the analyser itself (maximum of 500 results). The result sticker should be attached to the ID Now Community Results Record Sheet (EXT/POCT/34) and scanned to the POCT email for POCT staff to request and result to retain an electronic report in the patient record.

## 11 Quality Control

**Note: Always process the negative control swab first.**

### 11.1 Step 1 - Performing a Quality Control (QC) Test:

- Turn on and log in to the analyser.
- From the Home Screen Touch '**Run QC Test**'
- Touch '**COVID-19**' or '**Influenza A & B**'
- Select the QC Test to be Run; **Positive QC Test or Negative QC Test**
- Press 'edit QC Sample ID' and enter the QC lot number, then press the tick to confirm – failure to do so will hold back the QC results in POCcelerator
- Confirm the information entered for QC sample by touching '**OK**'
- Continue from Step 2 above for running the positive swab.
- Place QC results stickers on the outside of the box to record completion.

**Note:** A blank sterile patient swab should be used as a negative control for COVID-19 and influenza test kits.

Positive swabs are provided one in each box and come in foil packaging.

### 11.2 QC Failures

- All QC failures must be acted upon immediately, and the ID Now Instrument must not be used until both the negative and positive QC samples have passed
- If the test is invalid due to a dispensing error, repeat the test immediately with a new test kit and swab
- Check the expiry dates of all consumables used, and if everything is in date, repeat the test with a fresh kit and fresh QC sample
- If there is repeated failure, quarantine the box of kits, and repeat the test with a fresh kit from a new box
- A fresh QC sample should be used for each QC procedure
- Further QC failures must be reported to the POCT BMS as soon as possible and the ID Now Instrument must be taken out of use immediately
- Use an alternative ID Now Instrument for patient testing

### 11.3 QC Frequency

- QC must be performed on every box of test pieces before use (positive iQC swab and negative blank sterile swabs are included in each box)
- QC can be performed once for each trainee during a training session.
- Stock deliveries should be accepted into use by laboratory staff.

## 12 Maintenance

- The ID Now Instrument is maintenance-free and has no serviceable parts. In the case of instrument failure or damage, contact Abbott Technical Support.
- The ID Now Instrument should be cleaned using 70% alcohol wipes. Do not spray or pour solution directly onto instrument when cleaning.
- Ensure no excess liquid is used when cleaning as it may damage the instrument.
- The device must be cleaned following every test performed.
- A daily clean should also be performed and recorded on the QC and Maintenance Logs
- Abbott recommends that the exterior instrument surfaces and the surfaces visible under the open lid be cleaned daily.
- Clean surrounding bench area.
- Always clean instrument and surrounding areas immediately after possible patient **sample contamination**.

**Note:** ⚠ Do not disassemble the instrument for cleaning.  
 ⚠ Do not immerse in water or cleaning solutions (including green clinell wipes).  
 ⚠ Do not clean with soap or other solutions (including green clinell wipes).

## 13 Troubleshooting

Please refer to [appendix 1](#) which provides troubleshooting steps for specific error and warning codes. Once the steps listed in the appendix are executed, if the error or warning persists, contact Abbott Technical Support and inform a member of the POCT team. Please refer to the User Manual or contact a member of the POCT Team should an error or warning occur that does not appear in appendix 1.

