

The Johns Hopkins Hospital Point-of-Care Testing Program  
**Self-Study Packet**

**Rapid Strep A**  
**Beckman Coulter ICON® SC**

**Operator Competency**

Only operators who have completed a defined training program and can demonstrate competence will be able to perform Rapid Strep A testing.

Operator competency will be assessed annually by two methods.

1. Successful performance of quality control (positive and negative controls)
2. One of the following:
  - Testing an unknown specimen
  - Having a supervisor or qualified delegate periodically observe routine work
  - Written test

**Test Order**

A physician's order, standard protocol, or order by other health professionals authorized to request laboratory tests is required for Rapid Strep A testing.

**Reagents and Storage**

The test device, reagents and controls are stable through the expiration date printed on the outer box.

1. The test device, reagents and controls are stored at 2°- 30°C (35°- 86°F).
2. The test device must remain in the original sealed pouch, out of direct sunlight, until ready for use.
3. Do not freeze.
4. Do not use test device, reagents and controls beyond the expiration date.
5. The Beckman Coulter ICON® SC Strep A test kits, reagents, and controls are to be dated when initially opened.

**Precautions**

1. Use only reagents provided in the kit.
2. The test kit should be used only with the rayon swabs supplied with the kit.
3. Do not interchange materials from different product lots.
4. Do not interchange reagent bottle caps.
5. Do not interchange external control solution caps.
6. Do not use if the original pouch is damaged or the seal is broken.
7. Reagents A and B are slightly caustic. If these reagents come in contact with the skin or eyes, flush with a large volume of water.
8. Adhere to all Standard Precautions and CDC hand washing guidelines when performing this test.

**“Date Opened” Label**

The yellow “Date Opened” Label should be affixed to the Reagent A, Reagent B and Control Solution bottles when opening for the first time. Record the date opened on the label.

### Quality Control Label

A JHMI Quality Control label should be affixed to the Rapid Strep A test kit box when it is first opened. Record the open date at the top of the QC label in the space below “Date Opened”. Also record the date when weekly external QC is performed on the label.

### Quality Control Types

#### 1. Internal Procedural Control

Internal Positive Procedural Control: A red line appears in the control region (“C”); it confirms the application of sufficient volume, the sample and reagent wicked properly, the test reagents are working and the test procedure was performed correctly.

Internal Negative Procedural Control: If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the result.

#### 2. External Quality Control

Each test kit box contains two vials of external controls: Positive Control and Negative Control.

The use of external positive and negative controls assures that the test reagents are working properly and that the user has performed the test correctly.

### Quality Control Frequency

#### 1. Internal Procedural Control:

- Evaluated and documented with each quality control and patient test.

#### 2. External Quality Control:

- When opening a new test kit box, prior to be placed into service.
- Whenever a new lot or shipment of test kits is received
- Weekly on each opened test kit box.
- Whenever two consecutive “Invalid” results are obtained, either on the same patient or on two different patients.

### Quality Control

1. Record the lot numbers and expiration dates of the test kit and controls on the Rapid Strep A QC Log Sheet, along with the date, time and operator initials.
2. Ensure test devices, reagents and controls are at room temperature before use.
3. Remove test device from sealed foil pouch and label with level of control being tested.
4. From vertically held Reagent A bottle, dispense 4 full drops into Extraction Well.  
NOTE: Do not allow the dropper tip of the reagent bottle to come in contact with the Extraction Well.
5. From vertically held Reagent B bottle, dispense 4 full drops into Extraction Well.  
NOTE: Do not allow the dropper tip of the reagent bottle to come in contact with the Extraction Well.
6. Add 1 full drop of *thoroughly mixed* control solution into Extraction Well, holding bottle vertically.
7. Place a new swab on the swab stand in the Extraction Well.

