KCMC Biotechnology Laboratory, Microbiology	STANDARD OPERATING PROCEDURE	Effective Date 20 Sept 2007	SOP-Number MIC.019.03
		Page 1 of 8	Date 6 April 2008

Title: Determine HIV-1/2 Test for Detection of Antibodies to HIV-1/2

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Approvals/Date:

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This SOP has been read and understood by:

Name	Date
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Annual Review	
By	**Date**

Title: Determine HIV-1/2 Test for Detection of Antibodies to HIV-1/2

Document History:

Version Number	Reason for Changes	Date
MIC.019.02	Clarification of instructions for handling discordant test results.	20 Sept 2007
MIC.019.02	Change of Capillus to SDBioline in reporting and Discorday results sections	6 April 2008

Copies distributed to:

Name	Date

Title: Determine HIV-1/2 Test for Detection of Antibodies to HIV-1/2

PURPOSE

For detection of antibodies to HIV-1/HIV-2 in human serum, plasma or whole blood.

USE OF TEST

The Abbott Determine HIV-1/2 Test should be used with the SDBioline HIV-1/2 Test and only when both tests give identical results should test results be issued. Samples with discordant results must be tested using ELISA method to resolve discrepency.

PRINCIPLE

A blood sample is added to the sample pad in the test device. As it migrates through the pad it reconstitutes and mixes with a selenium colloid-antigen conjugate. If antibodies to HIV-1 or HIV-2 are present in the sample they bind to the antigen complex forming a red line at the patient window site. If antibodies are not present the antigen-selenium colloid flows past the patient window and no red line is formed.

SCOPE

This Standard operating Procedure applies to the testing of blood samples for antibodies using the Determine HIV-1/2 test by all technical staff in the microbiology laboratory that have been trained and are competent in performing this test.

STANDARD PRECAUTIONS

Standard precautions must be observed when handling patient specimens and while performing tests to protect from exposure to bloodborne pathogens. Refer to SOP SAF.001 BIOHADARD SAFETY.

SPECIMEN

Type: Whole blood or plasma may be tested.

Collection Container/Minimal Volume: EDTA/minimum 1 ml

Collection procedure: Follow procedures in the current version of MIC.012 ISAAC Specimen Collection SOP.

Specimen Storage:

- Whole blood EDTA specimens may be stored up to 7 days at 2-8° C. Never freeze whole blood specimens. If testing is delayed beyond 7 days, centrifuge, aliquot and freeze plasma at ≤ -20° C.
- Serum and EDTA plasma specimens should be stored at 2-8° C if the test is to be run within 7 days of collection. If testing is delayed more than 7 days, the specimen should be frozen ≤ -20° C.

Specimen Transport:

1. Place blood specimens in sealed bag with the lab request form in side pocket and transport in a sturdy, leakproof container bearing a biohazard label.

2. Transport to laboratory immediately.
3. If transport is delayed more than 24 hrs, refrigerate blood at 2-8^{o} C.

Specimen Receipt/Log Sheet Record

1. Refer to MIC.012 SPECIMEN RECEIPT, ISAAC STUDIES for specimen rejection criteria.
2. Enter the following on the Determine/Capillus HIV-1/2 Test Log Sheet:
   Date Collected
   Date Received
   Lot# Determine

TEST MATERIALS & STORAGE

Determine HIV-1/2 Test kit-100 tests (Abbott #7D23-33)
   Test Cards (10/kit)
   Chase Buffer (1 bottle/kit)
Precision pipette, capable of delivering 50 µl of specimen
Pipette tips
Timer
Gloves
Biohazard disposable container

Storage Requirements: Determine HIV-1/2 Test Kits are stored at room temperature 15-27° C until opened. Open kits are refrigerated at 2-8° C.

CALIBRATION - NA

QUALITY CONTROL

Internal Quality Control:
To insure assay validity, a procedural control is incorporated in the device and is labeled "control". If the control bar does not turn red by assay completion, the test result is invalid and the sample should be retested. Patient test results should not be reported.

External Quality Control:

Positive and Negative Controls:

Frequency : Each shipment of each lot and if there is a major change in testing environment.

