

Rapid Strep Test Procedure	Attachments <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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<u>APPROVAL(S)</u> Laboratory Medical Director	

Strep Screen for Group A
Clinic Lab Procedure (Pages 1-9)
Computer Entry (Pages 10-11)
Job Aide (Page 12-13)

I. PURPOSE/PRINCIPLE

This procedure provides direction for performing a rapid test on a throat swab for the detection Group A Streptococcus.

A throat screen is performed to detect the presence of Group A Streptococcus which is the primary causative agent of severe throat infection. A rapid diagnosis and early treatment of Group A Strep reduces the probability of complication such as rheumatic fever and glomerulonephritis.

The OSOM Ultra® Strep A Test is a color immunochromatographic assay using Dual Label Technology (DLT). A throat swab is subjected to a chemical extraction of a carbohydrate antigen unique to Group A Streptococcus. The Test Stick is then placed in the extraction mixture and the mixture migrates along the membrane. If Group A Streptococcus is present in the sample, it will form complexes with the anti-Group A Streptococcus antibody conjugated color particles located at two separate locations on the Test Stick. The complex will then be bound by the anti-Group A Streptococcus capture antibody and a visible blue Test Line will appear to indicate a positive result. A red Control Line will also appear to indicate the test is valid.

II. POLICY

Laboratory Staff will follow the approved techniques outlined in this procedure.

Specimen:

The specimen is collected by the provider/nurse/tech using a single, dry Dacron or Rayon swab. When swabbing the throat, be careful not to touch the tongue, sides or top of the mouth with the swab. Rub the swab on the back of the throat, on the tonsils and in any other area where there is redness, inflammation or pus. Bloody specimens can create an interfering background and can cause an invalid result. Do not use calcium alginate, cotton-tip, or wooden shafted swabs. The collection swab is returned to its plastic container, labeled and brought to the laboratory immediately.

Note: There are no longer any restrictions around a patient eating or drinking before a throat culture is obtained.

Reagents/Materials:

1. OSOM Ultra® Strep A 50 test kit (Genzyme)

Test Sticks Coated with Rabbit Anti-Group A Streptococcus, Test Tubes, Sterile Swabs
1 Reagent A (2 M Sodium Nitrite). Caution: Harmful if swallowed
1 Reagent B (0.3 M Acetic Acid). Warning: Severe eye irritant
1 Positive Control (Nonviable Group A Streptococci, 0.1% Sodium Azide)
1 Negative Control (Nonviable Group C Streptococci, 0.1% Sodium Azide)
1 Workstation
1 Directional Insert

Store Test Sticks and reagents tightly capped at 15° – 30°C
Do not use Test Sticks or reagents after expiration date. •

2. Timer

3. SSA (selective streptococcal agar)

For culture back up on negative rapid tests on patients less than 21 years of age and when requested by the provider.

Store at 2-8 °C

Bring to room temp before using.

4. Candle Jar and 34-36 °C incubator

Quality Control:

Positive and negative external controls must be run and documented on the rapid strep QC worksheet monthly and with each new lot number.

Internal Procedural Controls

The OSOM Ultra® Strep A Test provides three levels of procedural controls with each test run:

The color of the liquid changes from pink to light yellow after Reagent B is added to Reagent A and the extraction reagents are mixed. This is an internal extraction reagent control. The color change means you have mixed the extraction reagents properly. The color change also means that the reagents are functioning properly.

The red Control Line is an internal positive procedural control. For the Test Stick to be working properly, capillary flow must occur. The Test Stick must absorb the proper amount of sample and the Test Stick must be working properly for the red Control Line to appear.

A clear background is an internal background negative procedural control. If no interfering substances are in the specimen and the Test Stick is working properly, the background will be clear. A discernible result will be seen.

- If the red Control Line does not appear the test is invalid.
- If the background does not clear and interferes with the test result, the test is invalid.

External Quality Controls

Each kit contains Positive and Negative Control material. The controls are for external quality control testing. Use the Controls to test that the extraction reagents and the Test Sticks are working properly. Also use the Controls to test that you are able to correctly perform the test procedure, including the antigen extraction portion of the test procedure.