## 14 Limitations & Interferences of the Methods (please see individual test kit inserts for full details)

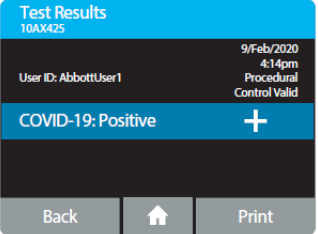
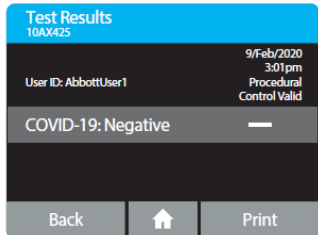
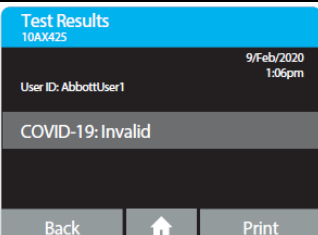
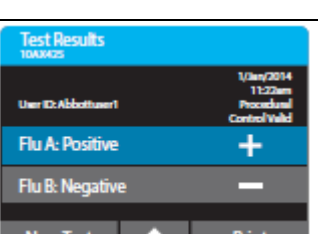
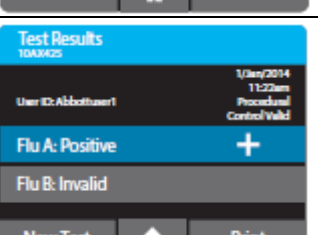
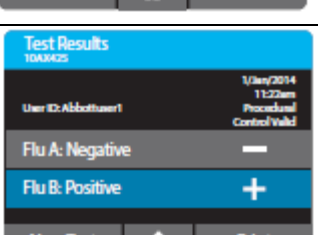
- The performance of the ID NOW COVID-19 and influenza A & B were evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- ID NOW Influenza A & B 2 performance depends on viral RNA load and may not correlate with cell culture performed on the same specimen. Viral nucleic acid may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply the corresponding virus(es) are infectious, or are the causative agents for clinical symptoms.
- Performance of ID NOW Influenza A & B 2 has not been established for monitoring antiviral treatment of influenza.
- Although this influenza test has been shown to detect A/H1N1 (pre-2009 pandemic), A/H7N9 (detected in China in 2013) and A/H3N2v viruses cultured from positive human respiratory specimens, the performance characteristics of this device with clinical specimens that are positive for the A/H1N1 (pre-2009 pandemic), A/H7N9 (detected in China in 2013) and A/H3N2v viruses have not been established.
- Negative results should be treated as presumptive and tested with an alternative authorized molecular assay, if necessary for clinical management, including infection control. **NB:** This is not routine procedure and is covered in the risk assessment.
- 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 COVID-19 or influenza.

- As with any molecular test, mutations within the target regions of the Abbott ID NOW COVID-19 and influenza tests could affect primer and/or probe binding resulting in failure to detect the presence of the virus.
- These tests cannot rule out diseases caused by other bacterial or viral pathogens.
- ID NOW COVID-19 is intended for testing a swab directly without elution in viral transport media as dilution will result in decreased detection of low positive samples that are near the limit of detection of the test.
- Swab samples eluted in VTM are not appropriate for COVID-19 testing and should only be used for flu where a safety cabinet can be used (main laboratory).
- The tests are qualitative and do not provide the quantitative value of detected organism present.

## 15 Results Interpretation

When the test is complete, the results are clearly displayed on the instrument screen. An individual result for Covid -19 will be provided. Results can subsequently be reviewed in POCcelerator (POCT staff only), from POCcelerator the results will move into the laboratory information system and then on into Millennium.

Instrument Display	Interpretation of Results and Follow-up Actions
	<p><b>COVID-19 Positive</b></p> <p>Positive results do not rule out bacterial infection or co-infection with other viruses.</p>
	<p><b>COVID-19 Negative</b></p> <p>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.</p> <p>A negative result does not rule out co-infections with other pathogens.</p>
	<p><b>The presence or absence of COVID-19 Viral RNAs cannot be determined.</b></p> <p>Repeat testing of the sample using new test components. If repeated Invalid results are obtained, results should be confirmed by another method prior to reporting the results.</p> <p><b>Note:</b> If the orange indicator does not fully rise or descend, insufficient sample will be taken up or dispensed. This may potentially result in invalid or false negative results.</p>
	<p><b>Flu A Viral RNA Detected; Flu B Viral RNA Not Detected.</b></p> <p>This result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.</p>
	<p><b>Flu A Viral RNA Detected; The presence or absence of Flu B Viral RNA cannot be determined.</b></p> <p>This result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype. Repeat testing using a new sample and test components.</p> <p><b>Note:</b> If the orange indicator does not fully rise or descend, insufficient sample will be taken up or dispensed. This may potentially result in invalid or false negative results.</p>
	<p><b>Flu B Viral RNA Detected; Flu A Viral RNA Not Detected.</b></p> <p>This result does not rule out co-infections with other pathogens or identify any specific influenza B virus lineage.</p>



If an Invalid result is received, one additional test may be run using the same Sample Receiver. These instructions should be followed:

- Remove the connected Test Base (orange) and Transfer Cartridge (white) from the instrument and connect the Test Base portion to an **UNUSED** Sample Receiver (blue). The connected Test Base and Transfer Cartridge **MUST** be attached to the Sample Receiver prior to disposal. A new Transfer Cartridge package (packet 2) will need to be opened and the Sample Receiver from there used.
- Remove the blue Sample Receiver separately and carefully from the instrument. The Sample Receiver should be retained and kept upright to avoid spilling the liquid contents. Ensure that required PPE is worn at all times during this process.
- From the Home Screen, start a new test. Follow the screen prompts; however, when asked to insert the Sample Receiver, reuse the Sample Receiver and DO NOT re-lute the swab.

