

# Accula™ Flu A/Flu B Test

CLIA WAIVED: FOR USE WITH NASAL SWABS

REF FAB1100CW

Pub. No. LBL-60008 Rev. C

IVD Rx only



**IMPORTANT:** Read the *Accula™ Dock Operators Guide (Pub. No. LBL-60058)* and the *Accula™ Flu A/Flu B Test Instructions for Use (Pub. No. LBL-60009)* thoroughly before running samples.

## A. PREPARE THE ACCULA™ DOCK

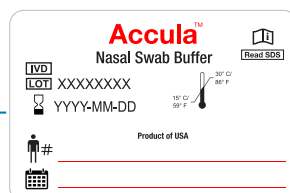
## B. PREPARE THE SAMPLE

The specimen must be eluted immediately after collection. The eluted sample can be stored up to 2 hours at 15°C to 30°C (59°F to 86°F). Do not freeze the eluted sample before testing.



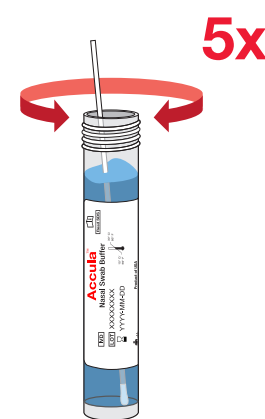
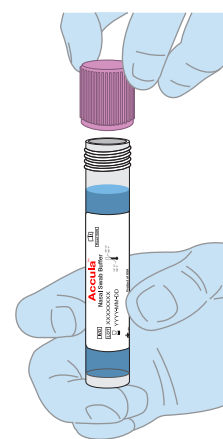
1. Place the dock on a flat surface.
2. Connect the AC adapter to the power cord, then insert the round connector of the AC adapter into the dock.
3. Plug the AC end of the power cord into an electrical outlet.

1



1. Label the Accula™ Nasal Swab Buffer vial with the patient identification (ID) and date.

2

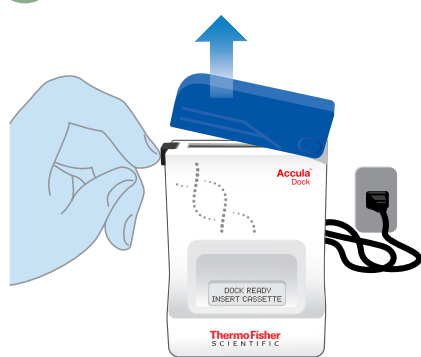


1. Remove the cap on the Nasal Swab Buffer vial.
2. Insert the swab specimen into the vial.
3. Rotate the swab 5 times against the wall of the vial.
4. Discard the swab into an appropriate biohazard container.
5. Replace the cap on the vial.

## C. TEST PROCEDURE

**NOTE:** Do not open the Accula™ Test Cassette foil pouch until the sample is ready for testing. The test must be initiated within 30 minutes of opening the foil pouch.

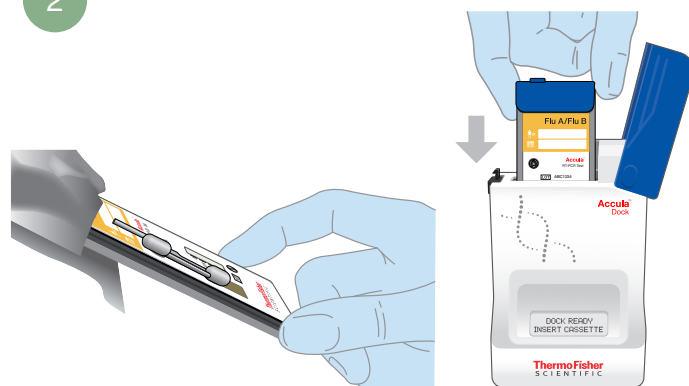
1



DOCK READY  
INSERT CASSETTE

1. Open the dock by depressing the black button on the top left side of the device.
2. Verify that the dock screen displays: "DOCK READY INSERT CASSETTE".

