KAISER PERMANENTE®
COLORADO LABORATORY

OSOM ULTRA STREP A TEST

(For use with throat swabs only)

PRINCIPLE

The OSOM Ultra Strep A test is a color immunochromatographic assay that uses antibody labeled particles in two separate locations of the test strip to identify Group A Strep from a swab of the tonsilar surface, posterior pharynx and areas with in the throat with inflammation or exudates.

A chemical extraction of the bacteria Group A Streptococcus is performed to which a test strip is added. The liquid extraction migrates along a membrane in the strip. If Group A Strep is present it will bind with the anti-Group A Strep capture antibody and form a blue line to indicate a positive test result.

SCOPE

All Medical Technologists and Medical Laboratory Technicians at the Lakewood and Pueblo North Laboratories

SPECIMEN COLLECTION AND HANDLING

1. Specimen collection is performed in patient care departments.
2. Two Dacron polyester sterile swabs are collected. Avoid the teeth, tongue, gums and cheeks. Culture both tonsilar surfaces, the posterior pharynx, and areas of the throat with inflammation and exudates. Testing should be performed as soon as possible after collection.
3. The specimens are labeled with patient visit record stickers or “zebra labels” containing the patient’s full name, MRN, DOB. Write the date and time when swabs were collecting as well as the collector’s initials.
4. Two orders need to be submitted in Health Connect by the ordering provider
    a. Rapid Strep Screen. Health connect display name = **GROUP A STREP SCREEN POCT [87880E]**
    b. BSS. Health connect display name = **STREP A PROBE, THROAT [87650B]**
5. Lab will always dispatch the Rapid Strep Screen order in Collections Inquiry of Cerner.
6. The Beta Strep Screen DNA Probe (BSS) order is dispatched in Collections Inquiry of Cerner if the Rapid Screen test is Negative on patients 18 years old and younger – see reporting results section.
7. The BSS order is canceled in ORV when the Rapid Screen is Positive or Negative for all patients 19 years or older – see reporting results section.

REAGENTS AND MATERIALS

1. OSOM Ultra Strep A Kit, GENZYME Catalog #147. (Kit contains materials for 25 tests plus positive and negative control vial.) Kits are stored at room temperature (15º – 30º C. or 59º – 86º F., # 147-25, 25 tests /kit, Onelink #: 10031294
2. Rapid Strep Patient and Quality Control Log Sheet
3. Timer, Fisher Brand certified Timer Traceable *Giant Digit Timer,* Cat.# 02-261-839, *KP # 0040-5903* - verified by HSS to be accurate

CALIBRATION

None

QUALITY CONTROL

1. Internal Quality Control:
   a. There are three internal controls present on the Strep A test stick which must be recorded with each swab tested.
      - The combination of the two reagents when the ampule is crushed results in a color change from pink to pale yellow. The color change indicates that the two reagents have been mixed and are functioning properly.
      - The red or pink line is an internal positive control. The control line indicates that the test worked accordingly and that sufficient specimen was applied to the test strip.
      - The clear background is an internal negative control and indicates that the test was correctly performed and that interfering substances are not present.
   b. If the **red or pink line does not appear** the test is **invalid**.
   c. If the **background does not clear** and the results cannot be read, the test is **invalid**.
   d. Document these each time a patient specimen is tested on the Rapid Strep Patient and Quality Control Log Sheet.
   e. If any of the three internal controls fail, obtain a second specimen and repeat the test.
   f. The patient / internal QC log is reviewed by the Laboratory Supervisor.

2. External Quality Control:

   a. The kit contains both a positive and negative control. These are both performed prior to patient testing and documented on the Rapid Strep Patient and Quality Control Log Sheet each time a new kit is opened. The positive and negative controls confirm that the reagents and test strips are working correctly, and determine if the test has been performed correctly.

To test the external controls upon opening a new kit:

1. Vigorously mix the both control vials
2. Label two test tubes with a permanent marker, positive and negative, respectively.
3. Add 1 free falling drop of control liquid to the appropriately labeled test tube.
4. Place a separate plain **sterile swab** into each of the test tubes
5. Complete testing as instructed below at step 3.

If either of the external controls fails, repeat the test on the controls.

PROCEDURE

1. Just before using, squeeze the Extraction Reagent Bottle and crush the ampule inside.

2. Shake the Extraction Reagent Bottle 3-5 times to mix the contents. Confirm the color change from pink to pale yellow. Add 6 drops of the Extraction Reagent to the Test Tube.

3. Immediately put the swab into the Test Tube. Vigorously mix the solution by forcefully rotating the swab against the test tube sides for at least 10 times. Best results are obtained when the specimen is vigorously extracted in the solution.