**Note:** Where repeated tests lead to invalid results, or if results do not agree with the clinical picture of the patient, request for a sample in VTM should be sent to the laboratory for analysis.

## 16 Performance Characteristics

Please refer to the test kit insert for performance characteristics for this test. Test kits inserts are available in every box of reagents and on the laboratory quality system (EXT/POCT/23, EXT/POCT/33).

## 17 Sources of Variation

- Performance characteristics of these tests have been established with the specimen type listed in the User manual 'Intended Use' sections only.
- The performance of these assays with other specimen types or samples has not been validated.
- Proper sample collection, storage and transport are essential for correct results.
- Leave test pieces sealed in their foil pouches until just before use.
- Do not tamper with test pieces prior to or after use.
- Do not use kit past its expiration date.
- Do not mix components from different kit lots or from other ID NOW assays.
- If any assay components are dropped, cracked, found to be damaged or opened when received, DO NOT USE and discard. Do not use scissors or sharp objects to open foil pouches as damage to test pieces can occur.
- Do not open the Sample Receiver before placing in the instrument. It will prohibit the Elution Buffer from reaching temperature and may impact test performance.
- If the Sample Receiver is spilled while opening, clean the instrument per instructions provided in the instrument User Manual and cancel test. Repeat test with a new Sample Receiver.
- All test pieces must be removed from the instrument according to removal instructions displayed on the instrument, and disposed of according to country and local requirements. Pieces must not be separated once they are assembled.
- All test pieces are single use items. Do not use with multiple specimens.
- Once reacted, the Test Base contains large amounts of amplified target (Amplicon). Do not disassemble the Test Base and Transfer Cartridge. In the case of a positive



sample, this could lead to amplicon leakage and potential ID NOW COVID-19 or influenza false positive test results.

- At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
- Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive samples may cause false positive results. Handle samples according to this SOP. Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the instrument User Manual.
- Visibly bloody samples must not be used with ID NOW COVID-19 or Influenza A & B 2.
- Do not touch the heads of the Control Swabs. Cross contamination with the Positive Control Swabs may occur due to the high sensitivity of the assays run on the instrument.

## 18 Uncertainty of Measurement

Details of the validation and verification for influenza and COVID 19 can be found on the laboratory quality management system under:

COVID 19: VAL/POCT/30

Influenza: VAL/POCT/36

The statistical data suggests consideration of the clinical presentation of the patient should be taken when interpreting results if there is any doubt in the result produced, or if invalid results are reported. If this is the case send a VTM sample to the laboratory for confirmation. Please also refer to section 18.

## 19 References & Related Documents / Standards

United Kingdom Accreditation Service (UKAS) BS EN ISO 15189: 2012 and BS EN ISO 22870:2016

### Policy Ref:

[613: Hand Hygiene Procedure](#)

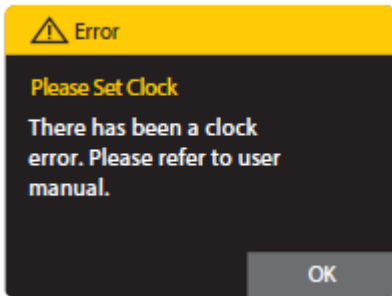
[775: Patient Identification](#)

[728: Consent to Examination or Treatment](#)

## 20 Appendix 1: Troubleshooting

### 20.1 Power On & Loading Error

#### Error: Please Set Clock



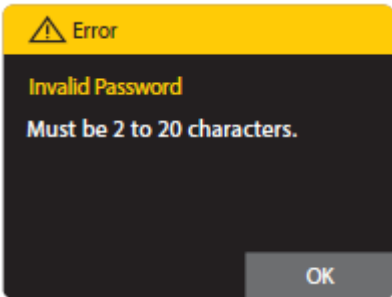
If the internal battery fails, the instrument will lose the time and date.

