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ABBOTT PRISM **HIV O Plus**

REF 3L68-68

G10316R06

Human Immunodeficiency Virus Types 1 and 2 (*E. coli*, *B. megaterium*, Recombinant) Antigen and Synthetic Peptide

Read Highlighted Changes: Revised March 2019

ABBOTT PRISM

Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to Symbols

	Caution	CONJUGATE WASH	Conjugate Wash	PROBE 20X CONC	Probe 20X Concentrate
	Consult instructions for use	CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.	PROBE DILUENT	Probe Diuent
	Manufacturer	DANGER: REPRODUCTIVE HAZARD	Danger: Reproductive Hazard	PROBE WASH	Probe Wash
	Store at 2-8°C	DISTRIBUTED BY	Distributed by	PRODUCED FOR ABBOTT BY	Produced for Abbott by
	Store at 15-30°C	EC REP	Authorized Representative in the European Community	PRODUCT OF USA	Product of USA
	Use by/Expiration date	HIV-1 CONTROL +	HIV-1 Positive Control	PURGE CONCENTRATE	Purge Concentrate
ACTIVATOR CONCENTRATE	Activator Concentrate	HIV-2 CONTROL +	HIV-2 Positive Control	REACTION TRAYS	Reaction Trays
ACTIVATOR DILUENT	Activator Diluent	IVD	*In Vitro* Diagnostic Medical Device	REAGENT COMPONENTS	Reagent Components
ACTIVATOR LINE TREATMENT	Activator Line Treatment	LINE CLEANER	Line Cleaner	REF	List Number
ASSAY KIT CARD	Assay Kit Card	LOT	Lot Number	RUN CONTROL ADAPTERS	Run Control Adapters
CAL –	Negative Calibrator	MASTER LOT	Master Lot	SAMPLE CUPS	Sample Cups
CAL +	Positive Calibrator	MICROPARTICLES	Microparticles	TRANSFER WASH	Transfer Wash
CALIBRATORS	Calibrators	PIPETTE TIPS	Pipette Tips	WARNING: SENSITIZER	Warning: May cause an allergic reaction
CONJUGATE	Conjugate	PRIME/PURGE ACCESSORIES	Prime/Purge Accessories	WARNING: SEVERE IRRITANT	Warning: Severe Irritant

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

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NAME AND INTENDED USE

The ABBOTT PRISM HIV O Plus assay is an *in vitro* chemiluminescent immunoassay (ChLIA) for the qualitative detection of antibodies to HIV-1 (anti-HIV-1) Groups M and O and/or antibodies to HIV-2 (anti-HIV-2) in human serum and plasma specimens. The ABBOTT PRISM HIV O Plus assay is intended to screen individual human donors, including volunteer donors of Whole Blood and blood components and other living donors, for the presence of anti-HIV-1 Groups M and O and/or anti-HIV-2. The assay is also intended for use in testing blood and plasma specimens to screen organ donors when specimens are obtained while the donor's heart is still beating, in testing blood specimens to screen cadaveric (non–heart-beating) donors, and as an aid in the diagnosis of HIV-1/HIV-2 infection. It is not intended for use in testing cord blood specimens.

SUMMARY AND EXPLANATION OF THE TEST

The ABBOTT PRISM HIV O Plus assay uses recombinant DNA-derived antigens corresponding to three viral proteins (HIV-1 Group M envelope, HIV-1 Group O envelope, and HIV-2 envelope) and one synthetic peptide corresponding to HIV-2 envelope.

Epidemiologic data suggest that the acquired immunodeficiency syndrome (AIDS) is caused by at least two types of human immunodeficiency viruses, collectively designated HIV. Human immunodeficiency virus type 1 (HIV-1), the first-discovered AIDS virus, has been isolated from patients with AIDS and from healthy persons at high risk for AIDS.[1-3] HIV-1 is transmitted by sexual contact, by exposure to blood or blood products, or by an infected mother to her fetus or child.[4]

HIV-2 was isolated from patients with AIDS in West Africa.[5] The HIV-2 virus is similar to the HIV-1 virus in its morphology, cell tropism, interaction with the CD4 cellular receptor, *in vitro* cytopathic effect on CD4 cells, overall genomic structure, transmission route, and its ability to cause AIDS.[5-8] HIV-2 has not spread substantially outside of West Africa; the prevalence of HIV-2 in North and South America and Europe is low. HIV-2 prevalence is stable or declining in West African countries.[8]

HIV-1 isolates have been classified into three groups: Group M (main), Group O (outlier), and Group N (non-M/non-O). Group M has 9 subtypes (A, B, C, D, F, G, H, J, K) and many circulating recombinant forms (CRFs).[9,10] Group M has been identified worldwide; however, the geographic distribution and regional predominance of Group M subtypes vary with epidemiological spread. All HIV-1 Group M subtypes have been found in Africa.[11-13] The predominant strain in North America, South America, Europe, and Australia is subtype B, although other subtypes are also present in these regions.[11-13] The predominant strains in Southeast Asia are CRF01_AE (formerly subtype E) and subtype B, while the predominant strains in India are subtype C.[11-13] Group O is found primarily in Cameroon and west central Africa, but also has been identified in the US and Europe.[14-19] HIV-1 Group O was identified as a strain highly divergent from the Group M strains.[20,21] The genetic diversity within Group O strains is similar to the level of diversity among Group M strains; however, Group O strains have not been classified into subtypes.[22] Group N has been identified only in Cameroon and is rare.[23-25] The global distribution and predominance of HIV-1 strains are affected by epidemiological factors and will continue to change over time.[11-13]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ABBOTT PRISM HIV O Plus assay is a three-step sandwich ChLIA. The reactions occur within the ABBOTT PRISM System in the following sequence:

- Microparticles coated with HIV antigens (recombinant proteins) are incubated with sample (either plasma, serum, calibrator, or control) in the incubation well of the reaction tray. During incubation, HIV-1 and/or HIV-2 antibodies present in the sample bind to the antigen(s) on the microparticles.
- After this first incubation is complete, the reaction mixture is transferred to the glass fiber matrix (matrix) of the reaction tray using the transfer wash. The microparticles are captured by the matrix, while the remaining mixture flows through to an absorbent blotter.
- A probe mixture (probe) consisting of biotinylated HIV-1 recombinant proteins and biotinylated HIV-2 peptide is added to the microparticles on the matrix and incubated. The probe binds to the microparticle-antibody complex created during the first incubation process. After the second incubation, the unbound probe is washed into the blotter with the probe wash.
- The acridinium-labeled anti-biotin conjugate is added to the microparticles on the matrix and incubated to bind any probe that is present. After the third incubation, the unbound conjugate is washed into the blotter with the conjugate wash.
- The chemiluminescent signal is generated by addition of an alkaline hydrogen peroxide solution. The resultant photons are counted.

