Adventist HealthCare

TRAINING UPDATE

Lab Location: SGMC & WOMC
Department: Core lab

Date Distributed: 2/10/2026
Due Date: 2/24/2026
Implementation: 2/11/2026

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
AHC.C3084.1 HIV Ag/Ab Combo (CHIV) by Atellica IM Analyzer
Description of change(s):
New SOP for go-live of HIV on the Atellica.

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**HIV Ag/Ab Combo (CHIV) by Atellica IM Analyzer**
Prepared by	Ashkan Chini Date: 10/16/2025
Owner	Robert SanLuis Date: 10/16/2025

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
HIV Ag/Ab Combo (CHIV)	Atellica IM Analyzer	HIVAA

Synonyms/Abbreviations
HIV Ag/Ab Combo

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The Atellica IM CHIV assay is a 2-step antigen/antibody sandwich immunoassay in which antigens are bridged by antibody present in the patient sample and antigen in the sample is bridged by antibody present in the reagents. The Solid Phase contains a preformed complex of streptavidin-coated paramagnetic microparticles and biotinylated HIV-1 and HIV-2 recombinant antigens, group O peptide antigen, and biotinylated anti-p24 antibody. This reagent is used to capture anti-HIV-1 and/or HIV-2 antibodies and/or HIV p24 antigen in the patient sample. The Ancillary Lite Reagent and Lite Reagent contain acridinium-ester-labeled HIV-1 and HIV-2 recombinant antigens, group O peptide antigen, and acridinium-ester-labeled anti-p24 antibodies used to detect anti-HIV-1 and/or HIV-2 antibodies and/or p24 antigen bound to the Solid Phase in the sample.
A direct relationship exists between the amount of HIV antibody activity and/or HIV p24 antigen present in the specimen and the amount of relative light units detected by the system. A result of reactive or nonreactive is determined according to the Index Value established with the calibrators.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (Lithium Heparin) Serum
Collection Container	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: 24 hours
	Refrigerated: 14 days
	Frozen: 8 months
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMOL (Specimen markedly hemolyzed)
Other Considerations	Allow Red Top or SST to clot completely prior to centrifugation. Before placing on system, ensure samples are free of: • Bubbles or foam • Fibrin or other particulate matter

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
HIV Ag/Ab Combo (CHIV)	Siemens, Atellica IM, Cat. No. 10995459
Probe Wash 3 (PW3)	Siemens, Atellica IM, Cat. No. 10995666

4.2 Reagent Preparation and Storage

Note: Ancillary Reagent is included in the reagent pack, the preparation and storage are the same as the Hepatitis B Surface Antigen II.

Reagent	HIV Ag/Ab Combo (CHIV)
Storage	Store at 2-8° C in an upright position. Protect from heat and light sources.
Stability	Reagents are stable onboard the system for 35 days.
Preparation	Reagent is liquid and ready to use. Note: Before loading primary reagent packs onto the system, mix them by hand and visually inspect the bottom of the reagent pack to ensure that all particles are re-suspended.

Reagent	PW3
Storage	Store at 2-8° C in an upright position. Protect from heat and light sources.
Stability	Reagents are stable onboard the system for 100 days.
Preparation	Reagent is liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
CHIV CAL	Siemens Atellica IM, Cat. No. 10995459

5.2 Calibrator Preparation and Storage

Calibrator	CHIV CAL
Preparation	Calibrators are liquid and ready to use.
Storage/Stability	• Store at 2-8°C in an upright position. • **Unopened-Opened:** stable until the expiration date on the product when stored at 2-8°C. • **Opened at room temperature:** remains stable for 8 hours.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	CHIV CAL

Assay Range	See Package Insert for specific assay ranges.
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values
Frequency	• When changing lot numbers of primary reagent packs. • At the end of the lot calibration interval (24 days), for a specified lot of calibrated reagent on the system. • At the end of pack calibration interval (35 days), for calibrated reagent packs on the system. • When indicated by quality control results. • After major maintenance or service. At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.
Calibration Scheme	See Package Insert for specific calibration scheme.

5.4 Calibration Procedure

Procedure	To load a new lot of reagent on IM Module: Note: Calibrate the new lot of reagent as soon as it is loaded on the instrument. If the reagent sits un-calibrated for a short period of time (24 hours) then it will not be eligible for a "Lot Calibration" and another new reagent will need to be loaded onboard. 1. From the home page of the IM Module Screen (small screen attached on the IM Module) make sure the analyzer status is in Standby. 2. On the IM Module Screen select Reagent Loader. Make sure the Reagent Drawer status is unlocked. Open the reagent drawer, load the reagent and then close it. Once the reagent is scanned, the IM Module Screen will populate message "Missing TDef for lot" next to the reagent. The Reagent Drawer status remains unlocked. 3. Both Reagent Master Curve and Calibrator Package Insert need to be scanned using the Atellica Solution's main monitor. To differentiate between the two: • Reagent Master Curve has MC TDEF printed right below the assay name. • Calibrator Package Insert has CAL printed right above the assay name.