**Action:** The Admin must log in and reset the date and time: **Home>Setup>Date; Home>Setup>Time.**

If this error occurs in a subsequent power up of the instrument, there may be an on-going time and date fault.

### 20.2 Initial Admin Setup Error

#### Error: Invalid Password

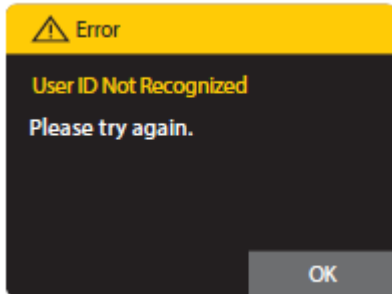


Passwords must be 2 to 20 characters long, are case-sensitive, and must be alphanumeric. The password cannot contain spaces.

**Action:** Choose a password that meets the above criteria.

### 20.3 User Login Errors

#### Error: User ID Not Recognised



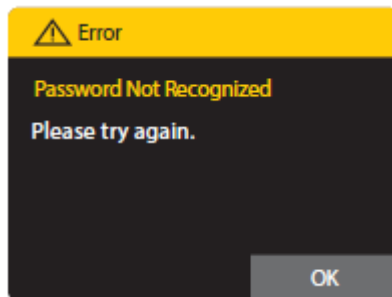
The instrument does not recognize the User ID entered.

**Action:** Press OK to try again. If the error persists, the Admin must log in to check that the User ID has not been deleted. If it has, or if this is a new User, the Admin must set up the User ID:

- **Home>Setup>Users or**
- **Home>Setup>Users>New User.**

User IDs are not case sensitive.

#### Error: Password Not Recognised

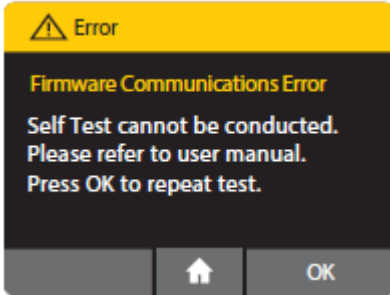


The instrument does not recognize the password entered.

**Action:** Press OK to try again. If the error persists, the Admin can log in to check or change the password: **Home>Setup>Users.**

## 20.4 Device Errors

### Error: Firmware Communications Error



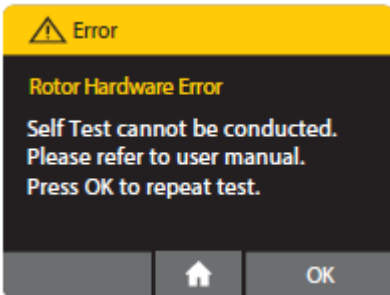
The instrument cannot conduct its Self Test.

**Action:** Press OK to try again. If the error persists, reboot the instrument by turning it off and on again.

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed:

**Home>Review Memory.**

### Error: Rotor Hardware Fault



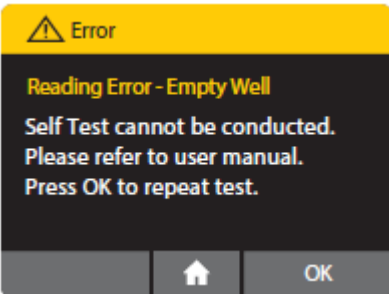
The instrument has failed its Self-Test due to a rotor fault.

**Action:** Open the lid and ensure there are no consumable parts or other items blocking movements of the test rotor.

If no obstruction is found and error persists, discontinue using the instrument and contact Abbott Technical Support.

### Error: Reading Error – Empty

The instrument has failed the Self-Test due to the empty wells having a high fluorescence reading.

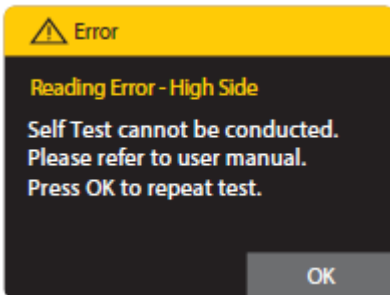


**Action:** Ensure that the Test Base is not in the Test Base holder, and press OK to try again. If the Test Base is not present, clean the Test Base well using a swab and ethanol and press OK to try again.