The amount of light emitted is proportional to the amount of anti-HIV-1 and/or anti-HIV-2 in the sample. The presence or absence of anti-HIV-1/HIV-2 in the sample is determined by comparing the number of photons collected from the sample to a cutoff value determined from a calibration performed in the same batch. If the number of photons collected from a test sample is less than the cutoff value, the sample is considered nonreactive for anti-HIV-1 and anti-HIV-2 by the criteria of the ABBOTT PRISM HIV O Plus assay. These specimens need not be further tested. If the number of photons collected from a test sample is greater than or equal to the cutoff value, the sample is considered reactive for anti-HIV-1 and/or anti-HIV-2 by the criteria of the ABBOTT PRISM HIV O Plus assay. Specimens that are initially reactive must be handled as described in the **Preparation for Analysis** section of this package insert and retested in duplicate. Reactivity in either or both of these duplicate tests (*i.e.*, repeatedly reactive) is highly predictive of the presence of HIV-1 and/or HIV-2 antibodies in individuals at risk for HIV infection. Follow appropriate FDA recommendations and regulations for specimens found to be repeatedly reactive. Customers outside the US must follow their country's government recommendations and regulations for specimens found to be repeatedly reactive. For further information regarding ChLIA technology, refer to the ABBOTT PRISM Operations Manual, Section 3.

Repeatedly reactive specimens obtained from people at risk for HIV infection are usually found to contain antibodies by supplemental tests included in the FDA or other country's recommendations. Certain specimens may require nucleic acid amplification testing or culture to ensure confirmation. A full differential diagnostic workup for the diagnosis of AIDS and AIDS-related conditions necessarily includes an examination of the patient's immune status and clinical history.

REAGENTS

NOTE: Each specific component description that follows is accompanied by a unique symbol. These symbols appear on both the component labels and on corresponding instrument tubing identifier labels. They are meant to facilitate identification and installation of reagent bottles within the ABBOTT PRISM System ambient reagent bay and refrigerator.

ABBOTT PRISM HIV O Plus Assay Kit (REF 3L68-68)

NOTE: Do not mix reagents from different bottles. Do not mix or interchange reagents from different ABBOTT PRISM HIV O Plus Assay Kits.

- **MICROPARTICLES** 1 Bottle (324 mL) HIV-1/HIV-2 (*E. coli*, *B. megaterium*, recombinant) antigen coated microparticles in phosphate buffer with CHAPS. Minimum activity with **PC**: 3.00 S/CO, Minimum activity with **PC2**: 2.00 S/CO, Minimum activity with **OPC**: 1.50 S/CO. Preservative: 0.1% sodium azide. (Symbol: ●)
- **CONJUGATE** 1 Bottle (331 mL) Anti-biotin (mouse monoclonal): acridinium conjugate in phosphate buffered saline with Triton X-100 and protein stabilizers. Minimum concentration: 0.050 µg/mL. Preservative: 0.1% sodium azide. (Symbol: ▲)
- **CAL –** 3 Bottles (10.4 mL each) Negative Calibrator. Recalcified human plasma. Preservative: 0.1% sodium azide. (Symbol: **NC**)
- **CAL +** 3 Bottles (10.4 mL each) Positive Calibrator. Recalcified, inactivated, human plasma reactive for anti-HIV-1. Minimum activity: 3.00 S/CO. Preservative: 0.1% sodium azide. (Symbol: **PC**)
- **HIV-2 CONTROL +** 3 Bottles (10.4 mL each) HIV-2 Positive Assay Control (1). Recalcified, inactivated, human plasma reactive for anti-HIV-2. Minimum activity: 2.00 S/CO. Preservative: 0.1% sodium azide. (Symbol **PC2**)

  NOTE: The ABBOTT PRISM HIV O Plus Calibration Report identifies the ABBOTT PRISM HIV O Plus HIV-2 Positive Assay Control (PC2) as "Pos Assay CTL (1)."
- **HIV-1 CONTROL +** 3 Bottles (10.4 mL each) HIV-1 Group O Positive Assay Control (2) containing HIV-1 Group O (mouse monoclonal) antibody in recalcified human plasma. Minimum activity: 1.50 S/CO. Preservative: 0.1% sodium azide. (Symbol: **OPC**)

  NOTE: The ABBOTT PRISM HIV O Plus Calibration Report identifies the ABBOTT PRISM HIV O Plus HIV-1 Group O Positive Assay Control (OPC) as "Pos Assay CTL (2)."
- **PROBE 20X CONC** 1 Bottle (16 mL) Probe 20x Concentrate containing biotinylated HIV-1/HIV-2 (*E. coli*, recombinant) antigen and synthetic peptide in borate buffer with protein stabilizers. Minimum concentration: 6.54 µg/mL. Preservative: 0.1% sodium azide. (No Symbol)

  NOTE: Probe 20x Concentrate **MUST** be mixed with Probe Diluent prior to use.
- **PROBE DILUENT** 1 Bottle (306 mL) Probe Diluent. Borate buffer with protein lysate and protein stabilizers. Preservative: 0.1% sodium azide. (Symbol: ■)

  NOTE: Probe Diluent **MUST** be mixed with Probe 20x Concentrate prior to use.

Other Reagents Required

ABBOTT PRISM HIV O Plus Wash Kit (REF 3L68-58)

- **TRANSFER WASH** 1 Bottle (3364 mL) Transfer Wash. Borate buffered saline. Preservative: 0.1% sodium azide. (Symbol: ∿)
- **CONJUGATE WASH** 1 Bottle (2794 mL) Conjugate Wash. TRIS buffer. Preservative: 0.1% sodium azide. (Symbol: ★)
- **PROBE WASH** 1 Bottle (2258 mL) Probe Wash. TRIS buffer. Preservative: 0.1% sodium azide. (Symbol: ⟶)

ABBOTT PRISM Activator Concentrate (REF 1A75-02 or 3L27-02)

- **ACTIVATOR CONCENTRATE** 4 Bottles (900 mL each) Activator Concentrate. 0.4% hydrogen peroxide/0.06% diethylenetriaminepentaacetic acid.

ABBOTT PRISM Activator Diluent (REF 1A75-01 or 3L27-01)

- **ACTIVATOR DILUENT** 4 Bottles (900 mL each) Activator Diluent. 0.3 N sodium hydroxide.

ABBOTT PRISM Run Control Kit (REF 3E60-10)

Or

ABBOTT PRISM Positive Run Control Kit (REF 3E60-11)

NOTE: Each batch **MUST** end in a release control (ABBOTT PRISM Positive Control). The ABBOTT PRISM Positive Control (included in Kit REF 3E60-10 or 3E60-11) must be used as the release control, which has been configured to validate the system functionality and release sample results. Refer to the ABBOTT PRISM Run Control Kit package insert or the ABBOTT PRISM Positive Run Control Kit package insert for detailed handling and use instructions.