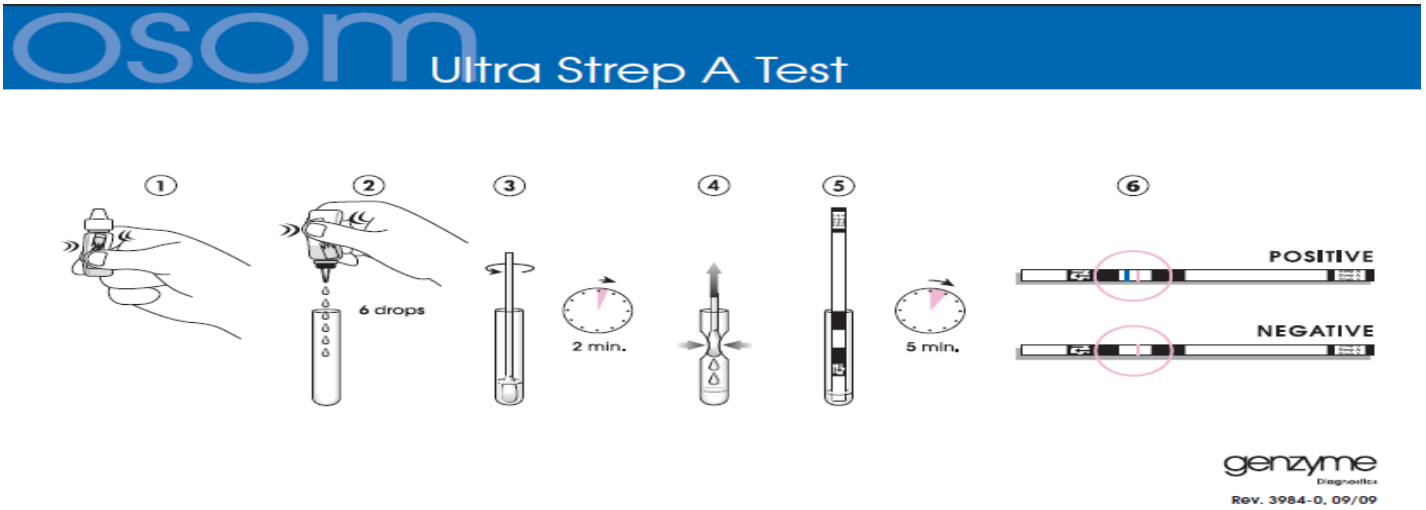
4. Let stand for 2 minutes. (Timing is critical)

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

6. Remove the test stick from the container; **re-cap the container immediately.** Place the absorbent end of the test strip into the extracted sample.

7. Set a timer for 5 minutes. Read the results at 5 minutes. Results are invalid after the read time.

8. Record results on the Rapid Strep Patient and Quality Control Log Sheet.



TEST PROCEDURE

STEP 1
Just before testing, squeeze the Extraction Reagent Bottle to crush the ampule inside.
Note: The ampule must be crushed before proceeding to the next step.

STEP 2
Vigorously shake the Extraction Reagent Bottle 3–5 times to mix the contents. The liquid in the Extraction Reagent Bottle should turn from pink to light yellow.

Add **6 drops** of the Extraction Reagent to the Test Tube.

STEP 3
Immediately put the swab into the Test Tube.

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

Let stand for 2 minutes.

STEP 4
Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn.

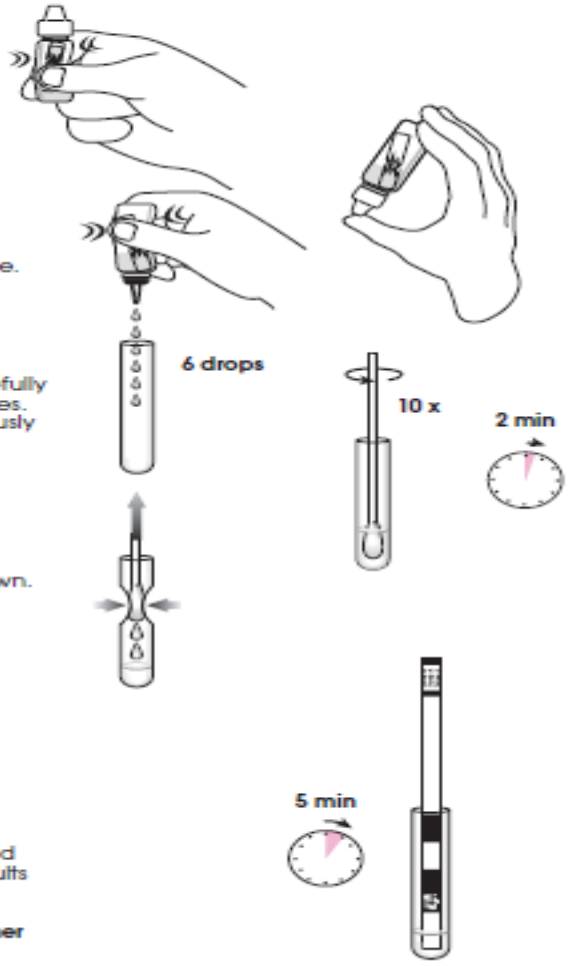
Discard the swab.

