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| Policy Type: Medical |
| Responsible Office: Director of Nursing |
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| **Rapid HIV Finger stick Testing****Policy and Procedure** |

**Purpose:** The Alere Determine Rapid finger stick Combo HIV-1/2 Ag/Ab test is used at Santa Rosa Community Health Centers in instances when patients are not able or willing to go to an outside lab (i.e. Quest, LabCorp, Sutter, etc.) for their HIV Screening test. This rapid HIV screening test is for use by trained health care professionals for the detection HIV-1/2 Ag/Ab.

**Policy:** According to National recommendations, Santa Rosa Community Health Centers screens all patients 15 years and older for HIV. Recommendations are to encourage patients to use outside (QUEST) labs and provide in-house rapid finger stick testing for HIV when outside lab use is unavailable. The test is only approved for use with blood specimens at the point of care and is considered a CLIA waived test.

**Level of Personnel:**  All MAs, trained health educators, LVNs, RNs, and clinicians, who have successfully completed initial training and maintained annual competency.

**Procedure:**

1. **Critical Elements**
2. Do not use kit beyond the expiration date.
3. Dispose of all test-devices in a proper biohazard container after testing.
4. Internal Procedural Controls must be documented with each test. A red line appearing in the control region is the internal procedural control.
5. External Quality Controls must be performed and documented per manufacturer recommendations, as follows: with each new lot, each new shipment, each new designated staff member conducting controls, if the temperature of the test storage area falls outside of 36 to 86°F, and/or if the temperature of the testing area falls outside of 59 to 86°F.
6. The device should remain in the sealed container until ready for use.
7. The test has been approved using blood only as the sample.
8. The test strip should be labeled with two patient identifiers.
9. **Supplies**
	1. Timer
	2. Disposable capillary tubes supplied with the kit
	3. Gloves
	4. Cotton ball
	5. Alcohol wipe
	6. 2.3mm depth lancet capable of producing 50 μL of blood
10. **Specimen Collection**

Specimen collected in clean dry pipette container and labeled with two patient identifiers per organizational policy.

1. **Test Procedure**
2. Open the aluminum pouch containing the Alere Determine™ HIV-1/2 Ag/Ab Combo Cards and remove a test strip by bending and tearing at the perforation.

***NOTE****: Removal of the test units should start from the right side of the Card to preserve the lot number which appears on the left side of the Card.*

1. Return the unused test units to the aluminum pouch and close the pouch with the zip lock.

***NOTE****: Store the unused cards and test units only in the aluminum pouch containing the desiccant package. Carefully close the zip lock, so that the cards are not exposed to ambient humidity during storage.*

1. Remove the protective foil cover from each Test Unit. Lay the Test Unit flat in the workstation. The test should be initiated within 2 hours after removing the protective foil cover from each test unit. Do NOT touch the sample pad with your fingers.

***NOTE****: Use of the workstation is optional. If the workstation is not used, place the test unit on a flat surface.*

1. Warm the patient’s hand and massage the finger with a downward motion before performing the finger stick.
2. Clean the patient’s finger with an alcohol wipe. Allow the finger to dry thoroughly.
3. Use a sterile lancet to puncture the skin just off the center of the finger pad and wipe away the first drop with a cotton ball.
4. Collect the second drop of blood by holding the capillary tube HORIZONTALLY and touch the tip of the capillary tube to the blood sample.

***NOTE****: Filling of the capillary is automatic- do NOT squeeze the bulb while collecting sample. Maintain this position until the flow of the sample has reached the fill line and stopped.*

1. Touch the tip of the capillary tube containing the blood sample to the sample pad (marked by the arrow symbol) and gently squeeze the bulb. Avoid air bubbles. Wait until all the blood is transferred from the capillary tube to the sample pad.