WARNINGS AND PRECAUTIONS

- **IVD**
- **For *In Vitro* Diagnostic Use**
- Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Safety Precautions

- ⚠ **CAUTION:** This product contains human-sourced and/or potentially infectious components. Refer to the **REAGENTS** section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens[26]. Biosafety Level 2[27] or other appropriate biosafety practices[28,29] should be used for materials that contain or are suspected of containing infectious agents. These precautions include, but are not limited to, the following:

1. Wear gloves when handling specimens or reagents.
2. Do not pipette by mouth.
3. Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where specimens or reagents are handled.
4. Clean and disinfect all spills of specimens or reagents using an appropriate disinfectant such as 0.1% sodium hypochlorite, or other suitable disinfectant.[30,31]
5. Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.[32,33]

- The human plasma used in the negative calibrator is nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.
- The human plasma used in the positive calibrator is reactive for anti-HIV-1. Plasma is also tested for HIV-1 either by an HIV-1 antigen test and is nonreactive, or by an HIV-1 NAT, and may be reactive. Plasma is nonreactive for HBsAg and anti-HCV.
- The human plasma used in the HIV-2 Positive Assay Control (1) is reactive for anti-HIV-2 and nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, and anti-HCV.
- The human plasma used in the HIV-1 Group O Positive Assay Control (2) contains HIV-1 Group O (mouse monoclonal) antibody in recalcified human plasma. Plasma is nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.

The following warnings and precautions apply to **MICROPARTICLES**, **CAL –**, **CAL +**, **HIV-1 CONTROL +**, **HIV-2 CONTROL +**:

Contains sodium azide.

EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

- The following warnings and precautions apply to **CONJUGATE**

WARNING:	Contains sodium azide and polyethylene glycol octylphenyl ether.
EUH032	Contact with acids liberates very toxic gas.
H401	Toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
Prevention	
P273	Avoid release to the environment.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

- The following warnings and precautions apply to the **PURGE CONCENTRATE**

WARNING:	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
Prevention	
P261	Avoid breathing mist / vapours / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents/container in accordance with local regulations.

- The following warnings and precautions apply to these components:
  - **PROBE 20X CONC**
  - **PROBE DILUENT**

DANGER:	Contains boric acid, disodium tetraborate decahydrate and sodium azide.
H360	May damage fertility or the unborn child.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P201	Obtain special instructions before use.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P308+P313	IF exposed or concerned: Get medical advice / attention.
Disposal	
P501	Dispose of contents/container in accordance with local regulations.

- This product contains sodium azide; for a specific listing, refer to the **REAGENTS** section of this package insert. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.
- Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

Handling Precautions

- Do not use kits beyond the expiration date.
- **Gently** invert each component several times prior to loading the original container on the ABBOTT PRISM System to ensure a homogeneous solution. Additional gentle inversion may be required to thoroughly resuspend microparticles. Avoid foaming.
- **Gently** invert calibrators and assay controls in the calibrator pack several times prior to each use.
- Each component of the ABBOTT PRISM HIV O Plus Wash Kit should be at room temperature (15-30°C) and then mixed before loading onto the ABBOTT PRISM System.
- Do not mix reagents or calibrators/assay controls from different bottles. Do not mix or interchange reagents from different ABBOTT PRISM HIV O Plus Assay Kits.
- Any lot of ABBOTT PRISM HIV O Plus Wash Kit can be used with any lot of ABBOTT PRISM HIV O Plus Assay Kit.
- Any lot of ABBOTT PRISM Activator Concentrate, ABBOTT PRISM Activator Diluent, and Control from an ABBOTT PRISM Run Control Kit or ABBOTT PRISM Positive Run Control Kit may be used with any lot of ABBOTT PRISM Assay Kit.
- Treat negative and positive calibrators and controls as potentially infectious.
- Avoid microbial and chemical contamination of samples, reagents, and

equipment. The use of disposable pipette tips is recommended for any preliminary sample transfer.

- Use accurately calibrated equipment.
- Do not freeze reagents.
- Failure to adhere to instructions in the ABBOTT PRISM Operations Manual or this package insert may result in erroneous test results.
- Use caution when handling samples, reagent bottles, and reagent caps to prevent cross contamination.

Additional safety and handling precautions and limitations for the assay kit, calibrators, specimens, controls, and other reagents are described in the ABBOTT PRISM Operations Manual, Sections 7 and 8.

Preparation of the Diluted Probe

NOTE: Preparation of probe solution does not require the diluent or concentrate to equilibrate to room temperature prior to combining and mixing.

1. Carefully empty the entire contents of the small probe 20x concentrate dropper bottle into the larger probe diluent bottle by slowly squeezing the dropper bottle several times while keeping the dropper tip within the opening of the probe diluent bottle. Avoid foaming. Solution will turn light red in color.
2. Write the date of preparation, the date of expiration, the lot number of probe 20x concentrate (REF 3L68H), and the preparer's name on the probe diluent label on the large bottle, in the spaces provided.

NOTE: The diluted probe must be used within 56 days of preparation.

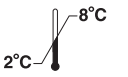
3. Reseal the large bottle and mix thoroughly by slowly inverting several times. Do not vortex.
4. Place in the ABBOTT PRISM System refrigerator. Refer to the ABBOTT PRISM Operations Manual, Section 5, **PREPARE AND LOAD REAGENTS**, for additional information.

Preparation of Activator Solution

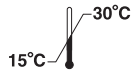
Activator solution must be prepared by mixing equal parts of ABBOTT PRISM Activator Concentrate and ABBOTT PRISM Activator Diluent. The activator solution expires 24 hours from preparation. The ABBOTT PRISM Activator Concentrate may be used immediately after removing from the refrigerator. The volume of activator solution required for multiple tests is calculated by the ABBOTT PRISM System software. Refer to the ABBOTT PRISM Operations Manual, Section 5, **PLAN WORK LOAD**, for additional information. Use clean pipettes and/or metal-free containers (such as plasticware or acid-washed and purified or equivalent water-rinsed glassware) to measure. Refer to the ABBOTT PRISM Operations Manual Glossary for the definition of purified water. Prepare the activator solution in the bottle provided in the ABBOTT PRISM Accessory Kit (REF 6A36-60). Cover the bottle opening securely with the cap provided and invert gently five to ten times to mix. Load the activator solution on the ABBOTT PRISM System. Refer to the ABBOTT PRISM Operations Manual, Section 5, **PREPARE AND LOAD ACTIVATOR SOLUTION**, for additional information.

NOTE: The activator solution must be used within 24 hours of preparation.

Storage Instructions



- Store the ABBOTT PRISM HIV O Plus Assay Kit, ABBOTT PRISM Run Control Kit, ABBOTT PRISM Positive Run Control Kit, and ABBOTT PRISM Activator Concentrate at 2-8°C.
- The diluted probe must be stored at 2-8°C and used within 56 days of preparation.



- Store the ABBOTT PRISM HIV O Plus Wash Kit and ABBOTT PRISM Activator Diluent at room temperature (15-30°C).
- The activator solution must be stored at 15-30°C and used within 24 hours of preparation.

- When stored and handled as directed, reagent and wash kit components are stable until the expiration date.
- Store ABBOTT PRISM Pipette Tips and ABBOTT PRISM Reaction Trays in their original packaging until use.

Indications of Instability or Deterioration of Reagents

The ABBOTT PRISM System will not continue to process samples when calibrator or positive assay control values do not meet specifications. This may indicate either deterioration or contamination of reagents, or instrument failure. Refer to the ABBOTT PRISM Operations Manual, Section 10, for additional information.