Positive Control

- Follow Step 2 in the TEST PROCEDURE section to dispense Reagent A and B into the Test Tube.
- Vigorously mix the Positive Control material. Add 1 free falling drop of the Positive Control from the dropper bottle into the Test Tube.
- Place a clean swab into the Test Tube.
- Follow the Steps 4 – 6 in the TEST PROCEDURE section to test the swab.

Negative Control

- Follow Step 2 in the TEST PROCEDURE section to • dispense Reagent A and B into the Test Tube.
- Vigorously mix the Negative Control material. • Add 1 free falling drop of the Negative Control from the dropper bottle into the Test Tube.
- Place a clean swab into the Test Tube. •
- Follow the Steps 4 – 6 in the TEST PROCEDURE • section to test the swab.

III. PROCEDURE

Always streak an SSA plate before beginning the Rapid Strep test

Rapid Antigen Test Procedure:

1. Open the swab container and lightly streak a primary inoculum on the SSA plate in the event a back up culture is required for patients less than 21 years of age or the patient is 21 years or older and the provider has selected a backup plate.
 - Always streak a plate, regardless of whether a patient is 21 years or older and the provider did not order a reflex culture. If the plate isn't needed, just toss it. The cost of the plate is negligible and it provides better patient care and experience should the provider want a culture performed after the rapid test has been resulted.

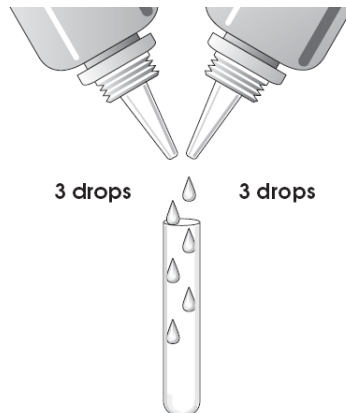
Replace the swab into the container until ready to perform the rapid antigen test.



- Negative rapid tests on patients less than 21 years of age or patients 21 years or older and the provider has selected a backup plate will have the SSA plate forward to Central Lab for back up culture. Patients 21 years or older will not require a back up culture unless specifically requested by the provider.

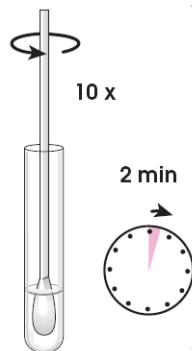
2. Proceed with Rapid Strep testing.

3. Just before testing, add 3 drops Reagent A (pink) and 3 drops Reagent B to the Test Tube (the solution should turn light yellow).

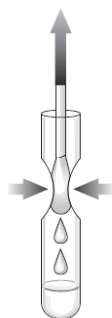


4. Immediately put the swab into the Tube. Vigorously mix the solution by rotating the swab forcefully against the side of the Tube at least ten (10) times. Best results are obtained when the specimen is vigorously extracted in the solution.

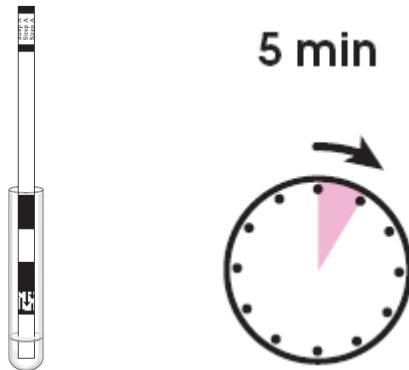
Let stand for 2 minutes



5. Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn. Discard the swab.

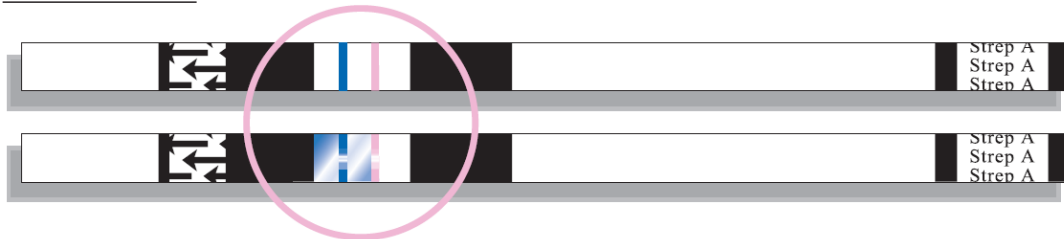


- Remove the Test Stick(s) from the container; re-cap the container immediately. Place the Absorbent End of the Test Stick into the extracted sample.



