Sutter Health Sacramento Sierra Region
We Plus You

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Performing the Quidel Sofia Influenza A+B Patient Test, IM.ANA10.07-/-SS.xx

Background

This procedure describes how to perform the Quidel Sofia Influenza A+B FIA test.

The CLIA complexity of this test is waived if used with direct nasal swab, nasopharyngeal (NP) swab, and NP aspirate/wash specimens.

The CLIA complexity of this test is moderate if a site uses specimens eluted in transport media.

Policy

Quidel Sofia Influenza A+B FIA test is considered STAT with a 60 minute TAT.

Order test code IFABEO (Influenza A &B Antigens): Add on PCR testing (test code FLUAB) may be added on within 72 hours if refrigerated wash/aspirate or NP swab in universal transport media sample is available.

Order test code IFABER (Influenza A and B Antigen with Reflex to PCR): If this test code is used, an automatic reflex order for FLUAB will be generated if both Sofia Influenza A and B results are both negative. The FLUAB test requires a wash/aspirate or NP swab in universal transport media sample.

Principle

The Quidel Sofia test system uses immunofluorescence technology to detect influenza virus nucleoproteins and allows differentiation of influenza A and B antigens.

The patient sample is placed in the reagent tube along with the reagent solution. Viral particles in the patient specimen are disrupted, exposing internal viral nucleoproteins. The patient specimen is dispensed into the test cassette sample well and the specimen then migrates through the test strip which contains various unique chemical environments. If influenza viral antigen is present, it will be trapped in a specific location.

The Sofia analyzer scans the test strip and measures the fluorescent signal by processing the results using a method specific algorithm. Test results are generated and displayed as Positive, Negative, or Invalid.

Specimen Requirements

Nasopharyngeal swab or Nasal wash/aspirate.

Acceptable swabs are nylon flocked NP swab or nasal swab supplied in the kit.

Acceptable viral transport media are: Copan UTM, Hanks's Balanced Salt Solution, M4, M4-RT, M5, M6,

Modified Liquid Stuarts, sterile saline, Starplex Multitrans.

When possible, use ≤ 1 ml media to avoid excessive dilution of patient sample.

Patient samples should be tested as soon as possible after collection.

Patient samples in VTM must be at room temperature before beginning the assay.

Nasal wash/aspirate can be stored refrigerated up to 24 hrs.

NP swabs in VTM can be stored refrigerated up to 72 hours with exception of Hanks Balanced Salt Solution, Modified Liquid Stuarts, and sterile saline.

Equipment/Reagents/Supplies

Quidel Sofia analyzer

Timer (optional)

Quidel Sofia Influenza A+B FIA kit

- Store kit at room temperature (15-30°C/59-86°F)
- Keep out of direct sunlight
- Stable until expiration date printed on the outer box

Fixed volume transfer pipettes (included in kit)

Printer paper

BD NP/UVT media collection kit.

Quality Control

Three types of quality checks are performed.

- Calibration check procedure: Refer to *Performing the Calibration Check on the Quidel Sofia Analyzer*
- External controls: Refer to *Running and Evaluating Controls on the Quidel Sofia Analyzer* procedure)
- Procedural/internal controls: These are built into each Sofia FIA test cassette and will run each time a patient or external control sample is tested. The procedural control is interpreted by the analyzer and must be valid in order to report patient test results.

Preparing Patient Sample: Swab without transport media/ "dry" swab (nasal or NP)

Step	Action
1.	Obtain the manual test patient worksheet or log.
2.	Record or verify kit lot# and expiration date on the worksheet or log. • Do not use test kits that are expired.
3.	Label a reagent tube with proper patient identification. Place in rack or holder.
4.	Prepare reagent: • Flick or shake the reagent solution vial down to that all the fluid is in the bulb. • Twist off the vial tab. • Slowly dispense all of the reagent solution into the reagent tube. • Gently swirl the reagent tube to dissolve its contents.

5.	Place the patient swab in to the reagent tube. • Roll the swab at least 3 times while pressing the swab head against the bottom and side of the reagent tube.
6.	**Leave the swab in the reagent tube for 1 minute.**
7.	Roll the swab head against the inside of the reagent tube as it is removed. Discard the swab in a biohazard waste container.
8.	Proceed to Test procedure. • The prepared specimen in a recapped reagent tube is stable for up to 12 hours at room temperature prior to testing.

Preparing Patient Sample: NP aspirate/wash or Swabs in Transport Media

Step	Action
1.	Obtain the manual test patient worksheet or log.
2.	Record or verify kit lot# and expiration date on the worksheet or log. • Do not use test kits that are expired.
3.	Verify that the patient sample is at room temperature.
4.	Label a reagent tube with proper patient identification. Place in rack or holder.
5.	Prepare reagent: • Flick or shake the reagent solution vial down to that all the fluid is in the bulb. • Twist off the vial tab. • Slowly dispense all of the reagent solution into the reagent tube. • Gently swirl the reagent tube to dissolve its contents.
6.	Fill the large, pink 250 µL fixed volume transfer pipette with patient sample from the collection container. • Avoid sampling mucoid portions of the sample.
7.	Empty the contents of the pipette into the reagent tube by firmly squeezing the top bulb. • Extra fluid in the overflow bulb should be left behind. • Discard the pipette in a biohazard waste container.
8.	Vigorously mix the patient sample in the labeled reagent tube.
9.	Proceed to Test procedure. • The prepared specimen in a recapped reagent tube is stable for up to 12 hours at room temperature prior to testing.