INSTRUMENT PROCEDURE

- For the software versions that may be used to perform the assay, refer to the ABBOTT PRISM Assay / Software Version Matrix located in the **Supplemental Information** tab of the ABBOTT PRISM Operations Manual.
- Refer to the ABBOTT PRISM Operations Manual for a detailed description of instrument procedures.
- Refer to the ABBOTT PRISM Operations Manual, Section 7, for limitations associated with test management.
- Solutions required for instrument cleaning and maintenance are described in detail in the ABBOTT PRISM Operations Manual, Sections 5 and 9.
- For optimal performance, it is important to follow the routine maintenance procedures defined in the ABBOTT PRISM Operations Manual, Section 9.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

- For living donors, serum (including serum collected in serum separator tubes), plasma collected in EDTA, potassium oxalate, sodium citrate, ACD-A, ACD-B, CP2D, CPD, or CPDA-1 anticoagulants, or plasma collected from segmented tubing may be used with the ABBOTT PRISM HIV O Plus assay. Follow the manufacturer's specimen collection instructions for serum and plasma collection tubes.

  CAUTION: Do not use specimens collected in heparin. Use of heparin as an anticoagulant may cause a reduction in sample net counts and in sample net counts/cutoff value (S/CO) for ABBOTT PRISM HCV; therefore, heparin is not recommended for any ABBOTT PRISM assay.
- For cadaveric donors, only **serum** may be used; follow general standards and/or regulations for collection.
- Do not use cadaveric **plasma** specimens.

Specimen Conditions

- This assay was designed and validated for use with individual human serum and plasma specimens. This assay has not been validated for use with pooled specimens.
- For living donors and cadaveric (non-heart-beating) donors, serum from heparinized patients may be incompletely coagulated resulting in potential instrument errors such as drain time errors due to the presence of fibrin. To prevent this phenomenon, draw specimen prior to heparin therapy or after heparin therapy is discontinued and activated partial thromboplastin time (aPTT) levels return within normal range.
- Do not use heat-inactivated specimens.
- Do not use specimens with obvious microbial contamination.
- Performance has not been established using umbilical cord blood or body fluids such as urine, saliva, semen, amniotic fluid, cerebrospinal fluid, or pleural fluid. These specimens should not be tested using the ABBOTT PRISM HIV O Plus assay.
- Clear, nonhemolyzed specimens should be used when possible. Specimens containing visible particulate matter may give erroneous or inconsistent test results.
- No qualitative performance differences were observed when a minimum of 24 nonreactive and 72 low-level reactive specimens were spiked with elevated levels of bilirubin (≤ 20 mg/dL), hemoglobin (≤ 500 mg/dL), red blood cells (≤ 0.4% v/v), triglycerides (≤ 3000 mg/dL), or protein (≤ 12 g/dL). However, specimens that contain greater concentrations of these potentially interfering substances have not been tested. The impact of greater concentrations of these potentially interfering substances on the ABBOTT PRISM HIV O Plus assay is unknown.

Preparation for Analysis

FAILURE TO FOLLOW THE SPECIFIED CENTRIFUGATION PROCEDURE MAY GIVE ERRONEOUS OR INCONSISTENT TEST RESULTS.

For ABBOTT PRISM HIV O Plus, inadequate centrifugation of nonfrozen plasma specimens can lead to elevated reactive rates due to platelet interference.

Nonfrozen plasmapheresis specimens do not require centrifugation. All other specimens (including previously frozen plasmapheresis specimens) must be centrifuged as described in this section.

Nonfrozen SERUM specimens must be centrifuged such that g-minutes are between 30,000 and 75,000. A refrigerated or nonrefrigerated centrifuge is acceptable for use. The acceptable time and force ranges that meet this criterion are listed in **Table I.**

Any specimen that is not tested or retested within 24 hours of initial centrifugation must be recentrifuged as described in **Table I.**

NOTE: Filtered cadaveric specimens that are not tested within 24 hours of initial centrifugation must be recentrifuged, but do not need to be refiltered.

Table I: Nonfrozen SERUM Specimens

Centrifugation Time (minutes)	RCF (x g)	g-minutes
10	3,000	30,000
15	2,000 - 3,000	30,000 - 45,000
20	1,500 - 3,000	30,000 - 60,000
25	1,300 - 3,000	32,500 - 75,000

Nonfrozen PLASMA specimens must be centrifuged such that g-minutes are between 45,000 and 75,000. A refrigerated or nonrefrigerated centrifuge is acceptable for use. The acceptable time and force ranges that meet this criterion are listed in **Table II.**

Any specimen that is not tested or retested within 24 hours of initial centrifugation must be recentrifuged as described in **Table II.**

Table II: Nonfrozen PLASMA Specimens

Centrifugation Time (minutes)	RCF (x g)	g-minutes
15	3,000	45,000
20	2,250 - 3,000	45,000 - 60,000
25	1,800 - 3,000	45,000 - 75,000

Previously frozen specimens must be mixed gently and thoroughly after thawing and centrifuged such that g-minutes are between 180,000 and 300,000. A refrigerated or nonrefrigerated centrifuge is acceptable for use. The acceptable time and force ranges that meet this criterion are listed in **Table III**.

ANY previously frozen specimen that is not tested or retested within 24 hours of initial centrifugation and not refrozen must be recentrifuged at 30,000 to 75,000 g-minutes.

Table III: Previously Frozen Specimens

Centrifugation Time (minutes)	RCF (x g)	g-minutes
15	12,000	180,000
20	9,000 - 12,000	180,000 - 240,000
25	7,200 - 12,000	180,000 - 300,000

Additional Centrifugation Information

Convert rpm to RCF as follows: $RCF = 1.12 \times \mathbf{r}_{max} \times (rpm/1000)^2$

Convert RCF to rpm as follows: $rpm = 1000 \times \sqrt{\frac{RCF}{1.12 \times \mathbf{r}_{max}}}$

RCF - The relative centrifugal force generated during centrifugation.

rpm - The revolutions per minute of the rotor on which the specimens are being spun (usually the digital readout on the centrifuge will indicate the rpm).

Centrifugation Time - The time should be measured from the time the rotor reaches the required RCF or rpm to the time it begins decelerating.

$\mathbf{r}_{max}$ - Radius of the rotor in millimeters. The radius measured is dependent on whether the rotor is a fixed angle rotor or a swinging bucket rotor. This value is typically provided with the rotor by the manufacturer. For the fixed angle rotor, $\mathbf{r}_{max}$ is the measure of the distance from the rotor axis (center) to the bottom of the specimen tube in the rotor or rotor adapter. For the swinging bucket rotor, $\mathbf{r}_{max}$ is the measure of the distance from the rotor axis (center) to the bottom of the specimen tube in the rotor adapter or bucket at full extension.

NOTE: If custom tube adapters (*i.e.*, adapters not defined by the centrifuge manufacturer) are used, then the radius ($\mathbf{r}_{max}$) should be manually measured in millimeters and the RCF calculated.

g-minutes - The unit of measure for the product of RCF (x g) and centrifugation time (minutes).

Filtration of Centrifuged Cadaveric SERUM Specimens

Failure to adhere to the following instructions may result in erroneous or inconsistent test results.

Wear personal protective equipment, including eyewear.

After centrifugation, filter each cadaveric specimen through a Millipore GV Filter as follows:

1. Label an empty tube with the specimen identification number matching the original tube.
2. Remove the plunger from a sterile 10 cc syringe.