***Caution****: Do not lift the Capillary Tube from the Sample Pad before all the blood has been transferred – a bubble may form which will prevent the complete transfer of sample. If a sample won’t expel, cover the small opening at the mark on the capillary with a gloved finger. Then squeeze the bulb until the sample is fully dispensed onto the Sample Pad.*

1. When all of the blood is transferred to the Sample Pad, wait one minute to ensure the Chase Buffer does not overflow the Sample Pad.
2. Add one drop of Chase Buffer to the Sample Pad.
3. Read the test result between 20 and 30 minutes after the addition of the Chase Buffer. Do not read Test Results after 30 minutes.

***NOTE****: Discard the used pipette tips, Capillary Tube, Test Units and any other test materials into a biohazard waste container.*

1. **Interpretation of Results**

***NOTE****: When testing whole blood samples, a faint pink background may be visible on the test membrane.*

**Nonreactive (One Line – Control Line)**

A **Pink**/**Red** control line appears in the control area of the test unit, and no **Pink**/**Red** Ab or Ag line appears in the lower test area and the upper test area of the test unit, respectively. A NONREACTIVE test result means that HIV-1 or HIV-2 antibodies and HIV-1 p24 antigen were NOT detected in the specimen.

**Antibody Reactive (Two Lines - Control and Ab Line)**

A **Pink**/**Red** control line appears in the control area AND a **Pink**/**Red** Ab line must appear in the lower test area of the Test Unit. The intensity of the Ab and Control lines may vary. Any visible **Pink**/**Red** color in both the control and lower test areas, regardless of intensity, is considered REACTIVE. A Reactive test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies.

**Antigen (HIV-1 p24) Reactive (Two Lines - Control and Ag Line)**

A **Pink**/**Red** Control line appears in the control area AND a **Pink**/**Red** Ag line must appear in the upper test area of the test unit. The intensity of the Ag and control lines may vary. Any visible **Pink**/**Red** color in both the control and upper test areas, regardless of intensity, is considered REACTIVE. A reactive test result means that HIV-1 p24 antigen has been detected in the specimen. The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 p24 antigen.

***NOTE****: A test result that is PRELIMINARY POSITIVE for HIV-1 p24 antigen in the absence of reactivity for HIV-1 or HIV-2 antibodies may indicate an acute HIV-1 infection in the test subject. In this case the acute HIV-1 infection is distinguished from an established HIV-1 infection in which antibodies to HIV-1 are present.*

**Antibody Reactive and Antigen (HIV-1 p24) Reactive (Three Lines - Control, Ab and Ag Lines)**

A **Pink**/**Red** Control line appears in the Control Area AND a **Pink**/**Red** Ab line must appear in the lower test area AND a **Pink**/**Red** Ag line appears in the upper test area of the test unit. The intensity of the Ab, Ag and Control lines may vary. Any visible **Pink**/**Red** color in the control area, the lower test area and the upper test area, regardless of intensity, is considered REACTIVE. The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen.

**INVALID (No Control Line)**

If there is no **Pink**/**Red** Control line in the Control Area of the Test Unit, even if a **Pink**/**Red** line appears in the Lower Test Area or the Upper Test Area of the Test Unit, the result is INVALID and the test should be repeated. If the problem persists, contact Alere™ Technical Support.



1. **Documentation**

The patient’s results and the performance monitor results must be recorded concurrently:

* 1. In the patient’s electronic medical record as rapid HIV positive or rapid HIV negative

**AND**

* 1. On Rapid HIV Testing Quality Control/Test Result Log in lab manual if not running weekly data reports.

 All records must be retained and retrievable for 3 years.

1. **Quality Control**
2. **Internal Quality Control**

For a test result to be valid there must be a visible **Pink**/**Red** control line. During the testing procedure the colloidal selenium conjugates released from the conjugate pad will be captured by the antibodies and antigens immobilized in the control area and form a **Pink**/**Red** control line for samples that are either positive or negative*.*

***NOTE****: A* ***Pink****/****Red*** *control line may appear even when a test sample has not been applied to the test unit.*

1. **External Quality Control**

**Alere Determine™ HIV-1/2 Ag/Ab Combo Controls should be tested under the following circumstances:**

• Each new untrained operator prior to performing tests on patient specimens

• When opening a new test kit lot

• Whenever a new shipment of test kits is received

• If the temperature of the test storage area falls outside of 2 to 30°C (36 to 86°F)

• If the temperature of the testing area falls outside of 15 to 30°C (59 to 86°F)

• At periodic intervals indicated by the testing facility

Controls should be tested in the same manner as serum or plasma samples in the following Test Procedure.