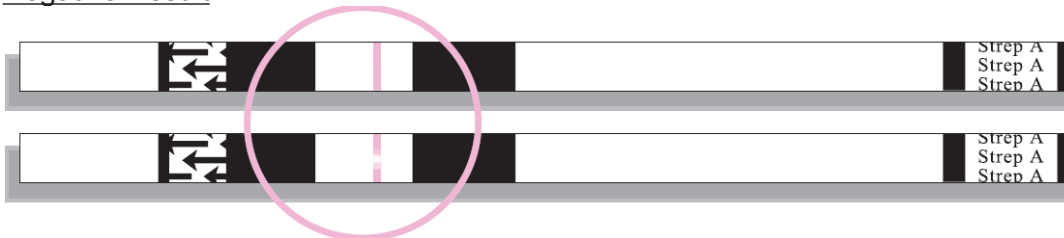
- Use a timer. Read results at 5 minutes. Positive results may be read as soon as the red Control Line appears. Negative results must be confirmed at 5 minutes. Results read after 5 minutes are invalid.

Positive Result



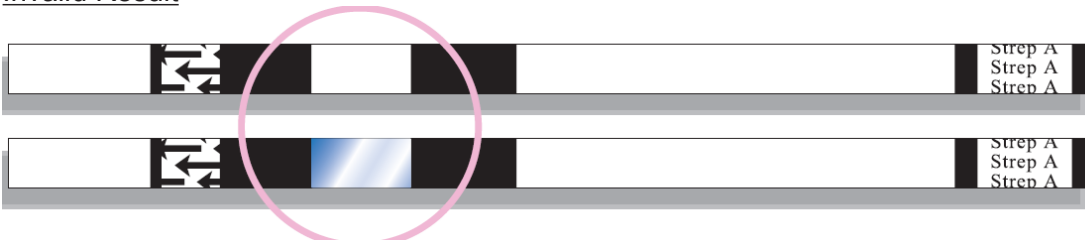
A blue Test Line and a red Control Line is a positive result. A positive result means that Group a Streptococcus antigen was detected. *Note that the blue line can be any shade of blue and can be lighter or darker than the line in the picture.*

Negative Result



A red Control Line but no blue Test Line is a negative result. A negative result means that no Group A Streptococcus antigen was detected, or the levels of antigen in the specimen were below the detection level of the assay

Invalid Result



If after 5 minutes, no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If expected QC Values are not attained, patient results will not be reported until troubleshooting is complete. If the rapid test fails, request recollection. If the patient is unavailable for recollection, enter “RICUL” (Result inconclusive, Refer to Culture).

Negative Result:

The red internal Control Line is visible but no blue Test Line. NOTE: The background (internal negative control) must be clear.

Positive Result:

The red internal Control Line is visible and a blue Test Line is present.

Uninterpretable Result:

Either the blue Test Line cannot be read as either positive or negative, or red internal Control Line is not visible and/or the background (internal negative control) is not clear.

Invalid Result:

After 5 minutes, no red internal positive control appears;

OR background (internal negative control) is not clear.

Resulting Invalid or Uninterpretable Results:

If the rapid test fails, request recollection. If the patient is unavailable for recollection, enter “RICUL” (Result inconclusive, Refer to Culture).

⇒ Document rapid result on the Rapid Strep worksheet.

Resulting

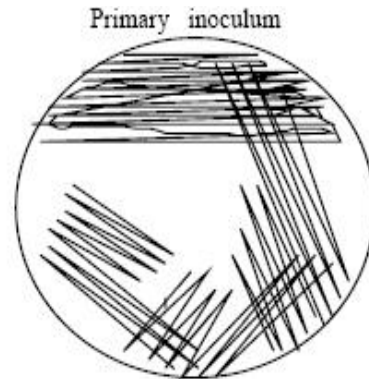
If expected QC Values are not attained, patient results will not be reported

Immediately enter the Rapid result into the computer so the results are available electronically.

