

## Chembio Rapid HIV 1/2 STAT PAK Quality Control Record

### Chembio HIV 1/2 Reactive & Nonreactive Controls

With every new lot of test kits or QC, start a new log (page 2)

#### HIV 1/2 QC Instructions

1. Run controls at least once a week, if there is a new lot or new kit shipment, or if the temperature of storage falls outside of range for the kit and running buffer (outside 46 to 86°F, room temp) or QC (36-46°F, refrigerated).
2. Verify HIV kit test lot # and control reagent lot # on the form is the same on product, check expiration dates.
3. QC is stored refrigerated and does not need to be brought to room temp before testing.
4. QC reagent is clear to straw-colored. Do not use if the reagent appears cloudy or discolored.
5. Label Test Device with Control name.
6. Touch the 5 µL sample loop provided to the control reagent, allowing the opening of the sample loop to fill with the liquid. Use separate and unused specimen loops for each control.
7. Holding the sample loop vertically, touch it to the sample pad in the center of the SAMPLE (S) well of the Test Device to dispense ~5 µL of control reagent onto the sample pad.
8. Invert the running buffer bottle and hold it vertically (not at an angle) over the sample well. Add 3 drops (~ 105 µL) of buffer slowly, dropwise, into the SAMPLE (S) well.
9. Read the test result between 15 and 20 minutes after the addition of the buffer. Read test results in a well-lit area. Do not read rest results after 20 minutes.

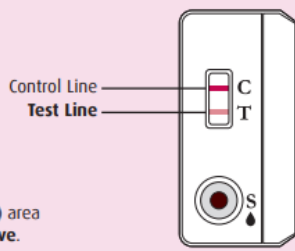
If the test results for the Nonreactive Control, HIV-1 Reactive Control or HIV-2 Reactive Control is not as expected, the test should be repeated first using a new Test Device. If it fails a second time, try new QC vials. If the HIV QC continues to not produce the expected results, contact your department's RN Manager.

#### REACTIVE RESULT

Two pink/purple lines – one in the TEST (T) area and one in the CONTROL (C) area – indicate a **reactive** result.

NOTE: The line in TEST (T) area may not look like the line in the CONTROL (C) area. One may be darker than the other.

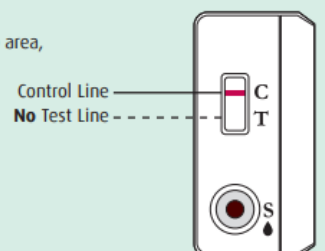
If **ANY VISIBLE LINE** appears in BOTH the TEST (T) area and in the CONTROL (C) area, the result is **reactive**.



#### NONREACTIVE RESULT

One pink/purple line in the CONTROL (C) area, with no line in the TEST (T) area is a **nonreactive** result.

A nonreactive result at 15 minutes means that HIV antibodies were not detected in the sample.



#### INVALID RESULTS