Testing Procedure

Step	Action
1.	Set the Sofia analyzer to **WALK AWAY** or **READ NOW** mode. Refer to Operating the Quidel Sofia Analyzer procedure for details on mode selection and user/patient ID entry.
2.	Remove test cassette from pouch and place specimen ID on cassette.

	• Do not open the foil pouch containing the cassette until ready for immediate use.
3.	Fill the small clear 120 µL fixed volume transfer pipette with patient sample from the reagent tube.
4.	Empty the contents of the pipette into the cassette well by firmly squeezing the top bulb. • Extra fluid in the overflow bulb should be left behind. • Discard the pipette in a biohazard waste container.
5.	Proceed to the next step based on the mode selected.

IF	THEN
WALK AWAY mode	Immediately insert the cassette into the analyzer. The analyzer will automatically time the test development (15 minutes) before scanning and displaying the test results.
READ NOW mode	Leave the cassette on the bench top and manually time the 15 minute development time. All the test to develop for the FULL 15 minutes before placing it into the Sofia for scanning and resulting. • The results will remain stable for an additional 15 minutes of development (30 minutes maximum total development time.)

6.	Record the internal control and patient test results on the worksheet or log. • Results cannot be read visually on the cassette. All results must be generated from the Sofia analyzer.

Interpretation of Results

Assay	Assay Results	Procedural Control Results	Interpretation
Influenza A	Positive	Valid	Positive for Influenza A
Influenza B	Positive	Valid	Positive for Influenza B
Influenza A	Negative	Valid	Negative for Influenza A
Influenza B	Negative	Valid	Negative for Influenza B
Influenza A or B	Invalid	Invalid	Invalid for Influenza A+B

Reporting of Results

Step	Action
1.	Login to Sunquest.
2.	Enter MEM at the function prompt.
3.	Enter the site-specific worksheet at the worksheet prompt. Press "A" to proceed to requested worksheet.

Site	Worksheet
SAFH	AFSIM
SAH	AMSIM
SDH	DVMAGI

	SMCS	GNMO
	SRMC	RVFLU
	SSMC	SMMAGI

4. Enter the Accession number to be resulted at the prompt.

5. Refer to the table below to report results.

Test Result	Report
Pos for Influenza A only	INAAGI = Pos INBAGI = Neg
Pos for Influenza B only	INAAGI = Neg INBAGI = Pos
Pos for both Influenza A and B	INAAGI=Pos INBAGI= Pos
Neg for both Influenza A and B*	INAAGI = Neg INBAGI = Neg
Invalid results obtained for Influenza A and B	Invalid results - *Do Not Report*. Request for sample recollection. Cancel test using code RNNOT (Nursing unit notified of need to recollect specimen)

Note for Negative results:

- For test code IFABEO, the "NEGFLU" ETC auto-appends to result. (Translation: "Negative test result does not exclude infection with Influenza A and/or B. Influenza A/B PCR is available upon request. Please contact lab within 72 hours of specimen collection.")
- For test code IFABER, an automatic reflex order for FLUAB is created under the same accession number. The "CDPCR" ETC auto-appends to the result (Translation: "Test reflexed to PCR assay.")

6. Enter "A" to accept and save results.

7. Verify correct entry of results.

Procedural Notes

Do not open foil pouch of test cassette until ready for immediate use to avoid exposure to ambient environment.

To obtain accurate results, the test cassette should not be left standing inside a laminar flow hood or in a heavily ventilated area during the 15-minute development step. The accentuated air flow can dry the sample and retard the flow of the sample through the test strip. If processing a sample inside a laminar hood, after adding the sample to the cassette, cover the test cassette or insert it back into the foil pouch until it is ready to insert into Sofia.

Visually bloody or overly viscous samples should not be used.

Positive results for Influenza A and B are rare and may be due to mist vaccines. Recollection and repeat

testing may be considered

A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype. A negative result does not exclude influenza viral infection. Negative results should be confirmed by virus culture or an FDA-cleared influenza A and B molecular assay.

If the test in invalid, a new test should be performed with a new patient sample and a new test cassette.

Related Documents

Operating the Quidel Sofia Analyzer

Running Quality Control on the Quidel Sofia Analyzer

Performing Calibration Check on the Quidel Sofia Analyzer

References

Quidel Sofia analyzer user manual

Quidel Sofia Influenza A+B FIA package insert

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Attachments:

No Attachments

Approval Signatures

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