Interpretation	Result	Further Action
Positive	POS	Discard SSA plate
Negative on patients < 21 yrs of age	NEG	Correctly label plate and send to Central Laboratory following specimen transport instructions for microbiology.
Negative on patients ≥21 yrs of age	NEG	If EPIC question - Perform a culture if negative screen ? (Sunquest test code PRFCU) is answered No or HIDE – Then Discard SSA plate if one has been plated. If EPIC question - Perform a culture if negative screen ? (Sunquest test code PRFCU) is answered Yes – Correctly label plate and send to Central Laboratory following specimen transport instructions for microbiology.
Invalid	<i>Recollect and Retest, If not possible enter: for < 21 RICUL</i>	Request recollection. If the patient is <21 years of age and unavailable for recollection, enter “RICUL” (Result inconclusive, Refer to Culture). If patient is ≥ 21 years of age, then enter “INVLD-RSUG” (Invalid. Recollection Suggested) Correctly label plate and follow specimen transport instructions for microbiology

	For ≥ 21 INVLD- RSUG	
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**FOR NEGATIVE RAPID STREP RESULTS COMPLETE PROCESS OF
STREAKING SSA PLATE FOR ISOLATION**



To Streak for Isolation:

Pass the loop back and forth through the primary inoculum (the first quadrant) several times. Turn the culture plate $\frac{1}{4}$ of a turn. Pass the loop back and forth approximately four times, while streaking into the second quadrant. Then continue streaking into the second quadrant WITHOUT going back into the first quadrant. Rotate the plate another $\frac{1}{4}$ of a turn and repeat the above process until all four quadrants are streaked.

Check pending logs at the end of the day for any un-resulted Rapid Strep tests.

FUNCTION: PL
Printer #
Today's date
GHP for hospital code
R for received
Wksht CM_ _(clinic initials)

REPORTING RESULTS

Clinic Labs: see the Computer Entry section of this procedure

Well@Work Clinics:

1. enter results on test log sheet
2. fax test log sheet to Central Lab for result entry into the Laboratory Computer System

Culture Screen Procedure for Group A Strep

1. Refer to the table for follow-up on Group A Strep Screens:

BSS ordered, Rapid Negative Screen and patient is < 21 years of age	<ul style="list-style-type: none"> • Send the SSA to Central lab. • BSC will not be part of the battery but will automatically reflex when the rapid screen is negative
BSS ordered, Rapid Negative Screen and patient is ≥ 21 years of age and test PRFCU is No or HIDE BSS ordered, Rapid Negative Screen and patient is ≥ 21 years of age and test PRFCU is Yes	<ul style="list-style-type: none"> • No further testing required. • Discard SSA plate • Send the SSA to Central lab. • BSC will not be part of the battery but will automatically reflex when the rapid screen is negative
BSS ordered, Rapid Positive	<ul style="list-style-type: none"> • No further testing required. • Discard SSA plate
Test of Cure/Treatment Failure	<ul style="list-style-type: none"> • Order BSC. • Setup SSA and send to Central Lab.
BSS ordered for test of cure/treatment failure	<ul style="list-style-type: none"> • Credit BSS (CR). Order BSC. • Inoculate a SSA. • Streak for Isolation.
BSS ordered and resulted for test of cure/treatment failure	<ul style="list-style-type: none"> • Contact Central Lab (Microbiology Department) for instructions. See computer entry. • Streak for Isolation.
BSS ordered and resulted as Positive, culture also requested	<ul style="list-style-type: none"> • Contact Central Lab (Microbiology Department) for instructions. See page 10, computer entry
Request to identify organisms or Perform sensitivity	<ul style="list-style-type: none"> • Ideally, recollect on a culturette or separate swab. • Order a MISC. Inoculate media from MISC packet. Add SSA to media plated if Strep is requested. • Streak for isolation.

2. Place a large barcode label on the cover of the plate and a small barcode label on the media side of the plate.
3. Streak plate for isolation. Immediately incubate the SSA plate in a candle jar at 34-36 °C. Place the plate, media side up, in the non-flammable candle jar. Carefully, light a tea light and place it on top of the agar plate. Seal the jar with the lit candle inside. The candle flame will consume most of the oxygen in the jar, extinguish and produce an elevated level of carbon dioxide. A

candle jar provides a carbon dioxide rich environment for the growth of microaerophilic organisms.

