AFFILIATED PHYSICIANS
ON-SITE VACCINATION AND WELLNESS SERVICES

Policy: P012 – **Strep A Rapid Testing**

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Strep throat is a bacterial infection of the throat and tonsils caused by Group A Streptococcal that generally causes throat irritation and swelling. Group B Strep (GBS) can cause septicemia, bone or joint infections, Meningitis, Pneumonia, or skin and soft-tissue infections.

I. **Purpose:** Conduct rapid test for symptomatic persons suspected of being infected with the Group A Streptococcal bacterium. Specimen is collected via upper respiratory swab and results within 5 minutes.

II. Policy:

a. McKesson Consult Strep A tests to be used
b. Test dipstick, reagents, and/or controls should be at room temperature (59-86 degrees F) prior to testing
c. A negative result from this kit should be confirmed by culture, therefore, if negative – patient is to be referred to primary care physician
d. A positive result from this kit should elicit follow up by patient's primary care physician for further treatment. **Clinician completing the rapid test that results as POSITIVE will be required to communicate with primary physician to alert of the result**
e. Affiliated Physician's Nasopharyngeal swabbing protocol includes proper use and management of personal protective equipment (PPE) - **[refer to PPE Policy and Procedure]**
f. Affiliated Physicians will confirm appropriate supplies are readily available to staff members working in accordance with strep testing events
g. For proper infection control practices all employees working strep testing events will adhere to Policy P001 - Hand Hygiene – **[refer to Hand Hygiene Policy and Procedure]**
h. Testing strategies, including clinical criteria for considering testing and recommended specimen type, are the same for children and adults according to the CDC
i. Expiration dates to be monitored and testing supplies to be discarded if past date
j. All specimen should be handled as if they are capable of transmitting disease
k. Tests are individually packaged and designed for single patient use
l. The McKesson Consult Strep A Tests should remain in its original sealed pouch until ready for use
m. Do not use the test cassette if the seal is broken or the pouch is damaged
n. Follow standard procedures for proper disposal of specimens and test cassettes

III. Procedure:

a. Quality Control Checks

i. External Quality Control - It is recommended that a positive and negative external control be run with each **new kit** and as deemed necessary
    1. Add 4 full drops of **Reagent 1**, and 4 full drops of **Reagent 2** into an extraction test tube. Tap the bottom of the tube gently to mix the liquid
    2. Add 1 full drop of the positive or negative control solution in the tube
    3. Place a clean swab into the tube. Rotate the swab 10 times in the tube. Leave the swab in the tube for 1 minute. Then press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab
    4. With the arrows pointing down, place the test dipstick into the solution and start the timer. The liquid should be at or just below the max line on the test dipstick
    5. Leave the dipstick in the tube and read the result at 5 minutes
    6. **IMPORTANT: The test is invalid after 10 minutes**

ii. Internal Quality Control – with each test performed
    1. Each McKesson Consult Strep A Test has built-in controls
    2. Control line at C position can be considered internal positive procedural control [confirms sufficient specimen volume and correct procedural technique]
    3. Red **Control line** (C) should always appear IF the test has been performed correctly
    4. IF the red Control line does not appear and remains clear – indicates a negative control with insufficient specimen volume or incorrect procedure

