Background
The ICON® SC Strep A – Direct Group A Streptococcus Antigen Test Strip is a rapid immunochromatographic assay for the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens. The test is intended for use in physician’s offices, hospitals and clinical laboratories as an aid in the clinical diagnosis of Group A Streptococcal infection.

Sample Collection and Handling
• Collect throat swab specimens following standard clinical procedures, using the swabs supplied with this kit. Throat swab specimens should be collected by healthcare professionals only.
• Swabs should be processed within 4 hours after collection, unless they are stored in a refrigerator (2-8°C). If stored in a refrigerator, swabs should be processed within 24 hours from collection.
• If a culture is required, it is recommended that two swab samples be collected. The first swab sample should be used for testing with ICON® SC Strep A as soon as possible after collection. The second swab may be stored in a liquid medium (about 200 µL) such as a Modified Stuart’s or equivalent, for up to 24 hours in the refrigerator.
• Care should be taken in collecting the throat swab specimens to avoid touching sides of the mouth and sampling inflamed or exudative areas. Presence of excess amounts of saliva or blood in the collected sample can interfere with test results.

Materials Provided
Each ICON® SC Strep A test kit contains all necessary reagents and materials for 25 tests.
• ICON® SC Strep A test devices: Contain a membrane coated with rabbit anti-Group A Streptococcus antibody for the test line and a second control antibody, and a conjugate pad impregnated with the rabbit anti-Strep A antibody-dye complex.
• Extraction Reagent A (6.5 mL): 2.0 M sodium nitrite solution.
• Extraction Reagent B (6.5 mL): 0.2 M phosphoric acid solution.
• Positive Control (1 mL): Extracted (non-infective) Group A Streptococcus antigen (equivalent to approximately 1 x 10⁸ CFU/mL) in phosphate buffered saline containing 0.1% sodium azide.
• Negative Control (1 mL): Extracted (non-infective) Group B Streptococcus antigen in phosphate buffered saline containing 0.1% sodium azide.
• Throat Swabs (25): Rayon swab with plastic shaft (use only the swabs supplied).

Materials Required (but not provided)
• Timer

Reagent Storage & Stability
• The ICON® SC Strep A test device should be stored at 2-30°C in its original sealed pouch, out of direct sunlight.
• Do not freeze.
• Kit contents are stable until the expiration date printed on the outer box.

Procedure

Materials Required (but not provided)

These instructions must be followed carefully to achieve optimal test results. Always perform the test under standardized conditions.
• If specimens, kit reagents, or ICON® SC Strep A test devices have been stored in the refrigerator, allow them to reach room temperature before use.
• Do not open the foil pouch until you are ready to perform the test.
• Several tests may be run at one time.
• To avoid contamination of reagents, do not allow the tips of the reagent bottles to come in contact with the extraction well.
• Label the device with the patient’s name or control number.
• To add Reagents A and B, hold the bottle in a vertical position above the extraction well and dispense 4 drops of each reagent.
• Place swab in to Extraction well and mix specimen with solution thoroughly by spinning the swab in one direction (Do not spin back and forth) about 5 times. Leave the swab in the Swab stand for 1-2 minutes. Spin the swab again in one direction about 5 times. Spinning back and forth, the rayon tip may get loosened.
• Slowly raise the device until it’s upright (Do not go past upright), keeping the other end of the device in contact with a flat surface. Keep upright for about 1-2 seconds. Tap device on a flat surface to ensure the liquid in the Extraction well flows into the hole.
• Immediately after tapping, slowly lower the device to the original position. Important: If specimen does not migrate in the test window within 1 minute, raise device upright again, tap once and lay flat again.
• Read the test results after 5 minutes, but not after 10 minutes.
• After testing, dispose of the ICON® SC Strep A test device and throat swab, following
proper laboratory practices. Consider any material that comes into contact with specimen to be potentially infectious.

Test Protocol

- Dispense *4 drops* of Reagent A into the Extraction well in the test device.

- Add *4 drops* of Reagent B into the Extraction well in the test device.

- Place the specimen swab on the swab stand in the Extraction well of the device. Hold the device with one hand and hold the swab with the other hand. **While pressing down on the swab**, spin the swab **in one direction** about 5 times to mix the specimen.

- Incubate 1-2 minutes with swab in well.

- Hold the device with one hand and hold the swab with the other hand. **While pressing down on the swab**, spin the swab again 5 times **in one direction**. Remove and discard the swab.

- Raise device until upright.

- Let stand 1-2 seconds. Tap device on flat surface to ensure liquid flows into hole.

- Immediately after tapping, slowly lay the device back down onto the flat surface.

- Read the test results after 5 minutes, but not after 10 minutes.

### Interpretation of Test Results

**POSITIVE:**
Two reddish-purple colored lines, both the Control line and the Test line, indicate that Group A Streptococcal antigen has been detected.

**NOTE:** The Test line may have a color shade of varying intensity (weak or strong band) depending on the concentration of antigen detected. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result. Any visible line should be read as a positive.

**NEGATIVE**
One colored line only in the Control line area, and no distinct colored line in the Test line area indicates that the specimen does not contain detectable levels of Group A Streptococcal antigen and is considered as presumptive negative. The American Academy of Pediatrics recommends that presumptive negative results be confirmed by culture.

**INVALID**
A distinct colored line in the Control line area should always appear. The test is invalid if no Control line forms in 5 minutes. In the absence of the Control line, the test should be considered invalid and should be repeated with a new device and a new swab sample.