Procedure	4. To scan the Reagent Master Curve, go to Set up – Test Definition – IM Test Definition. Scan the barcode. 5. To scan the Calibrator Package Insert, go to Calibration – Calibrator Definition. Scan the barcode. 6. Re-open the Reagent Drawer and close it. This time its status should change to locked, meaning the reagent is going to be loaded onboard ready for calibration. Refer to the Atellica Solution Operating, QC, Calibration and Maintenance procedure for specific instructions.

5.5 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
HIV Ag/Ab Combo QC (CHIV QC)	Siemens, Atellica IM, Cat. No. 10995528

6.2 Control Preparation and Storage

Control	HIV Ag/Ab Combo QC (CHIV QC)
Preparation	Quality Control materials are liquid and ready to use. Gently mix and invert the vials to ensure homogeneity of the material.
Storage/Stability	• Store at 2-8°C in an upright position. • **Unopened-Opened:** stable until the expiration date on the product when stored at 2-8°C. • **Opened at room temperature:** remains stable for 8 hours. • **Onboard the Atellica System:** remains stable for 8 hours.

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing (notated on the QC frequency sheets posted on the instruments).

Refer to the Siemens Atellica QC Schedule and in the Siemens Atellica Quick Reference Guide.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded, the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.

- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Siemens Atellica IM Analyzer

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -50°C.
- Centrifuge

7.3 Supplies

- System Fluids
- Assorted calibrated pipettes (MLA or equivalent) and disposable tips

8. PROCEDURE

Atellica IM HIV Ag/Ab Combo (CHIV) is required to perform this test.

HIV Ag/Ab Combo (CHIV) is performed on the Atellica IM Analyzer after the method is calibrated and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-up Protocol
1.	Perform any required instrument maintenance.
2.	Ensure that the instrument has sufficient primary and ancillary reagents.
3.	Check status of cuvettes and tips. Check waste levels. Fill or empty as appropriate.
4.	Check calibration status and re-calibrate as needed.

8.2	Specimen Testing
1.	Centrifuge the specimens.
2.	Load the sample in the Atellica rack and place the rack into the Sample Handler to initiate testing. **NOTE: If not equipped with an in-line decapper unit, samples must be de-capped prior to loading on the Atellica system
3.	Refer to the general operating procedure for detailed steps.
4.	Follow protocol in section 10.6 "Repeat Criteria and Resulting" for samples with results above the analytical measurement range (AMR). Investigate any flagged results and repeat as necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The system reports HIV antibody and/or p24 antigen results in Index Values and as reactive or nonreactive. The minimum level of antibodies to HIV-1/HIV-2 and/or p24 antigen that indicates reactivity is assigned an Index Value of 1.0. This is the cut-off Index Value. The cut-off Index Value of 1.0 is used to determine whether a specimen is reactive or nonreactive for p24 antigen and/or antibodies to HIV-1/HIV-2.

- **Nonreactive (NR)**: Specimens with an Index Value < 1.0 are considered nonreactive for antibodies to HIV-1and HIV-2 and p24 antigen.

- **Reactive (REA)**: Specimens with an Index Value ≥ 1.0 are considered initially reactive for antibodies to HIV-1and HIV-2 and p24 antigen and should be retested in duplicate after centrifugation for 10 minutes.

    - If one or both of the duplicates are reactive, the specimen is reported as reactive.
    - If both of the duplicates are nonreactive, the specimen is reported as nonreactive.

Note:
- Inadequate centrifugation may result in a higher rate of repeat reactive results.
- Repeatedly reactive specimens must be investigated.

10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Repeat Criteria and Resulting

Refer to section 10.1

11. EXPECTED VALUES

11.1 Reference Ranges

Nonreactive(NR)

11.2 Critical Values

None established

11.3 Standard Required Messages

If HIV 1/2 Antibody Antigen(HIVR) result is NONREACTIVE then
HIV 1 /2 Note. (HIVCC) is resulted with

HIV 1 antigen and HIV 1 2 antibodies were not detected. There is no laboratory evidence of HIV infection.
The performance of this assay has not been clinically validated in patients less than 2 years old.

If HIV 1/2 Antibody Antigen(HIVR) result is REACTIVE then
HIV 1/2 Note (HVRC) is resulted with

The repeatedly reactive screening assay result is confirmed by duplicate repeat testing, and indicates a POSSIBLE presence of HIV-1 antibodies or HIV-2 antibodies, and or HIV-1 p24 antigen. Additional testing is required for diagnosis. Therefore, these screening results must be correlated with results of reflex confirmatory tests, including the HIV-1 AND HIV-2 Antibody Differentiation assay and, if necessary, the HIV-1 RNA Qualitative Real-Time PCR.
The performance of this assay has not been clinically validated in

patients less than 2 years old.