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed:

**Home>Review Memory**

### Error: Reading Error – High Side



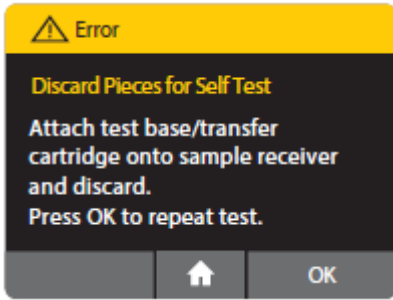
The instrument cannot conduct its Self-Test. The instrument has failed its Self-Test due to a target in the instrument not providing sufficient response.

**Action:** Press OK to try again, press Home to return to the Home menu. Without successfully completing Self-Test the user can review results and instrument details but cannot run a test.

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed:

**Home>Review Memory.**

**Error: Discard Pieces for Self-Test**



The instrument cannot conduct its Self Test if parts of the test are inside the instrument.

**Action:** Remove test pieces as shown under Running a Test, and press OK to try again.

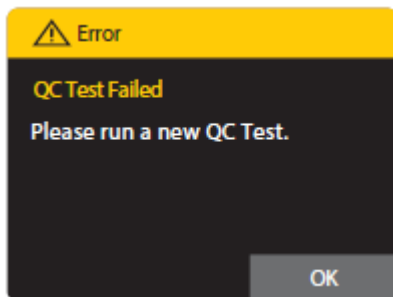
If this error persists or if there are no test pieces in the instrument, check that there is not a foreign object or contamination obscuring the detector window in the bottom of the sample receiver heater block as this may be registered by the instrument as a sample receiver consumable being in place.

Press OK to try again, press Home to return to the Home menu. Without successfully completing Self-Test the user can review results and instrument details but cannot run a test.

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed: **Home>Review Memory**.

**20.5 Home Errors**

**Error: QC Test Failed**

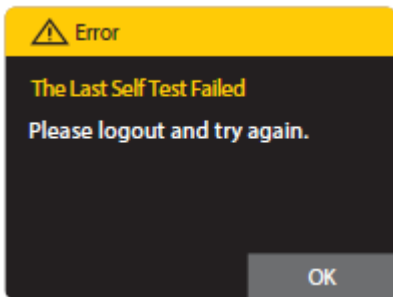


The QC test failed for the selected assay and must be repeated successfully before patient samples can be tested.

**Action:** Press OK to return to the Home screen and run a QC test again (**Home>Run QC Test**).

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed: **Home>Review Memory**.

**Error: The Last Self Test Failed**



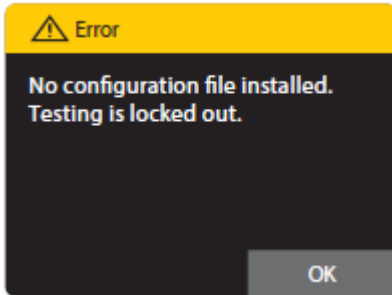
The instrument's last Self-Test failed.

**Action:** Press OK to return to the Home screen. Log out (**Home>Logout**) and try logging in again.

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed: **Home>Review Memory**.

## 20.6 Run Test / Run QC Test Errors

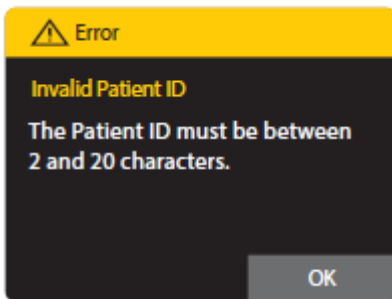
### Error: Configuration Not Installed



A configuration file has not been installed on the instrument.

**Action:** Press OK to return to the Home screen. Contact Abbott Technical Services.

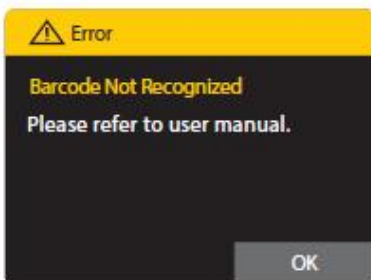
### Error: Invalid Patient ID



Patient ID must be 2 to 20 characters long, are not case-sensitive, and must be alphanumeric. The Patient ID cannot contain spaces.

**Action:** Press OK to try again. If the error persists while using the barcode scanner, enter the patient ID manually.

### Error: Barcode Not Recognised



The instrument has not recognized the barcode on the Test Base and cannot start the testing process.

