

Group A Strep Testing using Beckman Coulter ICON® SC Strep A Rapid Antigen Test

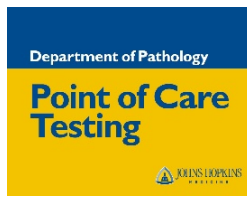
Fast Facts

- Reagent Requirements

ICON® SC Strep A Rapid Antigen Test Kit	
Storage Temperature	2° - 30°C
Stability	Manufacturer's expiration date.
Handling Requirements	<ul style="list-style-type: none"> - Record "<i>Open Date</i>" on each box once opened. - Consumables do not need to be dated <i>if they remain in the test kit at all times</i>. - Once one kit supply is depleted, all remaining supplies must be discarded. - <i>Do not</i> use beyond manufacturer's expiration date.
Handling Precautions	<ul style="list-style-type: none"> - Test Devices must remain in original sealed pouch, out of direct sunlight, until ready for use. - Reagents A and B are slightly caustic, and require flushing with large volumes of water if in contact with skin or eyes.

- Testing Procedural Notes

- QC must be performed at least weekly, and when a new Strep A Rapid Antigen Test Kit is opened.
 - Results must be recorded on the QC Log as Pos/Positive or Neg/Negative.
 - *Use of (+) and (-) signs are never acceptable in any circumstance.*
 - Internal Positive and Negative Procedural Controls must be evaluated for all testing.
 - Positive Control is acceptable when a red line is present in the test device "C" region.
 - Negative Control is acceptable when background color does not interfere with result interpretation.
 - Results are Invalid and testing must be repeated if the above is not true.
- Use only the Collection Swabs supplied with the ICON® SC Strep A Rapid Antigen Test Kit.
 - Collection of two swabs from each patient is recommended; in case of a negative result, it is recommended to send to Microbiology for culture.
 - Take care to avoid touching the tongue, cheeks, teeth, or gums.
 - The sterile tube a collected swab is placed in must be labeled with at least two unique patient identifiers, neither of which may be the room number.
- Testing immediately following collection is recommended; storage at room temperature up to 4 hours is acceptable if necessary, however.
- Test Devices must be labeled with QC or patient information prior to starting all tests.
 - Dispense 4 drops of Reagent A, then 4 drops of Reagent B in the Extraction Well.
 - For QC, add 1 drop of control solution then a sterile swab and rotate 5 times in one direction.
 - For patient testing, place the collection swab and rotate 5 times in one direction.
 - Incubate for at least 1 minute, but no longer than 2 minutes, then spin the swab 5 times and discard in a JHMI-approved biohazard waste container.
 - Bring Test Device upright for 1-2 seconds, tap on the testing surface and lower to horizontal.
 - Read results immediately at 5 minutes, and no longer than 10 minutes.
- For a full list of limitations and common interferences affecting this test, refer to POCTW010.
 - Recent antibiotic treatment or gargling with an antiseptic mouthwash may interfere with this test.



- **Operator Competency**

- *Initial Training and Competency*: Must be completed with a POCT Office-approved Super User/Trainer.
 - MyLearning module and quiz, QC, and Initial Training and Competency form must be completed.
- *Annual Competency*: Must be completed by all testing personnel, including Super Users/Trainers.
 - Both levels of QC must be completed and documented successfully at least once.
 - Applicable MyLearning module and quiz completed with a Passing score.

- **Troubleshooting Failed QC Results**

- Confirm the ICON® SC Strep A Rapid Antigen Test Kit is within manufacturer’s expiration date and has been properly stored.
 - If individual components have been separated from the kit, confirm lots are from the same Test Kit and none of the reagents are expired.
 - If acceptable, ensuring proper technique, repeat testing using the same materials.
 - If this repeat fails, open a new Strep A Rapid Antigen Test Kit and repeat testing.
 - If this repeat fails, cease testing immediately and contact the POCT Office (Resources).
 - Document all failures and Corrective Action steps on the QC log.

- **Resources**

- POCT Office available 24/7 for any additional assistance that may be needed.
 - Office Hours: Monday-Friday 7:30-15:30 (CMSC SB207)
 - POCT Office General Phone Line: 5-2645
 - Email POCTGroup@exchange.johnshopkins.edu
 - After Hours use CORUS: Pathology Staff – POCT Consult (covered 24/7 for critical needs)