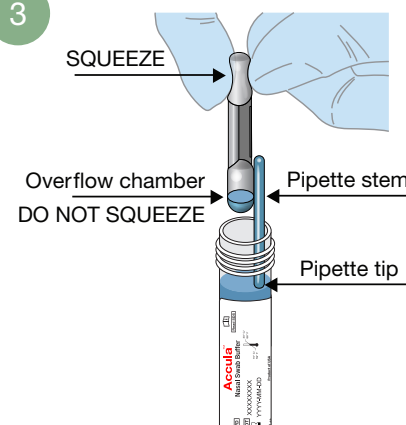
2



FLU A/FLU B  
CASS. INSERTED  
ADD SAMPLE  
THEN CLOSE LID

1. Remove the Accula™ Test Cassette and pipette from the foil pouch.
2. Label the cassette with patient identification (ID)/date.
3. Insert the cassette into the dock and press firmly to seat.  
**Do not close the dock lid.**
4. Verify that the dock screen displays: "FLU A/FLU B CASS. INSERTED" then "ADD SAMPLE THEN CLOSE LID".  
**Do not remove the foil tab covering the sample port.**

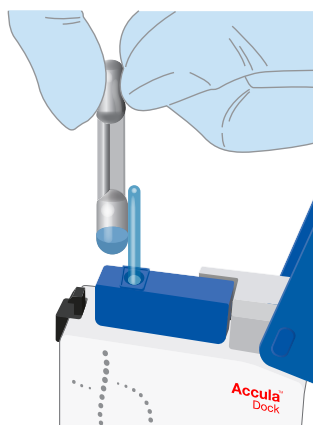
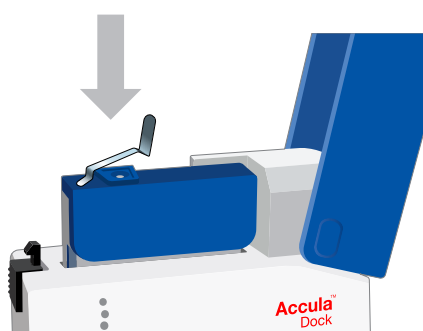
3



1. Invert the vial to mix, then remove the cap.
2. Firmly squeeze the top bulb and place the pipette tip into the sample.
3. Keeping the pipette tip well below the surface of the liquid, slowly release the top bulb to completely fill the pipette stem. Some liquid may also be in the overflow chamber.

4

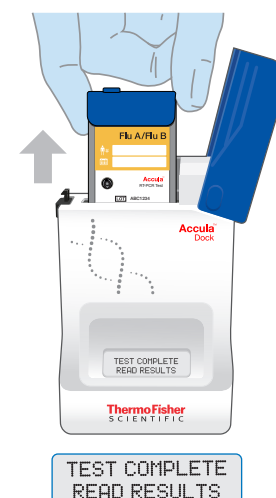
Once the foil tab is removed, the sample must be added within five minutes.



CASSETTE SEALED  
TEST STARTED  
TEST RUNNING  
REMAINING: 08:00

1. Remove the foil tab covering the sample port on the cassette then discard.
2. Insert the pipette tip containing the sample all the way into the sample port until resistance is met.
3. Squeeze the top bulb of the pipette firmly to dispense the sample into the cassette.  
**NOTE:** A small amount of sample may remain in the overflow chamber.
4. Verify that the dock screen displays: "SAMPLE LOADED CLOSE LID".
5. Immediately close the lid of the dock to automatically begin the test.
6. Dispose of the pipette in an appropriate biohazard container. The dock screen will briefly display "CASSETTE SEALED TEST STARTED", then "TEST RUNNING REMAINING: XX:XX"  
**Do not move or unplug the dock, or open the lid while the test is running.**

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- When test is done the dock screen displays: "TEST COMPLETE READ RESULTS"
1. Open the dock lid and remove the cassette.
  2. Interpret and record results.  
**NOTE:** Results should be interpreted within 1 hour of test completion.  
**Discard the cassette in an appropriate biohazard container.**

## D. INTERPRETATION OF RESULTS

### Interpretation of results

The appearance of any shade of blue test line at the FLU A and/or FLU B positions is a valid result that is interpreted as positive for the influenza A and/or influenza B viral RNA. A negative result contains only a blue test line at position C.

**Note:** The absence of a blue test line at the C position in conjunction with a blue test line at the FLU A and/or FLU B positions means that the Influenza A and/or Influenza B viral RNA was amplified and detected as a valid result. This can occur due to the overabundance of Influenza A and/or Influenza B RNA that competes with the positive control target.