4. Group A Strep Screen cultures will be read and finalized at Central Lab. For each reroute, remove plates from candle jar, tape a stack together and send them to Central Lab in the micro box.

PROCEDURE NOTES

1. The rapid test detects the antigen for Group A Strep. This antigen may remain in the patient's throat for a questionable period of time after treatment with antibiotics and may continue to give a positive rapid test. If a provider requests a strep recheck, order a BSC.
2. If a provider requests typing or sensitivities on strep, order a MISC culture with throat as the source and send to Central Lab.
3. For isolation of organisms other than Group A Strep, see Throat Culture (miscellaneous) procedure in the Micro Test Information section of the Central Lab Catalog.

TROUBLESHOOTING

Positive and negative controls must be run and documented on the rapid strep QC worksheet with each box opened.

Document Lot # information on the Q.C. worksheet.

Store controls at 15-30°C. Do not store near a heat/cold source. Expiration date is stated on the bottles.

1. Verify three levels of Internal Procedural Quality Control.
 - The color of the liquid changes from pink to light yellow after Reagent B is added to Reagent A and the extraction reagents are mixed.
 - The red Control Line is an internal positive procedural control.
 - A clear background is an internal background negative procedural control.
2. Check expiration date of kit and controls.
3. Check timing of procedure. The reaction disk must be read within 5 minutes after the solutions have been added.
4. Repeat the controls.
5. If the controls are still not performing as expected, open a new kit. Quality Control the new kit with the new set of controls.
6. Run old controls with new dip stick.
7. Run new controls with old dip stick.
8. Notify a Laboratory Technical Consultant or Central Laboratory Microbiology Lead. The manufacturer, Genzyme, may be called at 1- 800-332-1042

REFERENCES

1. Isenberg, H., Clinical Microbiology Procedures Handbook, ASM, Washington D.C., 1992

2. Forbes, Betty, Sahom, Daniel, and Westfield, Alice, Bailey & Scott Diagnostic Microbiology, 12th Edition, Mosby Elsevier, St. Louis, Missouri, 2007

3. Genzyme, OSOM Ultra® Strep A package insert, Rev. 3689-8, 01/09

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IV. DEFINITIONS

V. COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

VI. ATTACHMENTS

Job Aid

VII. OTHER RESOURCES

VIII. ENDORSEMENT

Laboratory Administration

Computer Order and Result Entry

STREP SCREEN, GROUP A, THROAT

Order Code: **BSS (RAPID ONLY)**
Order Code: **BSC (CULTURE ONLY, NO RAPID)**

ORDERING

Order code **BSS** is for **THROAT** specimens looking for **GROUP A BETA STREP ONLY**. **BSS is the Group A Rapid test and will reflex to a culture (BSC) if the rapid test is negative and the patient is < 21 years of age or if the patient is ≥21 and test PRFCU is Yes. Back up cultures will not be done for patients ≥ 21 years of age unless PRFCU test is answered Yes by provider in EPIC.**

At Order Receipt Modify (ORM) a prompt will come up for test PRFCU. If this test is answered Y or N – SAVE. If there is no answer in PRFCU and staff have no information from a paper order enter HIDE then SAVE.

Order code **BSC** is for **THROAT** specimens for **CULTURE ONLY** for **GROUP A BETA STREP**. **BSC does not include the rapid screen test.** Culture ONLY requests are usually ordered on symptomatic patients who have taken antibiotics for strep within the past 14 days: the rapid test can give a false positive because antigen may still be present even though organisms are gone.

Note: SC (charge test) is no longer used and has been made inorderable.

BSC (culture only).

If specimen from another source (anal, etc.) is submitted and BSS is incorrectly ordered:

- 1) Order the appropriate Central Lab culture (MISC, GENC, etc.)
- 2) Enter "Beta Strep" in the SREQ prompt for the culture.
- 3) Send credit form to Central lab to credit the BSS.

