



The Johns Hopkins Medical Institutions
The Johns Hopkins Hospital Point-of-Care Testing Program
Rapid Strep A Testing (ICON® SC Strep A)
Skills Checklist

Instructions: Instructor will supervise performance of skills by employee. All steps must be performed as indicated in order for competency to be determined adequate. Instructor will sign the form when all steps are performed correctly. The completed form is to be faxed to the Johns Hopkins Hospital Point-of-Care Testing Program Office, 410-502-1913. The original checklist is to be placed in the employee's personnel file.

REQUIRED PERFORMANCE SKILLS
I. PRE-ANALYTICAL
A. Specimen Requirements:
1. States acceptable specimen type (throat swabs specimens only)
B. Patient Assessment:
1. Assesses patient for any recent antibiotic treatment or gargling with antiseptic mouthwash.
C. Specimen Collection:
1. Describes/demonstrates proper swab collection from tonsils / back of throat <ol style="list-style-type: none">Assembles supplies/equipmentChecks expiration dates of Rapid Strep A kit components/QC performed as requiredGreets patient professionallyIdentifies patient using two identifiers (name/date of birth)Washes hands; dons gloves.Explains procedure to patient and positions patient comfortably.Instructs patient to tilt head back and open mouth as wide as possible.Uses a two-swab sample collection process<ol style="list-style-type: none">Depresses tongue with tongue bladeIntroduces first swab to back of throat/tonsil area without touching walls of buccal cavityRubs swab back and forth over back of throat, around tonsils and over inflamed /pus discharging areas.<ol style="list-style-type: none">Removes swab without touching tongue, cheeks, teeth or gums; places swab in sterile tube.Labels tube with two patient identifiersRepeats process using the second swab; places swab in a tube transport system (modified Stuart's medium).Labels tube with two patient identifiers; completes appropriate POE order/Pathology Requisition.
D. Storage and Stability Requirements:
1. States Rapid Strep A Kit storage and handling requirements <ol style="list-style-type: none">Store at 2-30°C (35-86°F)Keep Test Device in original sealed pouch, out of direct sunlight until ready to useDo not freeze.Test Device and Extraction Reagents are stable through the expiration date printed on boxDo not use beyond expiration dateDate kit box and Reagent A and B bottles when opened.Date kit box when weekly external QC is performedDo not interchange materials from different product lots.
2. States Control storage and handling requirements <ol style="list-style-type: none">Store at 2-30°C (35-86°F)Date control bottles when opened.Do not use beyond expiration date.
II. ANALYTICAL
A. Quality Control Requirements:
1. Must follow the manufacturer's instructions.
2. States Internal Procedural Control performance frequency: <ol style="list-style-type: none">Each QC testEach patient test
3. States number and describes Internal Procedural Controls <ol style="list-style-type: none">The reddish-purple Control Line must appear.The background must be clear



<p>A. Quality Control Requirements (continued):</p> <ol style="list-style-type: none">4. States number of External controls to be used.<ol style="list-style-type: none">a. Positive controlb. Negative control5. States External QC performance frequency<ol style="list-style-type: none">a. When a new kit box is openedb. Weeklyc. When a new lot number/shipment is receivedd. When two consecutive “Invalid” results are obtained
<p>B. Quality Control Procedure:</p> <ol style="list-style-type: none">1. Dates test kit box, extraction reagent bottles, and controls when opened2. Affixes a JHMI Quality Control Label to the newly opened test kit box3. Checks expiration dates of test kit, extraction reagent bottles and controls.4. Allows test kit components to reach room temperature if stored refrigerated5. Properly records date, operator initials, lot numbers and expiration dates of test devices, extraction reagents and controls6. Removes test device from sealed foil pouch and labels with level of control being tested.7. From vertically held Reagent A bottle, dispenses 4 full drops into Extraction Well.8. From vertically held Reagent B bottle, dispenses 4 full drops into Extraction Well.9. Adds 1 full drop of <i>thoroughly mixed</i> control solution into Extraction Well, holding bottle vertically.10. Places a new swab on the swab stand in the Extraction Well11. While pressing down on the swab, spins the swab in one direction about 5 times to mix.12. Leaves swab in the stand for 2 minutes.13. While pressing down on the swab, spins the swab again in one direction about 5 times.14. Removes and discards the swab into a JHMI-approved biohazard container.15. Slowly raises the device until it’s upright, keeping the other end of device in contact with flat surface.16. Does not go past upright.17. Lets stand 1-2 seconds.18. Taps device on flat surface to ensure liquid in Extraction Well flows into hole.19. Immediately after tapping, slowly lowers the device to original position.20. Sets timer for 5 minutes21. Reads result at 5minutes but not after 10 minutes.22. Discards all disposables into a JHMI-approved biohazard container23. Properly records results on the Rapid Strep A QC Log Sheet.24. Repeats procedure on the other level of control solution.25. Verifies quality control results are acceptable.
<p>C. Quality Control Failures/ Corrective Action:</p> <ol style="list-style-type: none">1. Verifies that all Quality Control results are within acceptable limits.2. Repeats control when QC result falls outside of the acceptable range.3. Records the repeated QC result on the Rapid Strep A QC Log Sheet.4. Documents the corrective action(s) taken in the Comment Section on the Rapid Strep A QC Log Sheet.5. Follows the troubleshooting guidelines in test procedure and documents all failed QC results and corrective actions on the Rapid Strep A QC Log Sheet.6. Suspends patient testing if Quality Control continues to fail.7. Contacts the Point-of-Care Testing Program Office for assistance in resolving the failed quality control problems.
<p>D. Patient Testing:</p> <ol style="list-style-type: none">1. Checks the expiration dates of the test devices, extraction reagents and controls2. Checks the JHMI QC Label affixed to the test kit box to verify that quality control has been performed on the box within the previous week.3. If QC has not been performed, stops and performs QC on the test kit box. Records QC results on the Rapid Strep A QC Log Sheet.4. Allows test kit components to reach room temperature if stored refrigerated.5. Removes test device from sealed foil pouch and labels device with 2 patient identifiers.