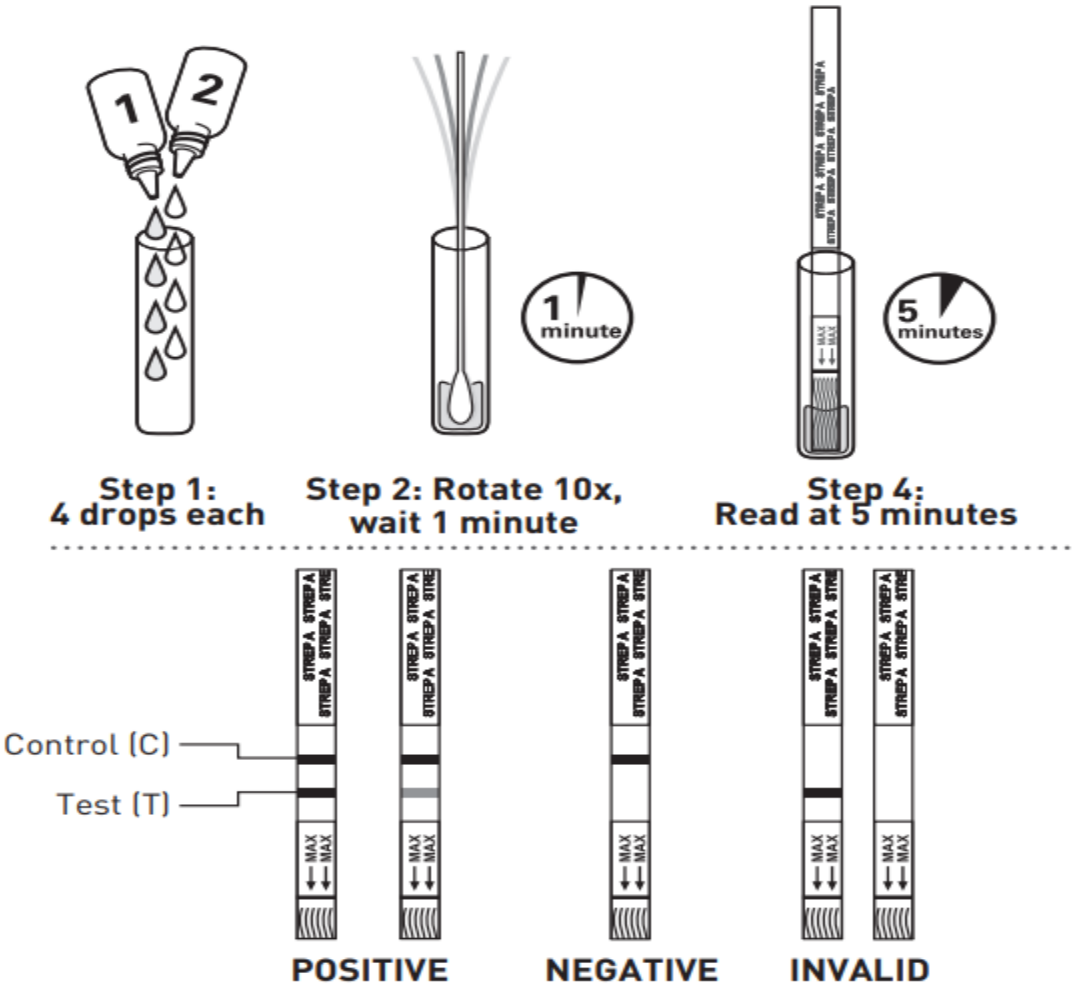
b. Medical personnel (RN, LPN, MA) to be identified for specimen collection
c. Test procedure must be followed to obtain accurate and reproducible results
d. Several test may be run at one time
e. Label the device with the patient identifier if multiple tests are being conducted
f. Test device must be placed on a level surface
g. Clinical Laboratory Improvement Amendments (CLIA) waived
h. Healthcare provider required to don PPE
    i. Surgical mask – acceptable during non-pandemic infectious phenomenon
    ii. N95 or equivalent required during pandemic infectious disease exposure potential
    iii. Gloves – nitrile preferred
    iv. Eye Protection – goggles or shield. Prescription eyeglasses are not acceptable forms of eye protection
    v. Gown
    vi. Hair net – available but not mandatory
i. Gather supplies
    i. McKesson Consult Strep A Test Kit item

ii. Dipstick canister [initial open date needs to be recorded on the canister]
    1. From initial open date – the remaining dipsticks are good for 12 months
iii. 1 test tube
iv. 1 sterile swab
v. Reagent Bottle #1
vi. Reagent Bottle #2
vii. Disposable barrier
viii. Tongue depressor
ix. Work station – test tube holder
x. Prepare smartphone timer

j. Pre-swab
    i. Verify with patient – Name, DOB, and symptoms
    ii. Obtain Vital Signs [heart rate, respirations, oxygen saturation level, pain level, blood pressure, temperature]
    iii. Provide brief overview of specimen collection process
    iv. Prepare barrier with supplies **[see supplies list]**

k. Swab Process – Adult and Pediatric
    i. Patient to sit comfortably with feet planted flat on floor and head tilted back at a 70-degree angle
    ii. Insert tip of swab via mouth, rubbing both tonsils as well as the back wall of the mouth (posterior pharynx). Important to avoid contact with the other structures inside the mouth such as tongue or cheeks. Use a tongue depressor to assist with this proper swabbing process

l. Testing Procedure: **[see diagram below]**
    i. Add 4 drops of Reagent 1 to an extraction test tube. This Reagent is RED
    ii. Add 4 drops of Reagent 2 to the same extraction test tube. This Reagent is colorless
    iii. The combination of these 2 Reagents changes the color of the solution to pale yellow
    iv. Tap the bottom of the tube gently to mix the liquid
    v. Immediately add the throat swab into the tube of pale yellow solution
    vi. Rotate the swab vigorously 10 times in the tube and leave in the tube for 1 minute
    vii. Press the swab against the wall of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid is left in the tube and discard swab
    viii. Remove a test dipstick from the canister and cover immediately - and place a single dipstick in the test tube with arrows pointing down and begin timing
    ix. The liquid should be at or just below the max line the test dipstick
    x. Leave the dipstick in the test tube for 5 minutes
    xi. Read result



m. Results: **[see Interpretation of Results above]**

i. Positive with Strep Test – 2 distinct red lines appear. 1 in the Control region (C) and another line should be in the test region (T). A positive result indicates that Strep A was detected in the sample

ii. If positive – clinician is to communicate with patient's primary care physician. If no PCP identified – patient will be responsible to follow up with a care provider within 24-48 hours

iii. If positive or negative, patient is to follow up with primary care physician for further assessment

iv. Invalid if Control line does not appear and should be repeated – with patient's consent

IV. Resources:

a. https://imgcdn.mckesson.com/CumulusWeb/Click_and_learn/4999_insert_2018-09.pdf

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