STEP 5
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.

STEP 6
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 are invalid after the read time. The use of a timer is recommended.



INTERPRETATION OF RESULTS

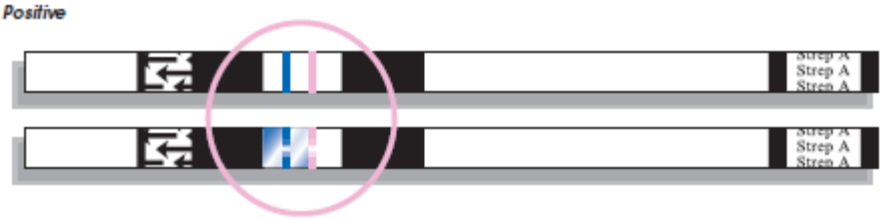
Positive – A **blue test line** and a **red control line** indicate a positive result. (Note: a blue or red line that is uneven in color intensity is still considered a valid test)

Negative – A **red or pink control line but no blue test line** indicates a negative result.

Invalid – *If after 5 minutes, **no red control line** appears or a **colored background** on the TEST Stick makes reading the test and control line impossible, the test is invalid*. (Repeat the test with a new specimen swab, Test Tube and Extraction Reagent bottle.)

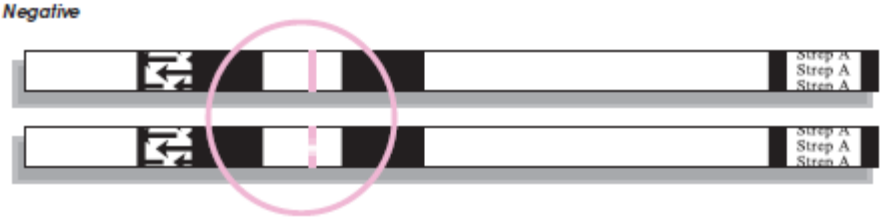
INTERPRETATION OF TEST RESULTS

Positive



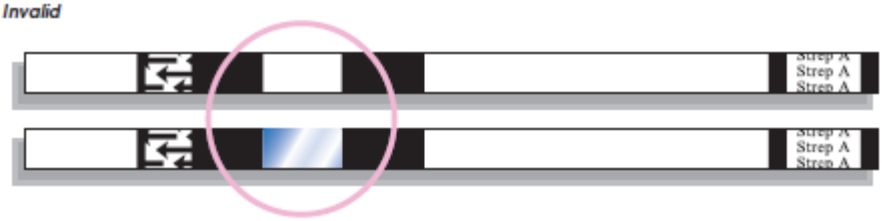
A blue Test Line and a red Control Line is a positive result. A positive result means that the assay detected Group A Streptococcus antigen in the specimen.
Note that the blue line can be any shade of blue and can be lighter or darker than the line in the picture.

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.

REPORTING RESULTS

1. “LTL” the Rapid Strep Screen test from CORR MAN OTHER and transfer it to COLK MAN OTHER (Lakewood) or COPN MAN OTHER (Pueblo North).

2. Results are verified in the LIS under the “ARE” application using the COLK or COPN MAN OTHER service resource.

3. Select Negative or Positive from the Drop down list, click on “PERFORM” and then “VERIFY”.

4. For Negative results on patients 18 years old or younger, dispatch the BSS order from Collections Inquiry and send to RRL Microbiology per the procedure.

5. For Negative results on patients 19 years or older and for all Positive results, cancel the Beta Strep Screen (BSS) test from Order Result Viewer with a cancel reason code of “Test Not Performed”.

NOTES

- Do not mix reagents or components from one kit with another kit.
- Do not use the kit after the expiration date on the kit box.
- This kit is not validated by the manufacturer for specimen sources other than the throat. Testing of rectal swabs is prohibited.

REFERENCE RANGE

Negative

LIMITATIONS

- The OSOM Ultra Strep A Test is a qualitative test for the detection of Group A Strep from a throat swab specimen. This test detects both viable and non-viable Group A Streptococci and may yield a positive result in the absence of living organisms.
- The quality of the test depends on the quality of the specimen; correct specimen collection is essential.
- All NEGATIVE rapid tests require a second swab be sent for Beta Strep Screen (probe) performed at RRL.
- As with all diagnostic tests, a definitive diagnosis should not be based on the results of a single test, but should be made by a physician after all clinical and laboratory findings have been evaluated.
- The *only* acceptable specimen for use with this kit is a throat swab. The kit is not validated by the manufacturer for rectal swabs and testing of rectal swabs could result in inaccurate results.

REFERENCES

Package insert from the OSOM Ultra Strep A Test.