C = Internal Positive Process Control  
 FLU A = Influenza A  
 FLU B = Influenza B  
 NC = Internal Negative Process Control

Window	Interpretation	Criteria
	Positive test for FLU A	A positive result for the presence of FLU A is indicated by: <ul style="list-style-type: none"> <li>• ANY blue test line at the FLU A position (even if faint)</li> <li>• WITH or WITHOUT a blue process control line at the C position</li> <li>• AND the absence of a negative process control line at the NC position</li> </ul>
	Positive test for FLU B	A positive result for the presence of FLU B is indicated by: <ul style="list-style-type: none"> <li>• ANY blue test line at the FLU B position (even if faint)</li> <li>• WITH or WITHOUT a blue process control line at the C position</li> <li>• AND the absence of a negative process control line at the NC position</li> </ul>
	Positive test for FLU A and FLU B	A positive result for the presence for both FLU A and FLU B is indicated by: <ul style="list-style-type: none"> <li>• ANY blue test line at the FLU A position (even if faint)</li> <li>• WITH or WITHOUT a blue process control line at the C position</li> <li>• AND the absence of a negative process control line at the NC position</li> </ul>
	Negative test for Flu A and Flu B	A negative result for the presence for both FLU A and FLU B is indicated by: <ul style="list-style-type: none"> <li>• The absence of ANY blue test line at BOTH the FLU A and FLU B positions</li> <li>• AND a blue process control line at the C position</li> <li>• AND the absence of a negative process control line at the NC position</li> </ul>
	Invalid result <sup>[1]</sup>	An invalid test result is indicated by: <ul style="list-style-type: none"> <li>• The absence of any lines in the C, FLU A, FLU B positions, AND ANY process control line at the NC position (even if faint)</li> <li>• The absence of lines in the C, FLU A, FLU B, and NC positions</li> <li>• The presence of lines in the C and NC positions, regardless of the presence or absence of lines in the FLU A or FLU B positions (the example shows lines at all four positions)</li> </ul>

<sup>[1]</sup> If an invalid result is obtained, the sample may be re-run with a fresh cassette only if the eluted sample in the nasal swab buffer has been stored for less than 2 hours at room temperature (15°C to 30°C, 59°F to 86°F)

### Dock cleaning

We recommend that the dock be cleaned each day that it is used. For more information, see *Accula™ Dock Operator's Guide* (Pub. No. LBL-60058).

### Quality control

#### Process controls

Each Accula™ Flu A/Flu B Test Cassette contains two internal process controls: an internal positive control (labeled 'C' on the cassette) and negative control (labeled 'NC' on the cassette). The positive process control is a non-infectious RNA bacteriophage in the cassette and is used as the positive process control to verify that all assay steps (lysis of the virus, reverse transcription, amplification and detection) were executed properly. A non-influenza nucleic acid target is used as a negative control for false positive results due to nonspecific binding.

#### External positive and negative controls

External controls may be used to show that the Accula™ Flu A/Flu B Test is working properly.

The Accula™ Flu A/Flu B Test contains two control swabs:

- 1 Accula™ Flu A Positive/Flu B Negative Swab (yellow shaft)
- 1 Accula™ Flu B Positive/Flu A Negative Swab (blue shaft)

We recommend that a Flu A positive/Flu B negative and a Flu B positive/Flu A negative control be run:

- Once for each new lot or shipment of kits received.
- Once for each new operator.
- As deemed necessary in order to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups.

Run control swabs using the same procedure as for a patient specimen. If external QC testing fails, repeat the test using a new control swab, reagent and test cassette, or contact Technical Support before testing patient samples.

For questions, assistance, or if the Accula™ Dock or Flu A/Flu B Test is not performing as expected, contact Technical Support at 1-800-955-6288, option 2 or [techsupport@thermofisher.com](mailto:techsupport@thermofisher.com)



Mesa Biotech™ 6190 Cornerstone Court East Suite 220 San Diego, California 92121, USA

For descriptions of symbols on product labels or product documents, see the [Accula™ Flu A/Flu B Test Instructions for Use](#) (Pub. No. LBL-60009).

The information in this guide is subject to change without notice.

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