   NOTE: Do not use a syringe smaller than 10 cc because excess pressure may build up, potentially causing damage to the filter unit or personal injury.
3. Remove the sterile filter from the package.
4. Securely screw the syringe to the filter.

   NOTE: Do not touch the tip of the filter to avoid possible contamination.
5. Pour a minimum of 1 mL of the centrifuged cadaveric serum into the syringe.

   NOTE: Additional volume may be required based on the number of ABBOTT PRISM assays performed. Refer to the **Specimen Volume** section of this package insert.
6. While holding the filter syringe unit over the tube, insert the plunger and slowly apply pressure to deliver the filtered cadaveric serum.

   NOTE: A clogged filter will resist pressure and no additional sample volume will pass through.
7. If necessary, replace the clogged filter as follows:
   a. Remove the sterile filter from the package.
   b. Carefully invert the syringe to a **filter-side-up** position with the syringe plunger intact to prevent sample leakage. Gently remove the clogged filter and dispose of it in a potentially infectious waste container.
   c. Securely screw the syringe to the filter.
   d. Slowly apply pressure on the plunger to deliver the filtered cadaveric serum into the tube.
   e. Repeat this step as needed to successfully complete the filtration process.

   NOTE: Filtered cadaveric specimens that are not tested within 24 hours of initial centrifugation must be recentrifuged, but do not need to be refiltered.

Storage and Shipping

- Living donor specimens may be stored at 30°C or colder for up to 7 days, 2-8°C for up to 14 days or frozen at -20°C or colder for up to 6 months (inclusive of shipping time). Storage at a combination of 30°C or colder and 2-8°C may not exceed 14 days.
- Cadaveric serum specimens may be stored at 30°C or colder for up to 2 days; 2-8°C or -20°C or colder for up to 14 days (inclusive of shipping time). Storage at a combination of these temperatures may not exceed 14 days.
- Prior to freezing, the serum or plasma should be removed from the clot or red blood cells to avoid hemolysis.
- Living donor specimens stored at -20°C or colder for greater than 6 months and cadaveric donor serum stored at -20°C or colder for greater than 14 days may be used for informational purposes (*e.g.*, lookback testing, discordant sample testing, clinical and validation testing).
- For collection of specimens from cadaveric donors, follow general standards and/or regulations.
- When shipping specimens, package and label specimens in compliance with applicable regulations covering the transport of clinical specimens and infectious substances.
- Twenty-six nonreactive and 78 low-level reactive living donor specimens showed no qualitative performance differences when subjected to 6 freeze/thaw cycles. However, some specimens that have undergone multiple freeze/thaw cycles or have been stored frozen for prolonged periods may give erroneous or inconsistent test results.
- Twenty-five nonreactive and 24 low-level reactive cadaveric specimens that were received frozen, showed no qualitative performance differences when subjected to 1 additional freeze/thaw cycle. However, some cadaveric specimens that have undergone multiple freeze/thaw cycles or have been stored frozen for prolonged periods may give erroneous or inconsistent test results.

Specimen Volume
The specimen volume required to test a single sample on the ABBOTT PRISM System varies according to the number of assays configured, which assays are selected, and the type (size) of specimen container used. The ABBOTT PRISM HIV O Plus assay requires a 100 µL sample dispense. For ABBOTT PRISM Sample Cups, the minimum specimen volume required for one ABBOTT PRISM HIV O Plus assay is 400 µL. For either primary or aliquot tubes, or additional assay volume requirements, refer to the ABBOTT PRISM Operations Manual, Section 5.

PROCEDURE

Materials Provided
- REF 3L68-68 ABBOTT PRISM HIV O Plus Assay Kit

Materials Required but not Provided
- REF 3L68-58 ABBOTT PRISM HIV O Plus Wash Kit
- REF 1A75-02 or 3L27-02 ABBOTT PRISM ACTIVATOR CONCENTRATE
- REF 1A75-01 or 3L27-01 ABBOTT PRISM ACTIVATOR DILUENT
- REF 5A07-01 ABBOTT PRISM REACTION TRAYS
- REF 5A07-10 ABBOTT PRISM PIPETTE TIPS
- REF 6A36-60 ABBOTT PRISM Accessory Kit
- REF 3E60-10 ABBOTT PRISM Run Control Kit

  or
- REF 3E60-11 ABBOTT PRISM Positive Run Control Kit
- REF 6A36-31 ABBOTT PRISM RUN CONTROL ADAPTERS
- Protective Disposable Gloves
- Disinfectant
- Purified Water-rinsed or Clean Disposable Measuring Equipment

For Cadaveric Specimens Only
- REF 2P41-01 Millipore GV Filters
- 10 cc Sterile Syringes

Additional Materials Available
- REF 7B36-01 ABBOTT PRISM SAMPLE CUPS
- REF 1A75-10 or 3L27-10 ABBOTT PRISM ACTIVATOR LINE TREATMENT
- REF 7A03-01 or 3L00-01 ABBOTT PRISM PRIME/PURGE ACCESSORIES
- REF 7A03-30 or 3L00-30 ABBOTT PRISM PURGE CONCENTRATE
- REF 7A03-31 ABBOTT PRISM LINE CLEANER

ABBOTT PRISM HIV O Plus Assay Procedure
Key procedures that require operator interaction for testing samples are listed below. For detailed information concerning batch time, maximum batch size, reagent handling and loading and associated procedural steps, refer to the ABBOTT PRISM Operations Manual, Sections 2, 5, and 7.

- Enter a Plan Work Load (refer to the ABBOTT PRISM Operations Manual, Section 5).
- Replace reagents as needed (refer to the ABBOTT PRISM Operations Manual, Sections 5 and 7). Prepare diluted probe, if necessary. Refer to the **Preparation of the Diluted Probe** section of this package insert.

  NOTE: Gently invert each component several times prior to loading on the ABBOTT PRISM System to ensure a homogeneous solution. Additional gentle inversion may be required to thoroughly resuspend microparticles. Avoid foaming. **Gently** invert calibrators and assay controls in the calibrator pack several times prior to each use. Each component of the ABBOTT PRISM HIV O Plus Wash Kit should be at room temperature (15-30˚C) and then mixed before loading onto the ABBOTT PRISM System.
- Verify that all tubing label symbols match the symbols on each reagent label. (Refer to the symbol key in the **REAGENTS** section of this package insert and the ambient reagent bay and refrigerator diagrams provided with the ABBOTT PRISM System).
- **Verify that all tubing is securely fastened to the corresponding wash and reagent bottles.**
- Inspect the waste containers. Empty and clean as defined in the ABBOTT PRISM Operations Manual, Section 9, if necessary.
- Prepare activator solution (refer to the **Preparation of Activator Solution** section of this package insert) and load onto the ABBOTT PRISM System.
- Verify that an adequate number of ABBOTT PRISM Reaction Trays are in the Tray Loader.
- Verify that an adequate number of ABBOTT PRISM Pipette Tips are in the Pipette Tip Racks.
- Perform the prime procedure. (Refer to the ABBOTT PRISM Operations Manual, Section 5).
- Initiate sample processing. Gently invert calibrators and assay controls in the calibrator pack several times. Open the bottles in the calibrator pack and place in the calibrator rack. Load the calibrator rack and sample racks, including the run controls. (Refer to the **QUALITY CONTROL PROCEDURES, Controls,** Control Handling Procedure, in this package insert.)
- After the calibrators and positive assay controls have been automatically pipetted, remove the calibrator rack. Close the calibrator and positive assay control bottles and return them to 2-8˚C storage.
- Each specimen is initially tested once, unless the operator overrides this automatic function of the ABBOTT PRISM System.
- Sample racks may be removed after the samples have been pipetted.

