True or False (use “T” for true and “F” for false):

_____ 1. The presence of excess amounts of blood or saliva in the collected specimen can interfere with test results.

_____ 2. The performance of the internal procedural controls is documented with each patient and quality control result.

_____ 3. Negative results can occur from inadequate specimen collection or antigen level below the detection limit of the test.

_____ 4. An Extraction Reagent bottle can be used with a Test Device from a different kit lot number.

_____ 5. Test specimens heavily colonized with *Staphylococcus aureus* can yield false positive results.

_____ 6. The ICON® SC Strep A Rapid Test can detect non-viable and viable Strep A organisms; therefore the test may detect organisms which cannot be demonstrated in culture.

_____ 7. The ICON® SC Strep A Test Device should be stored at 2-30° C in its original sealed pouch, out of direct sunlight.

_____ 8. The test results are read after 10 minutes, but not after 15 minutes.

_____ 9. Three (3) drops of Reagent A and three (3) drops of Reagent B are added to Extraction Well of the Test Device.

_____ 10. All negative ICON® SC Rapid Strep A results are to be confirmed by culture.

_____ 11. The use of external positive and negative controls assure that the test reagents are working properly and the user has performed the test correctly.

_____ 12. Patient results can be reported when the internal procedural controls have not worked properly or when the external quality controls have failed.

_____ 13. The date when external quality control is successfully performed is recorded on the JHMI QC Label affixed to the test kit box.
Multiple Choice (circle all answers that apply)

1. Specimens for the ICON® SC Strep A test should be collected with:
   a. A calcium alginate swab
   b. A cotton-tipped swab
   c. A rayon swab supplied with the kit
   d. A Culturette swab with modified Stuart’s transport media
   e. All of the above

2. The operator is responsible for:
   a. Proper storage of test kit and controls
   b. Proper documentation of QC and remedial actions for failed QC.
   c. Proper specimen collection
   d. Adherence to test procedure to achieve optimal test results.
   e. Documentation of internal procedural control performance with each patient and QC result.
   f. All of the above

3. Specimens for the ICON® SC Strep A test are collected from:
   a. The tonsils
   b. The tongue and cheek surfaces
   c. The back of the throat
   d. Saliva from the gums and teeth
   e. All of the above

4. Two levels of external quality control are performed on this test kit:
   a. Monthly
   b. When a new test kit box is opened
   c. Weekly on each opened box
   d. All of the above
   e. None of the above

5. The internal procedural controls for the ICON® SC Strep A test include:
   a. A reddish-purple Test Line that appears
   b. The Extraction Reagent changes color
   c. The background clears on the Test Device
   d. A reddish-purple Control Line that appears
   e. All of the above

6. Which of the following is NOT a correct interpretation of the Rapid Strep A test results?
   a. Negative result – a reddish-purple Control Line but no reddish-purple Test Line
   b. Invalid result – no reddish-purple Control Line and a reddish-purple Test Line
   c. Positive result – a reddish-purple Control Line and two reddish-purple Test Lines
   d. Positive result – a reddish-purple Control Line and a reddish-purple Test Line
   e. Invalid result – a reddish-purple Control Line and dense background color