D. Patient Testing (continued):

6. From vertically held Reagent A bottle, dispenses **4** full drops into Extraction Well.
7. From vertically held Reagent B bottle, dispenses **4** full drops into Extraction Well.
8. Places specimen swab on the swab stand in the Extraction Well
9. While pressing down on the swab, spins the swab **in one direction** about **5** times to mix.
10. Leaves swab in the stand for 2 minutes.
11. While pressing down on the swab, spins the swab again **in one direction** about **5** times.
12. Removes and discards the swab into a JHMI-approved biohazard container.
13. Slowly raises the device until it's upright, keeping the other end of device in contact with flat surface.
14. Does not go past upright.
15. Lets stand 1-2 seconds.
16. Taps device on flat surface to ensure liquid in Extraction Well flows into hole.
17. Immediately after tapping, slowly lowers the device to original position.
18. Sets timer for 5 minutes
19. Reads result at 5 minutes but not after 10 minutes.
20. Correctly interprets test result.
21. Discards all disposables into a JHMI-approved biohazard container
22. Sends the second swab for culture when the Rapid Strep A test result is negative.

E. Interpretation of Results:

1. Reads and clinically interprets the test results as follows:
 - a. Positive: Control Line- present Test Line- present Positive for Strep A
 - b. Negative: Control Line- present Test Line- absent Negative for Strep A or below detection level of assay; Send culture to lab
 - c. Invalid: Control Line- absent Test Line- present/absent
 - Invalid: Background does not clear, making it difficult to read the result Cannot be interpreted; Repeat test with new swab; Send culture to lab if still invalid

III. POST-ANALYTICAL

A. Documentation of Patient Results:

1. Records patient results on the Beckman Coulter ICON® SC Strep A Patient Results Log.
2. Documents the performance results of the Internal Procedural Control with each patient's result.
3. Records the test results in the patient's permanent record with the date, time and operator's initials and a checkmark (✓) or statement stating "QC okay" to note that the Internal Procedural Control performed appropriately and that acceptable external quality control was performed on that test kit box within the previous week.
4. Results are to be recorded as Positive, POS, Negative, NEG or Invalid; symbols are not to be used.
5. Notes results as a Point-of-Care test in order to differentiate these results from the central laboratory results.

B. Results Follow-up

1. A negative ICON® SC Step 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.

C. Limitations of Test:

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 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, teeth, and any bleeding areas of the mouth with the swab when collecting specimens.
6. 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.
7. Swab transported in liquid media prior to testing may result in reduced sensitivity due to dilution of organisms.



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C. Limitations of Test (continued):

8. 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.
9. This test does not differentiate between a carrier and an infected individual.
10. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

D. Training

1. Initial training will include:
 - a. Educator or Unit-base Training
 - b. Passing a written test
 - c. QC performance observed by Educator or Unit-based Trainer
 - d. Documentation on Rapid Strep A Skills Checklist

E. Competency Assessment

1. Ongoing competency will include:
 - a. QC performed and passed once a year
 - b. QC documented on single page competency sheet and filed in developmental resume
 - c. Written test once a year

F. Proficiency Testing

1. Proficiency testing samples, supplied by an outside organization, 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 requires documented remedial action.



Name: _____ Employee ID#: _____

Date: _____ Site: _____

Written Test Score: _____ O Pass O Fail QC Practical: O Pass O Fail

IV. QUALITY CONTROL RESULTS DOCUMENTATION

Test Kit		Positive Control (Acceptable Result: <input type="checkbox"/> Positive/POS)				Negative Control (Acceptable Result: Negative/NEG)				QC	
Lot #	Exp.Date	Lot #	Exp. Date	Result	Internal QC okay?	Lot #	Exp. Date	Result	Internal QC okay?	Pass (✓)	Fail (✓)

All of my questions have been addressed and I feel confident in performing the test.

Employee Signature: _____ Title: _____ Date: _____

The employee has performed the test satisfactorily according to the standard operating procedure>

Instructor Signature: _____ Title: _____ Date: _____