Sutter Health Sacramento Sierra Region
We Plus You

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Owner:	*Mary Cabral: Mgr, Laboratory*
Policy Area:	*Lab - Serology*
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Applicability:	*Sac Sierra Region*

Performing the Quidel Sofia RSV Patient Test, IM.ANA10.08.-/-SS.xx

Background

This procedure describes how to perform the Quidel Sofia RSV FIA test.

The CLIA complexity of this test is waived if used according to package insert instructions and only for patients <7 years old. Sofia RSV test performance has not been validated on patients 7 years old and older. Patients 7 years old or older must be tested with another method.

Policy

Quidel Sofia RSV FIA test is considered STAT with a 60 minute TAT.

Order test code is RSVEO.

Principle

The Quidel Sofia test system uses immunofluorescence technology to detect RSV nucleoproteins. 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 RSV 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 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 hours

NP swabs in VTM can be stored refrigerated up to 24 hours.

Visually bloody samples should not be used.

Equipment/Reagents/Supplies

Quidel Sofia analyzer

Timer (optional)

Quidel Sofia Influenza RSV 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" NP swab)

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 4 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 4 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
RSV	Positive	Valid	Positive for RSV
RSV	Negative	Valid	Negative for RSV
RSV	Invalid	Invalid	Results invalid.

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** Positive for RSV: RSVAGR = Pos

	Negative for RSV	RSVAGR = Neg
	Invalid results	Invalid results - *Do Not Report*. Request for sample recollection. Cancel test using code RNNOT (Nursing unit notified of need to recollect specimen)
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.

Visually bloody or overly viscous samples should not be used.

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

This test detects both viable (live) and non-viable RSV. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.

A negative test may occur if the level of antigen is below the detection limit of the test or if the sample was collected or transported improperly.

Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of the disease is high. False positive test results are more likely during periods of low RSV activity when prevalence is moderate to low.

Mycoplasma pneumoniae at levels greater than $1x10^5$cfu/ml may cross-react with the performance of this test.

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 RSV FIA package insert

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Attachments:

No Attachments

Approval Signatures

Step Description	Approver	Date
Lab Directors/Managers	Steven Stern: Mgr, Laboratory	9/5/2017
Lab Directors/Managers	Pamela Hill: Dir, Laboratory	8/29/2017
Lab Directors/Managers	Trudy Fidler: Dir, Lab	8/28/2017

Step Description	Approver	Date
Lab Directors/Managers	Mary Cabral: Mgr, Laboratory	8/24/2017
Lab Directors/Managers	Stephen Medland: Mgr, Clinical Lab	8/23/2017
Lab Directors/Managers	Dixie Matson: Dir, VA Fndtion Lab Operations	8/22/2017
Lab Directors/Managers	Cyndee Jones: Mgr, Lab	8/21/2017
Lab Medical Directors	Rowberry Ron: MD	8/21/2017
Lab Medical Directors	Hannah Wong: MD	8/21/2017
Lab Medical Directors	Marian Butcher: MD	8/17/2017
Lab Medical Directors	Andrea Ong: MD	8/16/2017
Lab Medical Directors	Kristen Vandewalker: MD	8/15/2017
Lab Medical Directors	Mary Keohane: MD	8/15/2017
Lab Medical Directors	Jamie Cassity: MD	8/15/2017
	Mary Cabral: Mgr, Laboratory	8/15/2017