### User Quality Control

Internal Procedural Control:
- A colored line in the Control line area is considered an internal positive procedural control. A distinct reddish-purple line will always appear in the Control area if the test procedure was performed correctly, the sample and reagent wicked properly, and the test reagents are working. If the Control line does not appear, the test is invalid and a new test should be performed. If problems
A clear background in the Test line area is considered an internal negative procedural control. If the test has been performed correctly with a negative sample and the test device is working properly, the background in the Test line area will be clear, providing a distinct negative result.

**External Quality Control:**
- Good laboratory practice recommends the use of external positive and negative controls to assure that the test reagents are working properly and that the user has performed the test correctly. If the controls do not perform as expected, review the Product Instructions to see if the test was performed correctly and repeat the test or contact Technical Marketing [(800)-877-6242] before performing patient specimens. The built-in purplish-red Control line indicates only the integrity of the test strip and proper fluid flow.
- It is recommended that the control test be performed, using the controls provided, before using a new lot or shipment of ICON® SC Strep A kits to confirm the expected Q.C. results. The frequency of additional Q.C. tests should be determined according to your laboratory’s standard Q.C. procedures. Upon confirmation of the expected results, the kit is ready for use with patient specimens.
- The Positive Control will produce a moderate positive result (two lines, one at the Test position (T) and the other at the Control position (C)) when the test has been performed correctly and the test device is functioning properly. Add 4 drops each of Reagents A and B into the extraction well. Then add one drop of thoroughly mixed Positive Control into the extraction well in a test device. Put a new swab into the extraction well and process the extraction in the same manner as you would for a patient specimen according to the Test Procedure.
- The Negative Control will yield a negative result (Control line only) when the test has been performed correctly and the test device is functioning properly. Add 4 drops each of Reagents A and B into the extraction well. Then add one drop of thoroughly mixed Negative Control into the extraction well in a test device. Put a new swab into the extraction well and process the extraction in the same manner as you would for a patient specimen according to the Test Procedure.
- In addition to the external Positive Control provided with the kit, a known live culture of *Streptococcus pyogenes* (Strep A) such as ATCC strain 19615 can be used for quality control testing. Live culture from an agar plate may be collected by swab and tested the same way as described for unknown samples in the Test Procedure. Negative Control can be used to dilute the culture organism to make a Positive Control.
- A known live culture of Group C streptococci such as ATCC strain 12388 can be used for negative quality control testing at minimum concentration of $10^6$ inactivated CFU per mL. Process the extraction in the same manner as you would for a patient specimen according to the Test Procedure.
- The Positive and Negative Controls provided with the kit do not monitor the extraction step. If the controls do not perform as expected, do not report patient results.
- The use of Positive and Negative Controls from other commercial kits has not been established with ICON® SC Strep A.

**Precautions**
- For *in vitro* diagnostic use only.
- Do not interchange materials from different product lots.
- Do not use after the expiration date indicated.
- The test kit should be used only with the swabs supplied with the kit.
- Do not interchange caps between reagents.
- Reagents A and B are slightly caustic. Avoid contact with eyes, sensitive mucous membranes, cuts, abrasions, etc. If these reagents come in contact with the skin or eyes, flush with a large volume of water.
- Do not smoke, eat or drink in areas where the specimens or kit reagents are handled.
- Wear disposable gloves while handling the kit reagents or specimens and wash hands thoroughly afterwards.
- All patient samples should be handled as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout all procedures and follow standard procedures for proper disposal of specimens.
The ICON® SC Strep A test device should remain in its original sealed pouch until ready for use. Do not use if the pouch is damaged or the seal is broken.

The control solutions contain sodium azide, which, on contact with lead or copper plumbing, may react to form explosive metal azides. Use a large volume of water to flush reagents on disposal.

Limitations

- The results obtained with this kit must be used only as an adjunct to other information available to the physician.
- This test should be used only for qualitative detection of Strep A antigen. Use of the kit for the semi-quantitative determination of Group A Strep has not been established.
- This test will not differentiate between a carrier and an infected individual.
- The ICON® SC Strep A test can detect non-viable as well as viable organisms. The test may therefore detect organisms which cannot be demonstrated in culture.
- This test is not intended as a substitute for bacterial culture testing; test results should be compared with culture identification until each laboratory establishes its own equivalences of performance. Additional follow-up testing using the culture method is recommended if the ICON® SC Strep A test result is negative and Group A Streptococcal infection is suspected. The American Academy of Pediatrics (Red Book, 1994 p. 433) recommends that cultures be performed on specimens with negative antigen detection results.
- Test specimens heavily colonized with Staphylococcus aureus (>10^10 CFU/mL) can yield false positive results.
- Proper throat swabs must be obtained for good quality test results.
- Pharyngitis can be caused by organisms other than Group A Streptococcus. This test does not provide any further information about pharyngitis other than the possibility of Strep A infection. If clinical signs and symptoms are not consistent with laboratory results, a follow-up throat culture and grouping procedure should be performed. Pharyngitis is also caused by other serological groups of Streptococcus as well as other organisms.

- A negative result may be obtained due to poor sample collection, or at the onset of the disease due to a low antigen level, below the sensitivity limit of the test. If symptoms persist or intensify, repeat testing with a fresh sample is recommended.
- Swabs transported in liquid media prior to testing may result in reduced sensitivity due to dilution of organisms.

Helpful Hints

Refer to Manufacturer’s Instructions for additional interpretation help. Technical assistance may be obtained by calling (800) 877-6242, or e-mail askpcd@beckman.com.

References

Refer to Manufacturer’s Instructions

Review and Update

A. Reviewed By: _________________________
B. Title: _______________________________
C. Review Date: _________________________

Manufactured for:

Beckman Coulter, Inc.
Brea, CA 92821 USA