  NOTE: No operator interaction is required for the following steps, which are automatically carried out by the ABBOTT PRISM System: reaction tray transport, calibrator/assay control/sample/release control pipetting, incubation, reagent dispense, sample reading, data reduction, run validity and result determination.
- After specimen processing is complete, perform the purge procedure. (Refer to the ABBOTT PRISM Operations Manual, Section 5).

Refer to the ABBOTT PRISM Operations Manual, Section 3, for a detailed description of ChLIA procedures. The ABBOTT PRISM HIV O Plus assay is a three-step ChLIA procedure.

QUALITY CONTROL PROCEDURES

Calibration
The ABBOTT PRISM HIV O Plus Negative and Positive Calibrators and the ABBOTT PRISM HIV O Plus HIV-2 Positive Assay Control (1) are automatically tested in triplicate at the beginning of each batch. The ABBOTT PRISM HIV O Plus HIV-1 Group O Positive Assay Control (2) is automatically tested once at the beginning of each batch. The ABBOTT PRISM System will not generate results when calibrator or positive assay control values do not meet specifications. This may indicate either deterioration or contamination of reagents or instrument failure.

Controls
1. The ABBOTT PRISM Positive Control **MUST** be included as the last sample in each batch as a release control. The operator is prompted to include this control as the last sample in every batch, and the ABBOTT PRISM Positive Control is automatically tested as a single replicate. This control must meet specifications defined in the ABBOTT PRISM Run Control package insert or the ABBOTT PRISM Positive Run Control package insert in order to validate the system functionality and release sample results. If this control does not meet specifications, refer to the ABBOTT PRISM Operations Manual, Section 10, for additional information.
2. Additional controls may be run at the operator's discretion (refer to the ABBOTT PRISM Operations Manual, Section 3).

   Invalidate controls: Additional controls may be run anywhere within a batch as an invalidate control. Specifications may be assigned to invalidating controls. If an invalidate control fails to meet assigned specifications, sample processing is shutdown and no sample results are calculated or provided by the instrument. When an invalidate control meets assigned specifications, sample processing continues, and a valid release control (ABBOTT PRISM Positive Control) result is required to release data.

   Non-validating controls: Additional controls may be run anywhere within a batch as a non-validating control. Specifications may be assigned to non-validating controls. A valid release control (ABBOTT PRISM Positive Control) result is required to release data. If the user-assigned specifications for the non-validating control(s) are not met and the release control specifications are met, there will be no effect on sample processing. In this case, reactive sample results must not be considered invalid.
3. Control Handling Procedure
   a. Place run control adapters into the sample rack. **The adapters can be placed in any rack position except 1, 2, 27, or 28.**
   b. Place each run control bottle into an adapter in the sample rack such that when the bottle flip-top cap is opened, it can be snapped into an open position within the adapter.
   c. As mentioned above, place an ABBOTT PRISM Positive Control after the last sample tested in the batch. **The controls can be placed in any rack position except 1, 2, 27, or 28.**

Refer to the ABBOTT PRISM Operations Manual, Section 3, for additional information on calibrators, assay controls, and run controls.

ASSAY PARAMETER SPECIFICATIONS

The ABBOTT PRISM HIV O Plus assay parameter specifications have been factory set. These parameters cannot be printed, displayed, or edited.

RESULTS

Calculation of Cutoff and S/CO Values

The ABBOTT PRISM System calculates the ABBOTT PRISM HIV O Plus assay cutoff value using the following formula:

Cutoff Value = Mean Negative Calibrator (NC) Net Counts + (0.15 × Mean Positive Calibrator [PC] Net Counts)

Example: Mean NC Net Counts = 1,000
Mean PC Net Counts = 12,000
1,000 + (0.15 × 12,000) = 2,800
Cutoff Value = 2,800

The ABBOTT PRISM System calculates the ABBOTT PRISM HIV O Plus assay S/CO for each sample and control using the following formula:

S/CO = Sample Net Counts ÷ Cutoff Value

Example: Sample Net Counts = 7,980
Cutoff Value = 2,800
7,980 ÷ 2,800 = 2.85
S/CO = 2.85

Interpretation of Results

- In the ABBOTT PRISM HIV O Plus assay, specimens with net counts less than the cutoff value are nonreactive and need not be tested further. Nonreactive specimens are considered negative for anti-HIV-1 and anti-HIV-2 by the criteria of the ABBOTT PRISM HIV O Plus assay.
- Specimens with net counts greater than or equal to the cutoff value are considered initially reactive by the criteria of the ABBOTT PRISM HIV O Plus assay. All initial reactive specimens retested within 24 hours of initial centrifugation do not require recentrifugation. All initial reactive specimens (excluding nonfrozen plasmapheresis) stored greater than 24 hours after initial centrifugation must be recentrifuged prior to retesting according to the **Preparation for Analysis** section of this package insert. Initially reactive specimens must be retested in duplicate using the ABBOTT PRISM HIV O Plus Assay Kit.
- If the sample net counts for both retests are less than the cutoff value, the specimen is nonreactive. Nonreactive specimens are considered negative for anti-HIV-1 and anti-HIV-2 by the criteria of the ABBOTT PRISM HIV O Plus assay.
- If the sample net counts for either duplicate retest are greater than or equal to the cutoff value, the specimen is considered repeatedly reactive. Repeatedly reactive results indicate the presence of anti-HIV-1 and/or anti-HIV-2 by the criteria of the ABBOTT PRISM HIV O Plus assay.
- Follow appropriate FDA recommendations and regulations for specimens found to be repeatedly reactive. Customers outside the US must follow their country's government recommendations and regulations for specimens found to be repeatedly reactive.
- Because of possible nonspecific reactions due to causes other than HIV infection, particularly when testing low prevalence populations (*e.g.*, blood donors), it is appropriate to further investigate specimens found to be repeatedly reactive by the ABBOTT PRISM HIV O Plus assay to prove that HIV antibodies are indeed present. Repeatedly reactive specimens obtained from people at increased risk for HIV infection are usually found to contain antibodies by supplemental tests, *e.g.*, Western blot, IFA, or RIPA.
- Although the association of infectivity of donated blood or plasma and the presence of anti-HIV-1/HIV-2 is strong, it is recognized that presently available methods for anti-HIV-1/HIV-2 detection are not sensitive enough to detect all potentially infectious units of blood, plasma, or possible cases of HIV-1/HIV-2 infection. A nonreactive test result does not exclude infection.