Controls: Known positive and negative HIV-1 serum samples.

Acceptable Results:

Positive HIV-1 Control – Positive

Negative HIV-1 Control - Negative

Corrective Actions:

1. Repeat test with new control sera.
2. If still unsatisfactory, test with new lot of reagents.

Documentation:

1. Enter Control results on Determine QC Record.
2. Complete a QC Deviation Form on all unacceptable results.
3. Review QC results monthly.

TEST PROCEDURE

For whole blood samples:

1. Add 50 µl of the sample to the sample pad (marked by the arrow symbol).
2. Wait one minute, then apply one drop of Chase Buffer to the sample pad.
3. After 15 minutes a positive result may be reported.
4. Wait 60 minutes before reporting a negative result
5. Do not interpret test results after 60 minutes.

For serum or plasma samples:

1. Add 50 µl of the sample to the sample pad (marked by the arrow symbol).
2. After 15 minutes a positive result may be reported. Wait 60 minutes before reporting a negative result.
3. Do not interpret test results after 60 minutes.

TEST INTERPRETATION

NO VISIBLE BAR IN CONTROL WINDOW – INVALID/ Do not report.

If there is no red bar in the control window of the strip, and even if a red bar appears in the patient window, the result is invalid, cannot be interpreted and test should be repeated. A very weak control bar also indicates a potential problem and the test should be repeated.

RED BARS IN PATIENT AND CONTROL WINDOWS /POSITIVE

Red bar appears in the control window (labeled "control") and in the patient window (labeled "patient") of the strip. Any visible red color in the patient window should be interpreted as positive.

RED BAR IN CONTROL WINDOW ONLY /NEGATIVE

One red bar appears in the control window of the strip (labeled "control") and no red bar appears in the patient window of the strip (labeled "patient").

DISCORDANT RESULTS

If result of Determine HIV test differs from the result obtained with SDBioline HIV test this discrepancy must be resolved as follows:

1. Send plasma sample for HIV ELISA test.
2. If ELISA test is POSITIVE the sample must be tested for the presence of HIV antigens using WESTERN BLOT.

REPORTING RESULTS/SUBSEQUENT TESTING

1. Report results of HIV-1/2 tests **only** if results of both SDBioline and Determine HIV-1/2 tests have identical results (both positive or both negative). If results of the 2 tests are "discordant" do not report results until resolved with additional testing (see above DISCORDANT RESULTS).
2. Record results on ISACC MISCELLANEOUS RESULT Data Form.
3. Positive samples should be submitted to the Immunology Laboratory for CD4 count.

TEST LIMITATIONS

1. Positive test results on infants should be interpreted with caution as a positive test may indicate acquisition of maternal antibodies.
2. A negative result does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.
3. Abbott Determine™ HIV-1/2 is designed to detect antibodies to HIV-1 and HIV-2 in human serum, plasma, and whole blood. Other body fluids or pooled specimens may not give accurate results.
4. The intensity of the patient bar does not necessarily correlate to the titer of antibody in the specimen.

REFERENCES

Package insert, Feb. 2003, Determine HIV-1/2 Test Kit, Abbott Laboratories, Abbott Park, IL. USA.

Phili, R. Vardas, E. 2002. Evaluation of a rapid immunodeficiency virus test at two community clinics in Kwazulu-Natal. S. Afr. Med. J. 92:818.

Hiroyasu, A, etal. 1999. Evaluation of a rapid immunochromographic test for detection of antibodies to human immunodeficiency virus. J. Clin Micro.37:367.

APPENDIX A – Determine QC sheet
APPENDIX B – Determine/Capillus Log sheet

Title: Determine HIV-1/2 Test for Detection of Antibodies to HIV-1/2

APPENDIX A

KCMC Biotechnology Laboratory — Quality Control

Microbiology — **Determine HIV-1/2 Test**

ACCEPTABLE RESULTS: Positive Control – Positive
Negative Control - Negative

YEAR :_____

DATE	LOT#	POS CONTROL	NEG CONTROL	BY

DOCUMENT ALL CORRECTIVE ACTION ON QC DEVIATION FORM

Supervisor Review :					

DETERMINE QC/QC