If a throat culture is submitted for organisms other than Group A Beta Strep (Diphtheria, Bordetella pertussis, Haemophilus, GC, etc.), please follow guidelines in the Central Lab Catalog. Micro Section, Throat Cultures (Miscellaneous).

RESULTING RAPID TEST: TEST BSS

WORKSHEET:

Function MEM, Worksheet CM__ (Group A Beta Strep Screen, Throat) with your clinic initials as part of the worksheet name. (Example- Brooklyn Center = CMBC)

<u>CODE</u>	<u>NAME</u>	<u>RESPONSE</u>
RAPID	Grp A Rapid Screen	POS or NEG

If resulting Rapid with POS, testing is complete. Discard SSA culture plate.

If resulting RAPID with NEG AND the patient is < 21 years of age:

The RAPID test with a negative result will automatically reflex to a culture (BSC).
Send culture plate to Central Lab.

If resulting RAPID with NEG AND the patient is ≥ 21 years of age and PRFCU is NO or HIDE: testing is complete.

Discard SSA culture plate.

If resulting RAPID with NEG AND the patient is ≥ 21 years of age and PRFCU is Yes:

The RAPID test with a negative result will automatically reflex to a culture (BSC).
Send culture plate to Central Lab.

**See Notes below if problems or questions with RAPID specimens and results.
Also please refer to Clinic Lab Procedure if questions on ordering proper tests.**

RECORDING RESULTS FOR RAPID TEST (BSS):

- 1) Use daily worksheet to record results.
- 2) Immediately enter RAPID results into computer, so results are electronically available to clinic and phone-line staff.

Note: If Rapid test is invalid or uninterpretable

- 1) Result Rapid test with RICUL (Result Inconclusive, Refer to Culture).
- 2) Request recollection. If the specimen is recollected during the same visit Encounter, order the recollected specimen on a new accession number (use new collect time).
- 3) If specimen is recollected, send credit form (CRW) to Central lab. Patient should be billed for only one BSS, but two BSSs could be ordered and resulted.
- 4) Send all plates to Central Lab for culture.

Note: If provider orders BSS/Rapid test AND later wants a culture follow-up when Rapid is POS for test of cure or treatment failure:

- 1) Provider will recollect specimen and order a **BSC test**.

Note: If Rapid test is NEG and culture is not set up (by mistake),

- 1) Notify provider.
- 2) Credit the BSC

SENDING PLATES TO CENTRAL LAB:

Send plates in each reroute.

PRINTING REPORTS:

Results file into Epic as soon as resulted.

CULTURE REPORTS:

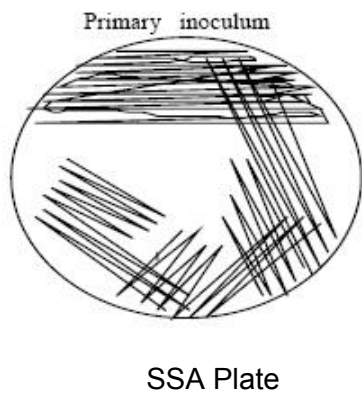
Results are filed into EPIC as cultures are finalized. On weekends, positive cultures are called to the respective urgent care location for follow-up.

LEJohnson, GBrors
AKHoward, GEFelland
SMDent, DBergo, ANicholas

Job Aid: OSOM Ultra Strep A Test

Procedure:

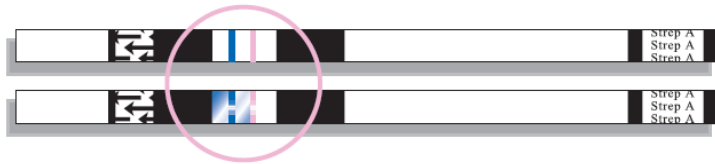
1. **Important:** Lightly streak swab to SSA plate first before performing Rapid Strep Test. Same swab is used and must be plated before extraction steps are initiated.