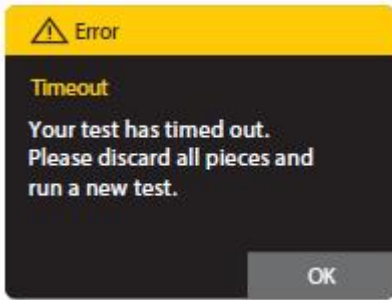
**Action:** Press OK to try again. The instrument will ask to remove the Test Base. The instrument will then perform a Self-Test. Once complete, try again using the same Test Base.

If the error persists, dispose of the Test Base and try a new Test Base.



**Note:** The barcode on the Test Base must face the back of the instrument to be recognized.

**Error: Timeout**



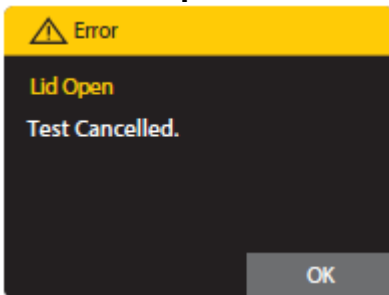
The instrument has timed out during any of the steps in the testing process. More than the defined amount of time elapsed during one of the steps outlined below.

For example:

1. Between inserting the Test Base and inserting the Sample Receiver.
2. Between the completion of the warm up and the addition and confirmation of the sample
3. Between adding the sample and transferring it from the Sample Receiver to the Test Base.
4. Between transferring the sample and closing the lid.

**Action:** Press OK. Remove and dispose of all test pieces and repeat with a new test. Follow the on-screen instructions closely.

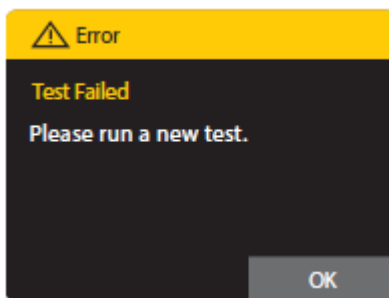
**Error: Lid Open**



The lid must not be opened during the testing process.

**Action:** Press OK. Remove and dispose of all test pieces and repeat with a new test.

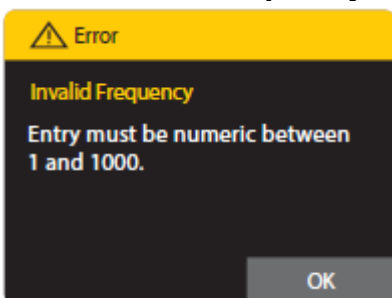
**Error: Test Failed**



The test has encountered an unrecoverable error.

**Action:** Press OK. Remove and dispose of all test pieces and repeat with a new test.

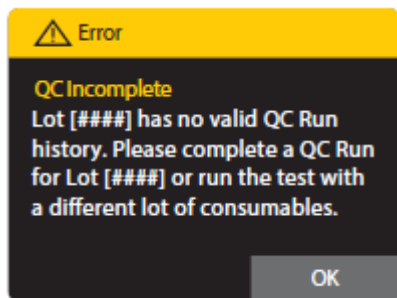
**Error: Invalid Frequency**



If the User enters a non-numeric or numerical value greater than 1000, for the QC frequency, this Error will appear.

**Action:** Press OK and enter a numeric value between 1 and 1000.

### Error: QC Incomplete



For assays configured with QC Lockout set to **Warn** or **Lockout**, this Error will appear when a new patient test is attempted with a lot that does not have a valid QC Positive and Negative result.

**Action:** Select OK to stop the patient test and proceed to conduct a QC run for the lot OR the user must use a different lot of consumables for the run.

### Error: Assay Locked Out

If a **frequency** is set under **lockout** within the QC Lockout function, when the assay **Frequency** expires and a user attempts to conduct a patient test for that assay; this error message will appear.

**Action:** Proceed to conduct a QC run for the assay before a patient test can be run.

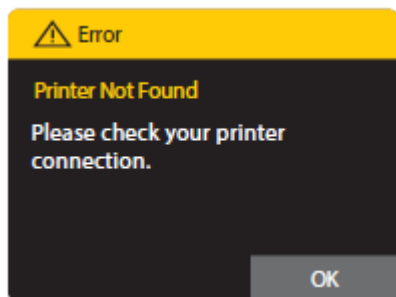
### Error: Lot Locked Out

If the consumable lot detected has been locked out by the administrator, this error message will appear.