If HIV 1/2 Antibody Antigen(HIVR) result is REACTIVE then
HIV Reflex (HIVRX) is resulted with

Confirmatory HIV 1 2 Antibody Differentiation test HAS BEEN ADDED (HIVD)
-and-
reflex test HIV 1/2 AB DIFFERENTIATION (XHIVDF)is added
** Note, XHIVDF is sent to Quest, if result is Indeterminate or Negative then Quest will order HIV-1 RNA, Qualitative (XHIV1M)

If HIV 1/2 Antibody Antigen(HIVR) result is NONREACTIVE then
HIV Reflex (HIVRX) is resulted with

Confirmatory test not indicated (HIVND)

****CAP surveys-** Reflexing to HIV 1/2 AB DIFFERENTIATION (XHIVDF) is blocked from occurring on the LIS.
DO NOT MANUALLY ADD IT ON !!
HIV 1/2 Notes (HIVCC, HVRC) are resulted with HIDE and HIV Reflex (HIVRX) is resulted with *CAP survey reflex not indicated* (CRFLX).

12. CLINICAL SIGNIFICANCE

Human immunodeficiency virus is the causative agent of acquired immunodeficiency syndrome (AIDS). Human immunodeficiency virus type 1 (HIV-1) has been identified as the primary cause of acquired immunodeficiency syndrome (AIDS). This retrovirus, a member of the lentivirinae subfamily, is spread by sexual contact, exposure to infected blood or blood products, and perinatal transmission. Human immunodeficiency virus type 2 (HIV-2) was isolated from AIDS patients in West Africa. These viruses share epitopes of the core proteins, but exhibit little or no cross-reactivity between the envelope glycoproteins. Comparison of the nucleic acid sequences for HIV-1 and HIV-2 shows approximately 60% homology in the conserved genes, such as *gag* and *pol* , and 30%–40% homology in less conserved regions. HIV-1 has been subdivided into group M and group O. The routes of transmission of HIV-1 and HIV-2 are the same. However, the transmission and the viral replication rate are much lower in HIV-2 infections. Clinical studies have shown that in HIV-2 infections there is a slower disease progression than in HIV-1 infections. In HIV-2 infections, there is a slower rate in the decline of CD4 T-cells and reduced viremia. Individuals infected with HIV-2 generally have a better clinical outcome. The Atellica IM CHIV assay uses yeast-recombinant-derived antigens corresponding to the viral envelope proteins. Recombinant antigens include an HIV-1 envelope protein and an HIV-2 envelope protein. A synthetic peptide is added for the detection of antibodies to HIV-1 group O. The assay uses 3 monoclonal antibodies specific to HIV p24 antigen to capture and detect HIV p24 antigen in a sample.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

Sample Type	Mean Index	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Serum A	0.16	7.5	8.8
Serum B	2.93	2.3	4.2
Serum C	4.92	1.6	3.7
Serum D	2.76	2.2	5.7

14.3 Interfering Substances

Specimens that are …	Demonstrate ≤ 10% change in results …
Hemolyzed	Up to 500 mg/dL of hemoglobin
Lipemic	Up to 1000 mg/dL of triglycerides
Icteric	Up to 40 mg/dL of conjugated bilirubin
Icteric	Up to 40 mg/dL of unconjugated bilirubin
Hyper-IgG	Up to 60 mg/mL of Immunoglobulin G
Hyperproteinemic	Up to 12 g/dL of total protein
Hypoproteinemic	As low as 3.5 g/dL of protein

14.4 Clinical Sensitivity/Specificity/Predictive Values

None.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.
Warning!

Contains: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Atellica IM CHIV High Calibrator)

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16. RELATED DOCUMENTS

1. Atellica Solution Operating, QC, Calibration and Maintenance procedure
2. Laboratory Quality Control Program
3. QC Schedule for Siemens Atellica Solution
4. Laboratory Safety Manual
5. Safety Data Sheets (SDS)
6. Atellica Solution Limits Chart
7. Quest Diagnostics Records Management Procedure
8. Atellica Solution System Error Messages Chart
9. Centrifuge Use, Maintenance and Function Checks (Lab policy)
10. Specimen Acceptability Requirements (Lab policy)
11. Repeat Testing Requirement (Lab policy)
12. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
13. Current package insert of Hepatitis B Surface Antigen II Reagent

17. REFERENCES

1. Package Insert, HIV Ag/Ab Combo (CHIV) Reagent, Siemens Healthcare Diagnostics Inc., 03/2025.
2. Package Insert, HIV Ag/Ab Combo Quality Control, Siemens Healthcare Diagnostics Inc., 04/2025.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

None