2. After streaking plate follow this five step procedure:

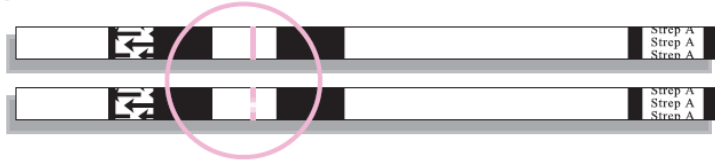
INTERPRETATION OF TEST RESULTS

Positive



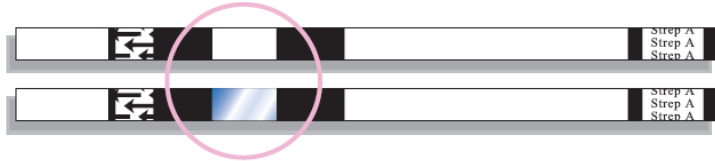
A blue Test Line and a red Control Line is a positive result. A positive result means that the assay detected Group A Streptococcus antigen in the specimen.
Note that the blue line can be any shade of blue and can be lighter or darker than the line in the picture.

Negative



A red Control Line but no blue Test Line is a negative result. A negative result means that no Group A Streptococcus antigen was detected, or the levels of antigen in the specimen were below the detection level of the assay.

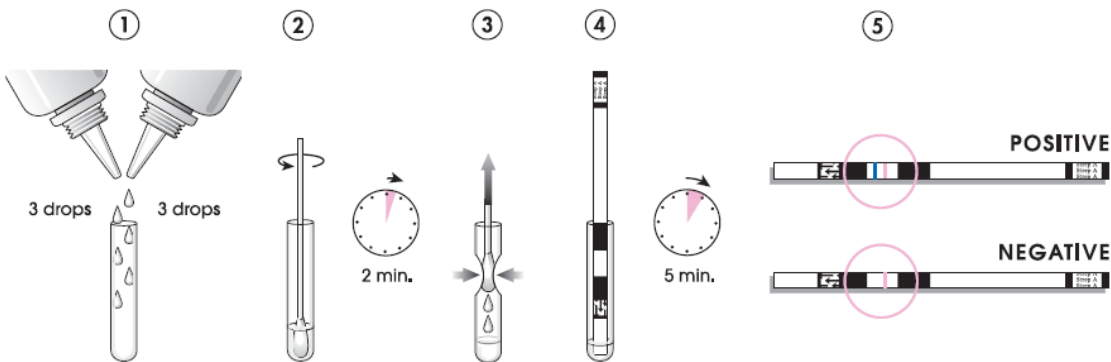
Invalid



If after 5 minutes, no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If this occurs, repeat the test using a new sample or contact Genzyme Diagnostics Technical Assistance.

Notes

A blue or red line that appears uneven in color density is still considered a valid line. In some cases, a trail of color may remain in the background; as long as the Test Line and Control Line are visible, the results are valid.



Resulting

If expected QC Values are not attained, patient results will not be reported

Immediately enter the Rapid result into the computer so the results are available electronically.

Interpretation	Result	Further Action
Positive	POS	Discard SSA plate
Negative on patients < 21 yrs of age	NEG	Correctly label plate and send to Central Laboratory following specimen transport instructions for microbiology.

<p>Negative on patients ≥ 21 yrs of age</p>	<p>NEG</p>	<p>If EPIC question - Perform a culture if negative screen ? (Sunquest test code PRFCU) is answered No or HIDE – Then Discard SSA plate if one has been plated.</p> <p>If EPIC question - Perform a culture if negative screen ? (Sunquest test code PRFCU) is answered Yes – Correctly label plate and send to Central Laboratory following specimen transport instructions for microbiology.</p>
<p>Invalid</p>	<p><i>Recollect and Retest, If not possible enter: for < 21</i> RICUL</p> <p>For ≥ 21 INVLD-RSUG</p>	<p>Request recollection. If the patient is <21 years of age and unavailable for recollection, enter “RICUL” (Result inconclusive, Refer to Culture). If patient is ≥ 21 years of age, then enter “INVLD-RSUG” (Invalid. Recollection Suggested)</p> <p>Correctly label plate and follow specimen transport instructions for microbiology</p>

Check pending logs at the end of the day for any un-resulted Rapid Strep tests.

FUNCTION: PL

Printer #

Today's date

GHP for hospital code

R for received

Wksht CM_ _(clinic initials)