Abbott

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ID NOW™ Performance Best Practices

Successful testing on ID NOW™ system requires the user adhere to guidelines and recommendations provided within the user manual, assay package inserts, instrument on-screen instructions, and documents contained within the CLSI documents. To achieve maximum performance of an ID NOW™ assay, this technical memorandum serves to highlight key aspects of the testing process, with particular focus on Step 4, transfer and dispense.

1. **Adopt Good Lab Safety and Disinfection Practices**

   a. Clean gloves should be used for all patient sample handling
   b. Daily cleaning of the ID NOW™ Instrument is recommended. Clean exterior surfaces and surfaces visible under the open lid, as well as the surrounding bench area, using a lint free cloth dampened with 70% Ethanol, 70% Isopropanol, or 10% Bleach. 70% Ethanol and 70% Isopropanol wipes are acceptable for the ID NOW™.

2. **Proper Sample Collection**

   a. Due to the sensitive nature of molecular technology, the amount of sample required to perform testing is **less** than that of rapid antigen detection tests. Excessive or aggressive sample collection may compromise test results. Refer to each ID NOW product inserts for more specific details.
   b. Strictly adhere to guidelines for respective sample collection tech tips documents. Follow the link to Nasal, Nasopharyngeal, and Throat swab collection for all ID NOW assays except COVID-19.
   c. Use the following links for COVID-19 sample collection only. COVID-19 Nasopharyngeal swab collection COVID-19 Throat sample collection COVID-19 Nasal swab collection

3. **Proper Test Procedure**

   a. When prompted, remove the foil seal and place the patient swab to be tested into the Sample Receiver.
   b. Mix the swab in the liquid 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.

4. **Transfer and Dispense** – successful testing requires proper transfer of sample

   a. **Press OK** before proceeding with transfer of sample. Quality assurance measures are in place throughout the entire testing process. Failure to follow prompts as displayed on screen may lead to invalid or false test results.
   b. Press white Transfer Cartridge **FIRMLY** into blue Sample Receiver and observe RISE of orange indicator which indicates sample was successfully pipetted into Transfer Cartridge. **DO NOT BE AFRAID TO PUSH.**
   c. To complete transfer process, lift, connect and firmly press white Transfer Cartridge into orange Test Base. Observe the orange indicator **DESCEND** back into white Transfer Cartridge which indicates sample was successfully transferred into reaction tubes of orange Test Base. **DO NOT BE AFRAID TO PUSH.**
   d. Make sure the test is in progress before walking away. After closing the lid to begin testing, you can ensure no previous prompts were missed by waiting until you see the "Testing" "Do Not Open" screen before walking away.

5. **Dispose** – test components are designed as single use only. **ALWAYS** connect the three test pieces as a single unit for proper disposal. **NEVER** throw pieces away individually and **NEVER** disassemble the pieces once they are connected.

   a. Wrap the assembled test pieces in a glove which provides an added barrier to prevent amplicon contamination and dispose of gloved test in a covered biohazard waste container.
   b. Properly dispose of testing components to minimize risk of amplicon contamination.

ID NOW™ Troubleshooting Tips and Repeating Tests

Main causes of inaccurate results:

1. **Sample dispense errors**
   a. Visually inspect the orange indicator of the white Transfer Cartridge to verify that it fully descended. If the orange indicator is still visible at the top of the white Transfer Cartridge, the specimen was not transferred into the reaction tubes of the orange Test Base.
   b. Visually inspect the orange Test Base reaction tubes to confirm the liquid levels in both tubes are equal and that all dry (lyophilized) reagents dissolved properly with minimal bubbles. If the orange indicator was fully descended and the reaction tubes are dry, the sample was never pipetted from the blue Sample Receiver.

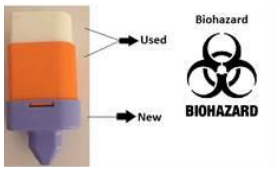
2. **Procedural errors**
   a. Confirm test kits are stored at proper temperatures per package insert
   b. Do not remove the foil seal on blue Sample Receiver until prompted by the instrument
   c. Timing is important; follow procedural steps as displayed on the screen
   d. Press OK when prompted
   e. If any test pieces are accidently dropped, do not use any of the pieces for testing

3. **Interfering substances** – Listed in the package insert

Procedure for repeating tests:

1. The used, connected, orange Test Base and white Transfer Cartridge **MUST** be attached to a blue Sample Receiver prior to disposal.
   a. Open a new Specimen Receiver/Transfer Cartridge package (#2)
   b. Remove the blue Sample Receiver from the package and open by removing the foil seal.

   c. Remove the used, connected, orange Test Base and white Transfer Cartridge from the instrument.
   d. Connect the used pieces to the new, **UNUSED**, blue Sample Receiver and dispose.



2. Retain the used, blue Sample Receiver for repeat testing.
   a. Remove the used, blue Sample Receiver carefully from the instrument.
   b. Keep upright to avoid spilling the liquid contents.

3. Repeat test.
   a. Close the lid (of analyzer) to initiate the Self-Test. From the Home Screen, begin a new test.
   b. Use a new orange Test Base and white Transfer Cartridge.
   c. Follow the screen prompts; however, when asked to insert the blue Sample Receiver, **reuse the existing blue Sample Receiver from the initial test.**
   d. **DO NOT** re-elute the swab or add additional sample.

If an inaccurate result is obtained using the repeat procedure, do not retest the sample again. The result should be documented according to facility protocol. Additional testing should only be attempted with an alternate method.

If unexplained, invalid, dual positive or false test results continue to be obtained, please contact Technical Support for assistance.

Technical Support Advice Line

Further information can be obtained by contacting Technical Support on:

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