**Action:** Press OK and Contact Administrator

## 20.7 Printing Result Error

### Error: Printer Not Found



The instrument has not recognised the printer.

**Action:** If printer is not connected, connect it. If it is connected, check the printer connection. Press OK to try again.

If this error persists, completely unplug the printer, reconnect to the instrument and press OK to try again.

Confirm the printer power supply is connected and the printer is turned on. Confirm printer power LED is illuminated. Confirm USB data cable is connected at the printer and the instrument.

If the problem persists, remove USB connector at the instrument, wait 10 seconds, and reconnect.

Repower the instrument and try again. The test result can be printed from the Review Memory screen.

## 20.8 Review Memory Error

### Error: Test Result Not Valid

The stored result has been corrupted and cannot be viewed.

**Action:** Press OK to return to the list of test results.

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**20.9 Search Result Error**  
**No Results Found.**

No results have been found matching the search criteria.

**Action:** Press OK and try searching again using new search criteria

**20.10 Export Results and Export Log file Errors**  
**Error: USB Device Not Found**

The instrument has not recognized the USB drive.

**Action:** If a USB drive is not connected, connect it. If it is connected, check the connection.

If this error persists, try using a different USB drive.

Press OK to return to the Review Memory screen.

**Error: Export Failed**

The export was not successful.

**Action:** Repeat the export process. If this error persists, try using a different USB drive.

Press OK to return to the Review Memory screen.

**20.11 Network Errors**

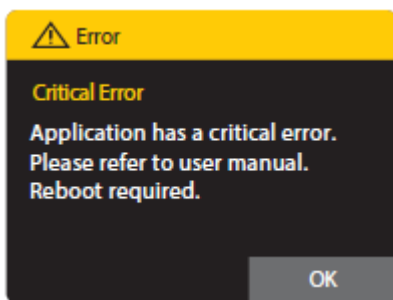
If a network related error appears (see below), please report to the POCT Leads as soon as possible.

Examples of network errors are:

- IP Address Invalid
- Subnet Mask Invalid
- Network Errors
- Port Number Invalid
- Installation Failed
- Memory Almost Full / Memory Is Full

**20.12 Miscellaneous Errors**

**Error: Critical Error**



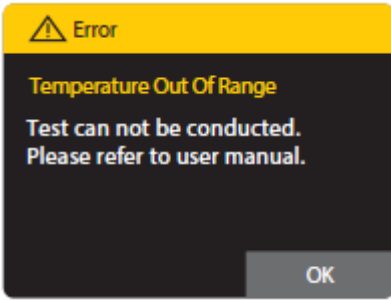
The software has encountered a critical error and the application can only restart to recover.

**Action:** Press OK to reboot the instrument

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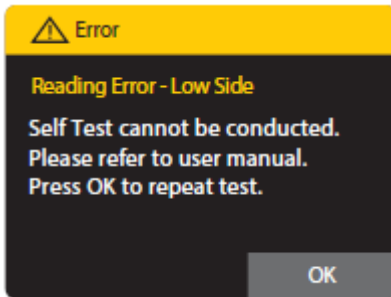
**Error: Temperature Out of Range**



The heater temperature is not at the required temperature to perform a test.

**Action:** Make sure that the lid is closed and wait 5 minutes for the heater to warm the sample receiver and test base receiver. Repeat the test. If the error persists, reboot the instrument by turning it off and then on again.

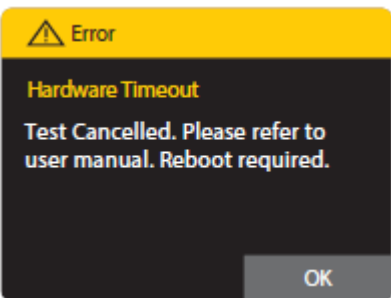
**Error: Reading Error – Low Side**



The instrument has failed its Self-Test due to a target in the instrument not providing a correct response.

**Action:** Press OK to try again or press Home to return to the Home menu. Without successfully completing Self-Test the user can review results and instrument details but cannot run a test.