Reading Results

Some S/CO values may be flagged with "<" or ">" symbols. For more information on sample reports, refer to the ABBOTT PRISM Operations Manual, Section 5: Operating Instructions, Reports. The ABBOTT PRISM System reports sample results in net counts and S/CO. Net Counts are used by the ABBOTT PRISM System to interpret results. The S/CO value is provided in reports to show reactivity relative to the cutoff value. In the ABBOTT PRISM HIV O Plus assay, specimens with S/CO values of less than 1.00 are reported as nonreactive. Specimens with an S/CO value of greater than or equal to 1.00 are reported as reactive.

System Errors

For a description of the error codes that appear on ABBOTT PRISM System reports, refer to the ABBOTT PRISM Operations Manual, Section 10.

LIMITATIONS OF THE PROCEDURE

- This assay was designed and validated for use with individual human serum and plasma specimens. This assay has not been validated for use with pooled specimens.
- **Do not use specimens collected in heparin. Use of heparin as an anticoagulant may cause a reduction in sample net counts and in S/CO for ABBOTT PRISM HCV; therefore, heparin is not recommended for any ABBOTT PRISM assay.**
- For living donors and cadaveric (non-heart-beating) donors, serum from heparinized patients may be incompletely coagulated resulting in potential instrument errors such as drain time errors due to the presence of fibrin. To prevent this phenomenon, draw specimen prior to heparin therapy or after heparin therapy is discontinued and activated partial thromboplastin time (aPTT) levels return within normal range.
- False-reactive test results can be expected with any test kit. False-reactive test results have been observed due to nonspecific interactions. Refer to the **SPECIFIC PERFORMANCE CHARACTERISTICS** section of this package insert for assay performance characteristics.
- Some specimens that have undergone multiple freeze/thaw cycles or have been stored frozen for prolonged periods may result in erroneous or inconsistent test results.
- An increased occurrence of drain time errors may be observed for cadaveric specimens.
- Do not use cadaveric **plasma** specimens.
- All specimens, except nonfrozen plasmapheresis specimens, must be centrifuged according to the **Preparation For Analysis** section of this package insert prior to running the assay.
- Inadequate centrifugation of nonfrozen plasma specimens can lead to elevated reactive rates due to platelet interference.
- Performance has not been established using umbilical cord blood or body fluids such as urine, saliva, semen, amniotic fluid, cerebrospinal fluid, or pleural fluid. These specimens should not be tested using the ABBOTT PRISM HIV O Plus assay.
- Do not use heat-inactivated specimens.
- Do not use specimens with obvious microbial contamination or gross lipemia.
- Do not use specimens with obvious gross hemolysis (dark red to black). No qualitative performance differences were observed when living donor specimens were spiked with 500 mg/dL of hemoglobin. No qualitative performance differences were observed for living donor specimens with up to 1690 mg/dL endogenous levels of hemoglobin. No qualitative performance differences were observed for cadaveric donor specimens with up to 631 mg/dL of hemoglobin.
- Avoid microbial contamination of reagents or wash kit components by carefully following handling precautions within this package insert.
- The ABBOTT PRISM HIV O Plus assay does not discriminate between HIV-1 and HIV-2 antibody reactivity.
- A test result that is negative does not exclude the possibility of exposure to or infection with HIV-1 and/or HIV-2. Negative results in this assay in individuals with prior exposure to HIV-1 and/or HIV-2 may be due to antibody levels below the limit of detection of this assay or lack of antibody reactivity to the HIV antigens used in this assay.
- The presence of HIV-1 and/or HIV-2 antibodies is not a diagnosis of AIDS. Follow appropriate FDA recommendations for specimens found to be repeatedly reactive. Individuals who are repeatedly reactive should be referred for medical evaluation, which may include additional testing.
- A person who has antibodies to HIV-1 is presumed to be infected with the virus, except a person who has participated in an HIV vaccine study who may have developed antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation, and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.

SPECIFIC PERFORMANCE CHARACTERISTICS

Assay Reproducibility

Assay reproducibility was determined by testing a 6-member panel consisting of 1 specimen nonreactive for anti-HIV-1/HIV-2 (panel member 1), 2 diluted specimens reactive for anti-HIV-1 (panel members 2 and 3), 2 diluted specimens reactive for anti-HIV-2 (panel members 4 and 5), and 1 diluted specimen reactive for anti-HIV-1 Group O (panel member 6). Panel members were prepared in recalcified human plasma. Each panel member was tested in replicates of 4 in 5 runs over 5 days with each of 3 reagent lots at 5 sites. The Negative, Positive, and Supplemental Positive Controls were tested once at the beginning and end of each run on each subchannel. The Negative and Positive Calibrators, HIV-2 Positive Assay Control (1), and HIV-1 Group O Positive Assay Control (2) were tested in triplicate at the beginning of each run on each subchannel. The intra-assay and inter-assay standard deviation (SD) and percent coefficient of variation (%CV) were determined with a variance component analysis[34] for a random effects model[35] (Table IV).

Table IV
ABBOTT PRISM HIV O Plus Assay Reproducibility

Panel Member or Control	Number of Replicates	Mean S/CO[a]	Intra-assay SD	Intra-assay %CV	Inter-assay[b] SD	Inter-assay[b] %CV
1	300	0.29	0.027	9.3	0.028	9.6
2	300	3.20	0.139	4.3	0.151	4.7
3	299[c]	7.30	0.302	4.1	0.363	5.0
4	298[d]	3.01	0.086	2.9	0.149	4.9
5	298[c,e]	7.00	0.208	3.0	0.337	4.8
6	300	3.10	0.110	3.5	0.172	5.6
Negative Control	300	0.31	0.028	9.0	0.029	9.4
Positive Control	300	2.83	0.124	4.4	0.128	4.5
Supplemental Positive Control	300	2.67	0.086	3.2	0.146	5.5
HIV-1 Group O Positive Assay Control (2)	450	5.87	0.245	4.2	0.302	5.1

[a] Cutoff Value = Mean Negative Calibrator Net Counts + (0.15 × Mean Positive Calibrator Net Counts)

Calibrator or Control	Number of Replicates	Mean Net Counts	Intra-assay SD	Intra-assay %CV	Inter-assay SD	Inter-assay %CV
Negative Calibrator	448[f]	731	43.3	5.9	57.9	7.9
Positive Calibrator	448[f]	9,800	476.4	4.9	642.7	6.6
HIV-2 Positive Assay Control (1)	450	10,107	354.9	3.5	504.3	5.0

[b] Inter-assay variability includes intra-assay variability.

[c] One replicate was invalid due to instrument detection of high dark counts.

[d] Two replicates were removed because the sample was suspected of being contaminated.

[e] One replicate that had an S/CO value of 32.13 was excluded from the analysis. When this replicate was included in the analysis, the mean S/CO was 7.09, the intra-assay SD was 1.434, the intra-assay %CV was 20.2, the inter-assay SD was 1.480, and the inter-assay %CV was 20.9.

[f] Two replicates were invalid due to instrument detection of high dark counts.

