



Instructions for Performing External Control Testing

1. Obtain the quality control (QC) material. Check the expiration date and check that the material has been stored and handled according to the current manufacturer's requirements and instructions.
2. Record the following on the QC log: initials of the person performing the test, test date, test name, test lot number, QC test material lot number, and QC test expiration date.
3. Test the QC material following the current manufacturer's instructions and record the results on the QC Log.
4. If the results are acceptable according to the current manufacturer's instructions, then the QC passes, and the patient's results can be reported.
5. If controls do not give the expected results, then the patient's results should not be reported until the problem is identified and corrected.
 - ✓ Check to see if the instructions in the current manufacturer's instructions were followed correctly.
 - ✓ Look for possible sources of error such as outdated reagents or test devices.
 - ✓ Check to see if reagents were stored correctly.
 - ✓ Make sure controls or reagents were not cross-contaminated by accidentally switching caps on kit or control vials.
 - ✓ Follow the troubleshooting steps in the current manufacturer's instructions or site specific procedure.
 - ✓ For additional assistance, contact the manufacturer, technical representative, or the person who directs or supervises the testing.
6. Once a problem has been identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient samples, and report the results.

Quality Control Log – Instructions

Quality Control Log – Qualitative Test

1. Record the Facility Information on the top of the form.
2. Enter the initials of the person performing the QC, date of QC, Test Name, Test lot number and expiration date.
3. Record the QC material lot number, expiration date, positive and negative control results.
4. If the results are not acceptable, QC fails. Troubleshoot (check expiration dates, storage condition etc.), retest the QC and document the corrective action taken.
5. The QC results should be reviewed by another person for verification. The reviewer will initial and date the form.

Quality Control Log – Quantitative Test

1. Record the Facility Information on the top of the form.
2. Enter the initials of the person performing the QC, date of QC, Test Name, Test lot number and expiration date.
3. Record the QC material lot number, expiration date, positive and negative control results.
4. If the results are not acceptable, QC fails. Troubleshoot (check expiration dates, storage condition etc.), retest the QC and document the corrective action taken.
5. The QC results should be reviewed by another person for verification. The reviewer will initial and date the form.

Note: Qualitative tests are interpreted as positive, negative; reactive, non-reactive; or invalid. Quantitative tests give a number result that corresponds to the amount of substance being measured, are reported in specific measurement units, and have an expected range.

This job aid is a component of the free, on-demand CDC training course “Ready? Set? Test!”
Find the course at <https://www.cdc.gov/labtraining>.