**Error: Hardware Timeout**

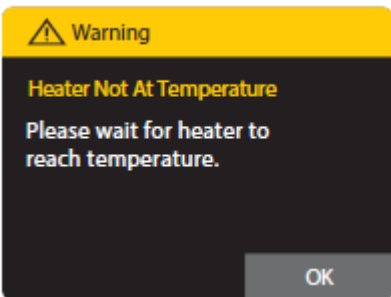


The instrument hardware encountered an internal hardware response error.

**Action:** Repeat the test. If the error persists, reboot the instrument by turning it off and then on again.

**21 Warnings**

**Warning: Heater Not At Temperature**



The instrument has not yet reached the required temperature.

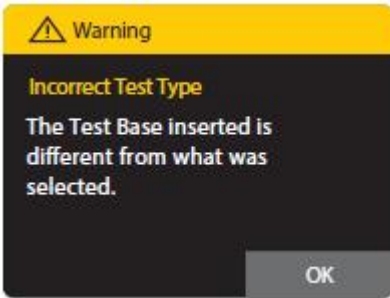
**Action:** Press OK to return to the Home screen and wait for the white light on the front of the instrument to stop flashing before trying again.

If the error persists, power off the instrument, disconnect the DC power input connector, wait 10 seconds, reconnect and turn on the instrument. When the white light on the front of the instrument stops flashing, try again.

If this error persists, tests cannot be run on the instrument. However, the stored data can still be viewed: **Home>Review Memory**.

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### Warning: Incorrect Test Type

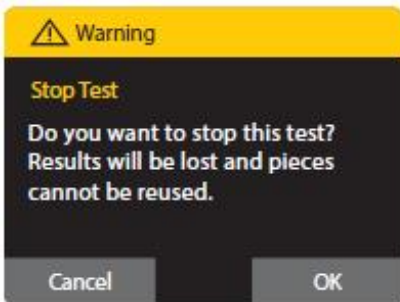


A test base was inserted that does not match the test type initially selected from the menu.

**Action:** The test must be restarted. Remove the test base and close the lid to allow the instrument to perform a self-test. Restart the test, as desired.



### Warning: Stop Test



The Home button was pressed during testing. Testing cannot be stopped and then resumed after one or more test pieces have been placed in the instrument.

**Action:** To continue testing, press Cancel. The timeouts will continue counting even with this screen displayed.

To cancel the test, press OK. Remove and dispose of all test pieces.



### Warning: QC Frequency Exceeded

If a **frequency** is set under **warn** within the QC Lockout function, when the assay **Frequency** expires and a user attempts to conduct a patient test for that assay; this warning message will appear.

**Action:** Select OK to proceed with the run or select Cancel to stop the patient test and proceed to conduct a QC run for the assay.

## Warning: QC Frequency Low

For all assays; this warning message will appear when the **testing interval** has been configured and the number of days remaining has either reached 3 (unit set to days) or when number of tests remaining is at 10%.

**Action:** Select OK to proceed with the run or select Cancel to stop the current patient test and proceed to conduct a QC run for the assay.

### 21.1 Setup Warnings

#### Warning: Reboot Required

This Warning will display in the Connectivity sub-menu when switching between Connectivity protocol types.

#### Warning: Reset Factory Default

If the instrument is reset to factory default settings, all Users, patient and QC results, preferences and chosen settings, including language, will be lost.

The instrument will start up as it did when first received from the manufacturer, and can be reconfigured by the Admin.

Abbott suggests exporting all user, patient and QC results to a USB drive prior to resetting to factory default.

Press Cancel to return to the Setup menu. Press OK to reset to factory default.

### 21.2 User Warnings

#### Warning: Delete User

If a User is deleted, all data associated with the User will be lost. However, stored data files will not be affected.

**Action:** Press OK to permanently delete the user. Press Cancel to return to the Setup Users screen

Copy number	Location held
1	SOP folder in ED
2	SOP folder in ONC OP
3	On the intra net POCT web page
4	Q-pulse
5	SOP folder in MAU DAA
6	SOP folder in Children's ward
7	SOP folder in OPAU
8	SOP folder in SAU
9	SOP folder in BBC
10	SOP folder in Chippenham Maternity
11	SOP folder in Frome Maternity
12	SOP folder in TAU
13	SOP folder in Keynsham health centre
14	SOP folder in Paulton hospital
15	SOP folder in St. Martins Hospital