Good Laboratory Practices (GLP) necessitates testing external control material along with the test samples to ensure proper performance of the test kit. The HIV Controls are used to verify proper functioning of the test and the operator’s ability to properly perform the test and to interpret the results.

Each kit control box contains four vials as follows: one red-capped HIV-1 reactive control vial, one green-capped HIV-2 reactive control vial, one lavender-capped HIV-1 p24 antigen control vial, and one white-capped non-reactive control vial.

**External QC Procedure**

1. External control material stored at refrigerated temperatures must be brought to room temperature (15 to 30°C; 59 to 86°F) prior to testing.
2. The test(s) should be initiated within 2 hours after removing the protective foil cover from each test.
3. Removal of the test units should start from the right side of the test card to preserve the lot number which appears on the left side of the test card.
4. Remove the protective foil cover from each test and place it on a flat surface or in the workstation.
5. Label the Test Device with Control Reagent name or identification number.
6. Open a Control Vial containing the Control Reagent.
	1. Squeeze the pipette bulb and place the pipette tip into the Control Reagent.
	2. Gently release the bulb to bring the liquid above the fill line on the pipette.
	3. Raise the pipette and gently squeeze the bulb to bring the liquid down to the fill line.
	4. Touch the pipette tip to the Sample Pad and squeeze the pipette bulb to release all of the liquid. **Use a new pipette tip or disposable pipette with each new Control Reagent.**

***Note****: Do not add Chase Buffer when running External Controls.*

1. Read the test result between 20 and 30 minutes after the addition of the Control Reagent in a well-lit area. **Do not read test results after 30 minutes.**
2. Discard the used Test Device and any other test materials into a biohazard waste container.
3. Reseal the Control Reagent Vials and store them in their original container at 2 to 8°C (36 to 46°F).

**Expected Results**

**Nonreactive control (One Line – Control Line)**

 One **Pink**/**Red** line appears in the control area of the strip

**HIV-1 p24 Antigen Control (Two Lines- Control and Ag Line)**

Two **Pink**/**Red** lines appear in both the control area and the upper test area (labeled “Ag”) of the strip.

 **HIV-1 Reactive Control (Two Lines- Control and Ab Line)**

Two **Pink**/**Red** lines appear in both the control area and the lower test are (labeled “Ab”) of the strip.

 **HIV-2 Reactive Control (Two Lines- Control and Ab Line)**

Two **Pink**/**Red** lines appear in both the control area and the lower test area (labeled “Ab”) of the strips.

***Note****:* *ANY visible* ***Pink****/****Red*** *color in the Ag/Ab sections in conjunction with the control section is considered REACTIVE.*

**Storage and Stability of Controls**

Alere Determine™ HIV-1/2 Ag/Ab combo controls should be stored at 2 to 8°C

(36 to 46°F). Do not use beyond the indicated expiration date. Open the control vials only when you are performing tests. Recap and store the control vials in their original container at 2 to 8°C (36 to 46°F) after use.

1. **Limitation of the Procedure**

 Review package insert for other limitations and interferences.

1. **Expected Values**

Nonreactive (negative) results are expected in healthy women and men.

1. **Training/Competency Assessment**

Competency is assessed after initial training and annually (within 365 days) using at least two of the following methods:

1. Performing a test on a blind specimen.
2. Supervisor observes performance of routine work.
3. Each user’s quality control performance is monitored.
4. Written testing specific to the method.

Operators that have not completed annual competency should not perform patient testing.

# **Revision History and Originators**

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