FAQ and Revised Recommendation for QC Testing for Rapid Test for Recent Infection

May 15, 2019

This updated document provides answers to common questions and replaces previous recommendations on QC testing for HIV rapid test for recent infection (RTRI) to make it more practical and feasible.

What are quality control (QC) specimens? QC specimens are well-characterized specimens with known HIV status. For RTRI, QC panel should include *three specimens* with the following status: *1) HIV-negative, 2) HIV-positive/recent infection, and 3) HIV-positive/long-term infection.* Plasma specimen selected for QC preparation should have clear HIV status including HIV recent or long-term status; specimens with ambiguous result should be avoided.

Purpose of QC testing: Periodic QC testing ensures that test kit reagents are performing well and are not compromised during transportation or storage. QC testing is not meant to test competency of tester but it may indirectly help them maintain their competency.

Source of QC specimens: We recommend that a country's national reference laboratory (NRL) prepare its own QC panels following the Panel Preparation SOPs advised by ILB/DGHT, CDC Atlanta. Processed plasma from rejected blood units from local blood banks can provide a valuable source of QC specimens. Specimens should be characterized with the HIV national testing algorithm and RTRI assay that is used in country. As an alternative, a QC panel is also available from Maxim Biomedical (Cat# 92002) which can be procured in the interim if in-country material is not available.

What type of specimen should be used for QC material? Both plasma specimens and dried tube specimens (DTS) can be used for RTRI QC material. Country can choose the same specimen type as used in existing QC and/or PT program. Each QC batch should be assigned with a unique lot number and each QC tube should be properly labeled indicating the QC sample ID (e.g., QC-Neg, QC-Recent, QC-Long term) and lot number (usually as date without separators; e.g. Lot 043019 indicates that lot was prepared on April 30, 2019) .

What are the suggested mechanisms of QC distribution? QC material for RTRI should be prepared in large batch by the national lab and distributed to regional/district level for further distribution to testing sites.

Who should perform QC testing and how often?

- NRL/Above-site level facilities involved in RTRI test kit distribution should perform QC testing upon reception of every new shipment of test kits; if there are more than one lot in one shipment, every lot needs to be verified with the QC panel. The new shipment/lot that failed on QC testing may require further investigation and should not be distributed to testing sites for RTRI testing service. To facilitate the tracking and troubleshooting of a problematic shipment/lot, each kit and QC panel should be labeled with received date upon receipt.
- All the testing sites that provide RTRI testing service should test the QC panel at least once a month. If there are two or more testers at a site, we recommend rotation among testers. To facilitate the tracking and troubleshooting of a problematic shipment/lot, each kit and QC panel should be labeled with received date upon receipt.
- Additionally, QC testing should be performed at any time when recommended kit storage condition is breached, such as, but not limited to high temperature, high humidity, or water damage, before testing client specimens. Repeatedly failed QC results indicate compromised kit quality. Affected test kit should be discarded immediately.

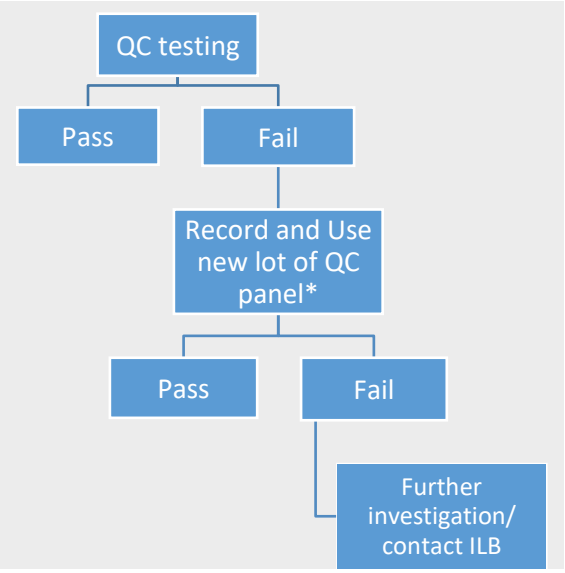
How to record and manage QC testing result?

- QC testing results should be recorded in a QC Logbook or HTS register. The following information of QC testing should be captured in the record.
  - QC panel: 1) lot number, 2) date QC panel was received, 3) QC specimen IDs, and 4) QC test results
  - Test kit: 1) lot number of RTRI test kit, 2) expiration date of RTRI test kit, and 3) date that test kit was received
  - Testing: 1) name of tester and 2) date of testing
- QC testing results should be reviewed by site/facility technical supervisor within one week of testing date. The QC testing record should be reported to NRL, aggregated and reviewed on a monthly basis. Any failed QC testing should be followed up as shown in flow diagram and reported immediately to NRL for troubleshooting.

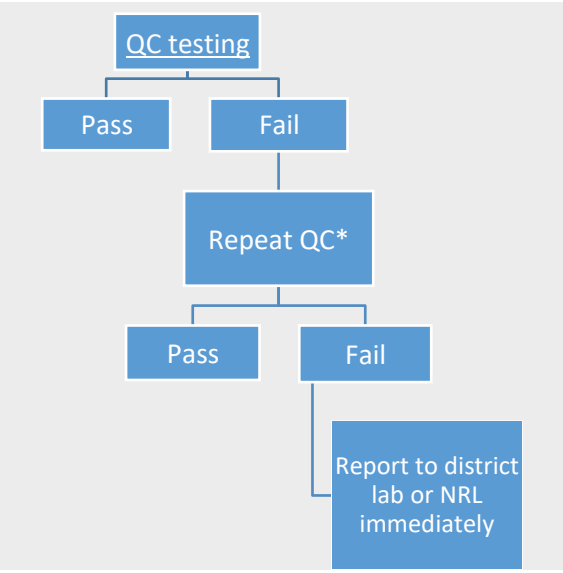
Troubleshooting of failed QC testing: NRL is responsible for analyzing QC testing results and initiating immediate response to failed QC result.

- If only individual test sites reported failed QC testing, an on-site supportive investigation should be conducted by regional/district level: the storage condition of test kit and QC panel need to be checked; QC testing should be repeated with auditor from regional/district level on site; if necessary, on-site refresher should be conducted for performing RTRI testing.
- If cluster of test sites reported failed QC testing, the NRL needs to rule out potential problem of QC panel or test kit distributed to those test sites. Central lab should retest the same lot of QC panel and test kits. If QC passes, it should conduct an on-site investigation at the distribution center (regional level/district level) that is responsible for the QC panel/test kit distribution reviewing transport and test kit storage to those test sites.
- Aggregated QC results will also be reviewed by ILB/CDC to ensure satisfactory test kit performance in the field. If troubleshooting cannot resolve the problem and indicates an issue with the kit lot, please reach out to ILB as soon as possible (Bharat Parekh, bparekh@cdc.gov; Ernest Yufenyuy, eyufenyuy@cdc.gov; or Xiaojuan Tan, xtan@cdc.gov).

QC Testing at NRL/Above-Site



QC Testing at Testing Site



** Preferably by Tester-2 if available. If QC passes when performed by Tester-2, follow up cause of failure by Tester-1 (SOP, training etc.). Results of QC, whether pass or fail, should be recorded in QC logbook or HTS register.*