

# Quality Assurance In Serology

1. **Validation of Procedure and Reagents**
  - a. Must have a process for verifying appropriate performance of procedure.
  - b. Must have a process to verify that reagents will react in a positive manner when the substance being tested for is present.
  - c. Must have a process to verify that the reagents will NOT react in the absence of the substance being tested for.
2. **Procedure**
  - a. The kits are tested with known positive and negative controls.
  - b. A positive control contains the substance being tested for and must give a positive reaction when tested according to the manufacturers directions.
  - c. A negative control DOES NOT contain the substance being tested for and must give a negative reaction when tested according to the manufacturers directions.
  - d. The interpretation of the test is based on comparing the positive and negative control results with the patient results. ALWAYS LOOK AT YOUR CONTROL RESULTS FIRST so you can recognize and interpret your patient results properly.
  - e. The control solutions may be provided by the manufacturer, this is the preferred method since the manufacturer becomes responsible for the validity of the substances provided as controls
  - f. The control solutions may be created by the institution as long as the appropriate published guidelines are followed.
3. **Process**
  - a. Procedure will vary depending upon type of kit being used.
  - b. Kits that utilize “icons”, “test pads”, or other self-contained reagents usually have built in controls either positive or positive and negative.
  - c. Kits with *built in controls* usually require that prior to putting a new lot number into use you must “sacrifice” two of the items to run a known positive and known negative control.
    - 1) Expensive but necessary.
    - 2) Only done once per kit.
  - d. Kits *using particulate reagents* (latex, red blood cells, etc.) must be tested each time the kit is used.
    - 1) Positive and negative control reagents are provided in the kit.
    - 2) Run each time the kit is utilized.
    - 3) Critical to record the results along with patient results.
    - 4) Failure to run controls may lead to erroneous interpretation of the test.
4. **Quality Assurance - Problem Solving**
  - a. If the controls give the expected results the patient results are valid.
    - i. If repeat testing gives valid results this points to a technical error.
    - ii. The employee MUST review their process to determine where it went wrong.
    - iii. A written report should be submitted which documents the error, allows the employee to reflect on their work routine to determine what went wrong which caused the error and allow the employee to document what changes they will make to their work routine to prevent this error from happening again.

- b. If the positive control gives a negative result AND/OR the negative control gives a positive result the test is invalid.
  - c. If the expected results of the test are INVALID.
    - i. Record the results obtained.
    - ii. Repeat the test, if the controls give expected results report out the test.
    - iii. If the results are still invalid use another kit.
      - (1) if the new kit yields valid results - report out
      - (2) if the new kit yields invalid results consult with your supervisor.
  - d. When invalid control results are obtained upon repeat testing there must be a process in place to report the problem to the manufacturer.
    - i. The kits are very expensive and a free replacement should be offered.
    - ii. Other labs using the same kit must be notified by the manufacturer so corrective action, ie kit replacement, can be done.
5. **Preventing Errors**
- a. READ THE PROCEDURE CAREFULLY, word by word, step by step. Most errors occur because the individual does not read the procedure carefully enough.
  - b. If, after reading the instructions thoroughly and carefully, you are uncertain as to how to proceed ASK APPROPRIATE QUESTIONS. Point out the item to your instructor and ask for clarification.
  - c. FILL IN EVERY BLANK REQUIRED. Many “errors of omission” occur because the individual performing the test does not review the recording results form carefully.
    - i. Patient name must be recorded last name first.
    - ii. If uncertain as to the ID number of the patient ASK.
    - iii. Every test performed must be recorded somewhere USING THE APPROPRIATE UNITS, this includes controls, patient results, and standards, if utilized.
    - iv. If you are uncertain as to the completeness of your recording results sheet ask your instructor BEFORE YOU THROW ANYTHING AWAY.
    - v. In the lab world “not recorded = not done” and someone would have to repeat your work.
6. **Written Records**
- a. All records must be written in indelible INK, no pencil or erasable ink allowed.
  - b. White out or obliterating incorrect entries is NOT allowed for any reason, this is considered *falsification of the patient record*.
  - c. The correct method for correcting a patient record is as follows:
    - i. Draw a single line through the incorrect entry.
    - ii. Write the corrected entry directly above or to the side of the incorrect entry.
    - iii. Write your initials and the date next to the corrected entry.