### **Quality Control (continued)**

8. 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.  
NOTE: Do not spin back and forth, the rayon tip may loosen.
9. Leave swab in the stand for 2 minutes.
10. Hold the device with one hand and hold the swab with the other hand. While pressing down on the swab, spin the swab again **in one direction** about **5** times.  
NOTE: Do not spin back and forth, the rayon tip may loosen.
11. Remove and discard the swab into a JHMI-approved biohazard waste container.
12. Slowly raise the device until it's upright, keeping the other end of the device in contact with a flat surface. (Do not go past upright.)
13. Keep upright 1-2 seconds.
14. Tap device on flat surface to ensure the liquid in the Extraction Well flows into the hole.
15. **Immediately after tapping**, slowly lower the device to the original position.  
NOTE: If specimen does not migrate in the test window within 1 minute, raise device upright again, tap once and lay flat again.
16. Set timer for 5 minutes.
17. Read result at 5 minutes. **NOTE: DO NOT READ THE RESULT AFTER 10 MINUTES.**
18. Repeat procedure on the other level of control.
19. Recap the reagent and control solution bottles and store at 2°- 30°C (35°-86°F).
20. Verify quality control results are acceptable.
21. Record results on the Rapid Strep A QC Log Sheet
22. Discard all disposables into a JHMI-approved biohazard waste container.
23. Record the date QC was performed on the JHMI QC Label affixed to the Rapid Strep A Test Kit Box.

### **Quality Control- Results Documentation Summary**

1. Record date, time, operator initials and lot numbers and expiration dates of test kit and controls on the Rapid Strep A QC Log Sheet.
2. Record results as Positive/ POS. or Negative/ NEG. Do not use (+) or( -) signs to document results.
3. Record whether the Internal Procedural Control performed correctly.
4. Place a √ mark in the QC Pass/Fail box to note whether QC passed or failed.
5. Document any QC failures and corrective actions in the Comment Section of the Rapid Step A QC Log Sheet.

### **Quality Control Failures and Corrective Actions**

If one or more of the controls fail to yield the expected results:

1. Check that the test devices, Reagent A, Reagent B, and controls have not expired.
2. Repeat test, ensuring that adequate amounts of Reagents A and B and control material are added.
3. If repeat test fails, repeat the test again using a newly opened test kit box with new test devices, new bottles of Reagents A and B and new control solutions.
4. If repeat test fails again, **STOP PATIENT TESTING AND REPORTING OF PATIENT RESULTS** until the quality control issues are resolved and the expected results are obtained and recorded.
5. Document all steps taken in the Comment Section of the Rapid Strep A QC Log Sheet.
6. Contact the POCT Program Office for assistance.

### Specimen Collection

1. Use at least 2 unique patient identifiers (neither to be the patient's room number) to verify a patient's identity when collecting samples for testing.
2. Assess patient for any recent antibiotic treatment or gargling with antiseptic mouthwash.
3. The proper specimen for Rapid Strep A testing is a throat swab specimen.
4. Collect throat swab specimens following standard clinical procedure using the swabs supplied in the kit.
5. Use a two-swab collection process.
6. Label the sterile specimen container with the swab with 2 patient identifiers.
7. Gloves must be worn during sample collection and testing (Standard Precautions).

