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

Fast Facts

**Reagent Requirements**

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<th>ICON® SC Strep A Rapid Antigen Test Kit</th>
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**Handling Requirements**

- Record “Open Date” on each box once opened.
- Consumables do not need to be dated if they remain in the test kit at all times.
- Once one kit supply is depleted, all remaining supplies must be discarded.
- Do not use beyond manufacturer’s expiration date.

**Handling Precautions**

- 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**

1. 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.
2. 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.
3. Testing immediately following collection is recommended; storage at room temperature up to 4 hours is acceptable if necessary, however.
4. 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.
5. 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**
  o *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.
  o *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**
  o 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**
  o 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)