### Patient Testing

1. Check the JHMI QC label on the test kit box or the Rapid Strep A QC Log Sheet to make sure that quality control has been performed for the week. If not, perform QC.
2. Allow test devices and reagents to reach room temperature if stored refrigerated.
3. Remove the test device from the sealed foil pouch.  
NOTE: Test should be performed immediately after opening pouch to obtain accurate results.
4. Label the test device with 2 patient identifiers.
5. From vertically held Reagent A bottle, dispense **4** full drops into Extraction Well.  
NOTE: Do not allow the dropper tip of the reagent bottle to come in contact with the Extraction Well.
6. From vertically held Reagent B bottle, dispense **4** full drops into Extraction Well.  
NOTE: Do not allow the dropper tip of the reagent bottle to come in contact with the Extraction Well.
7. Place the specimen swab on the swab stand in the Extraction Well of the device.
8. 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.  
NOTE: Do not spin back and forth, the rayon tip may loosen.
9. Leave swab in the stand for 2 minutes.
10. Hold the device with one hand and hold the swab with the other hand. While pressing down on the swab, spin the swab again **in one direction** about **5** times.  
NOTE: Do not spin back and forth, the rayon tip may loosen.
11. Remove and discard the swab into a JHMI-approved biohazard container.
12. Slowly raise the device until it's upright, keeping the other end of the device in contact with a flat surface. (Do not go past upright.)
13. Keep upright 1-2 seconds.
14. Tap device on flat surface to ensure the liquid in the Extraction Well flows into the hole.
15. **Immediately after tapping**, slowly lower the device to the original position.  
NOTE: If specimen does not migrate in the test window within 1 minute, raise device upright again, tap once and lay flat again.
16. Set timer for 5 minutes.
17. Read result at 5 minutes. **NOTE: DO NOT READ THE RESULT AFTER 10 MINUTES.**
18. Discard the used test device, swabs, and other disposables into a JHMI-approved biohazard waste container.

**Interpretation of Test Results**

The Result Window of the Test Device displays two regions:

- The control “C” line: the internal positive procedural control line that is evaluated with each test
- The region “T”: represents the specimen being tested

Result area background color: the internal negative procedural control that should be white to light pink in color and not interfere with the ability to read the test.

Interpretation Chart:

<b>“C” Region</b>	<b>“T” Region</b>	<b>Other</b>	<b>Test Result</b>
Line Present	<b>NO</b> Line		Negative
Line Present	Line Present		Positive
<b>NO</b> Line	Line Present or <b>NO</b> Line		Invalid
		Result Window has red/dark background, making it difficult to read the result	Invalid

**Documentation of Patient Results**

1. Record patient results on the Beckman Coulter ICON® SC Strep A Patient Results Log.
2. Document the performance results of the Internal Procedural Control with each patient’s result.
3. Record the patient’s result, along with the date, time and operator initials on the chart, EPR or flow sheet.
4. When documenting the results in the patient’s chart, place a check mark (√) or “QC okay” next to the result to indicate that the Internal Procedural Control reacted correctly and that external Quality Control has successfully been run within one week.
5. Results are to be recorded as Positive/ POS, Negative/NEG or Invalid; symbols are not to be used.
6. Results should be noted as Point-of-Care Testing results to distinguish them from laboratory results.

**Results Follow-up**

1. A negative Rapid Strep A test result should be confirmed by a throat culture sent to the Lab.
2. If clinical signs and symptoms are not consistent with the Rapid Strep A test result, a follow-up throat culture and grouping procedure should be performed.

### **Limitations and Interferences**

1. Proper throat swabs must be obtained for good quality test results.
2. The ICON® SC Strep A test can detect non-viable as well as viable Group A Streptococcus bacteria. The test may therefore detect organisms which cannot be demonstrated in culture.
3. A negative result obtained from this kit should be confirmed by culture. 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.
4. Test specimens heavily colonized with Staphylococcus aureus ( $10^{10}$  CFU/mL) can yield false positive results.
5. Excess blood, saliva, or mucus on the swab specimen may interfere with test results. Avoid touching the tongue, cheeks, and teeth and any bleeding areas of the mouth with the swab when collecting specimens.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
7. The ICON® SC Strep A is for *in vitro* diagnostic use. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
8. This test will not differentiate between a carrier and an infected individual.
9. Swabs transported in liquid media prior to testing may result in reduced sensitivity due to dilution of organisms.
10. 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.
11. If clinical signs and symptoms are not consistent with laboratory results, a follow-up throat culture and grouping procedure should be performed.

### **Proficiency Testing**

1. Proficiency testing samples, supplied by an outside organization (CAP), will be performed 3 times a year using the ICON® SC Strep A test kit.
2. The performance of proficiency testing is to be rotated among trained operators.
3. Proficiency testing assesses the accuracy and reliability of test results.
4. A score of  $\geq 80\%$  is considered acceptable performance.
5. Unacceptable performance required documented remedial action.