Assay Specificity

A total of 6,284 fresh serum specimens and 6,181 fresh plasma specimens from volunteer blood donors were collected and tested at 4 geographically distinct blood centers (Table V). A total of 3,134 specimens from plasmapheresis donors were collected and tested at a fifth geographically distinct blood center (Table V). The initial and repeat reactive rates for the serum specimens were 0.06% (4/6,284) and 0.03% (2/6,284), respectively. Both the initial and repeat reactive rates for the plasma specimens were 0.08% (5/6,181). Both the initial and repeat reactive rates for the plasmapheresis donor specimens were 0.10% (3/3,134). Repeatedly reactive specimens were further tested using an FDA-licensed HIV-1 Western blot, an FDA-licensed HIV-2 EIA, and a research use only HIV-2 Western blot. Based on these supplemental test results, 8 of the 10 specimens were negative and 2 specimens were indeterminate.

Specificity based on assumed zero prevalence of antibody to HIV-1 and/or HIV-2 in blood donors was estimated in these studies to be 99.94% (15,589/15,599) with a 95% confidence interval of 99.88% to 99.97%.

An internal study was performed to evaluate 342 serum and plasma repository specimens collected from individuals with medical conditions unrelated to HIV infection (Table V). Four of the 342 specimens (1.17%) were initially reactive and 3 of these specimens (0.88%) were repeatedly reactive. Of the 3 repeatedly reactive specimens, 2 were negative by supplemental testing and 1 was indeterminate.

An internal study was performed to evaluate 166 specimens collected from pregnant females. Specimens were collected during each trimester of pregnancy (Table V). Both the initial and repeat reactive rates for these specimens were 0.60% (1/166). The repeatedly reactive specimen was negative by supplemental testing.

An internal study was performed to evaluate 77 serum specimens containing potentially interfering substances (Table V). The initial and repeat reactive rates for these specimens were both 5.19% (4/77). Three specimens were positive and 1 specimen was negative by supplemental testing.

Table V
Reactivity of the ABBOTT PRISM HIV O Plus Assay in Blood Donors, in Specimens from Individuals with Medical Conditions Unrelated to HIV Infection, in Pregnant Females, and in Specimens Containing Potentially Interfering Substances

Category	Number Tested	IR (% of Total) (95% CI)	RR (% of Total) (95% CI)
Volunteer Donors			
Serum	6,284	4 (0.06) (0.02 - 0.16)	2 (0.03) (0.00 - 0.11)
Plasma	6,181	5 (0.08) (0.03 - 0.19)	5 (0.08) (0.03 - 0.19)
Plasmapheresis Donors	3,134	3 (0.10) (0.02 - 0.28)	3 (0.10) (0.02 - 0.28)
Total Donors	15,599	12 (0.08) (0.04 - 0.13)	10 (0.06) (0.03 - 0.12)
Medical Conditions Unrelated to HIV Infection[a]	342	4 (1.17)	3 (0.88)[b]
Pregnant Females	166	1 (0.60)	1 (0.60)
Specimens Containing Potentially Interfering Substances[c]	77	4 (5.19)	4 (5.19)

IR = Initially Reactive; RR = Repeatedly Reactive; CI = Confidence Interval

[a] Specimens from individuals with medical conditions unrelated to HIV infection included the following categories: anti-CMV positive (17), anti-EBV positive (18), anti-HSV positive (21), acute and recovered HAV infection (16), anti-HBs positive (20), anti-HTLV-I/HTLV-II positive (21), anti-HCV positive (27), rubella antibody positive (26), toxoplasma antibody positive (20), *E. coli* infections (1), yeast infection (13) syphilis serology positive (17), anti-nuclear antibody positive (17), rheumatoid factor positive (17), influenza vaccine recipients (46), small pox vaccine recipients (10), elevated IgG and elevated IgM (12), and oncology (23).

[b] The 3 repeatedly reactive specimens included the following categories: anti-CMV positive, anti-HBs positive, and anti-HTLV-I/HTLV-II positive.

[c] Specimens contained the following potentially interfering substances: elevated triglycerides (28), elevated bilirubin (26), and elevated hemoglobin (23).

Assay Sensitivity

A total of 1,388 serum and plasma specimens from individuals known to be positive for HIV antibodies were tested with the ABBOTT PRISM HIV O Plus assay (Table VI). Of the 1,388 specimens tested, 1,388 specimens (100.00%) were repeatedly reactive.

Plasma specimens from individuals at increased risk for HIV infection were tested with the ABBOTT PRISM HIV O Plus assay (Table VI). This study included a total of 605 specimens from the United States and 512 specimens from an HIV-2 endemic area (Republic of Côte d'Ivoire). Of the 1,117 specimens tested, 156 specimens (13.97%) were repeatedly reactive. Of the 156 repeatedly reactive specimens, 136 specimens (87.18%) tested positive by supplemental testing.

The overall sensitivity was estimated in these studies to be 100.00% (1,524/1,524) with a 95% confidence interval of 99.76% to 100.00%.

Table VI
Reactivity of the ABBOTT PRISM HIV O Plus Assay in Individuals Known to be Positive for HIV Antibodies, and at Increased Risk for HIV Infection

Category	Number Tested	ABBOTT PRISM HIV O Plus Number RR (% of Total)	Number Positive by Supplemental Testing (% of RR)
Preselected Anti-HIV-1 Positive[a]	1,007	1,007 (100.00)	1,007 (100.00)
Preselected Anti-HIV-2 Positive	328	328 (100.00)	328 (100.00)
Anti-HIV-1 Group O Positive[b]	53	53 (100.00)	53 (100.00)
Increased Risk for HIV Infection			
United States[c]	605	71 (11.74)	55 (77.46)
HIV-2 Endemic Area[d]	512	85 (16.60)	81 (95.29)
Total	2,505[e]	1,544 (61.64)	1,524 (98.70)

RR = Repeatedly Reactive

[a] The preselected anti-HIV-1 positive category included 809 specimens from asymptomatic individuals, 99 specimens from symptomatic individuals, and 99 specimens from individuals diagnosed with AIDS.

[b] Thirty-one specimens were diluted 1:10, 18 specimens were diluted 1:20, and 4 specimens were undiluted.

[c] The following risk factors were included: sex with HIV infected partner, men who have sex with men, intravenous drug users, multiple sex partners, and patients with sexually transmitted diseases.

[d] The following risk factors were included: sex with an HIV infected partner, men who have sex with men, intravenous drug users, and multiple sex partners.

[e] Of these 2,505 specimens, an additional 5 specimens were determined to be repeatedly reactive by a licensed reference test and negative by the ABBOTT PRISM HIV O Plus Assay. Of the additional 5 specimens, none were positive by supplemental testing.

An internal study was performed to test specimens from individuals known to be positive for HIV-1 Group M antibodies. The Group M subtypes included in this study are shown in Table VII. A total of 276 plasma specimens were tested with the ABBOTT PRISM HIV O Plus assay. Of these 276 specimens tested, 276 specimens (100.00%) were reactive.

Table VII
HIV-1 Group M Subtypes Tested

Subtype	ABBOTT PRISM HIV O Plus Number Tested
A	23
B	14
C	14
D	20
F	4
G	16
CRF01[a]	61
CRF02	22
CRF09	1
CRF11	11
CRF13	3
URF[b]	87
Total	276

[a] CRF = circulating recombinant form

[b] URF = unique recombinant form

Sensitivity was also evaluated using 160 serial bleeds from 20 commercially available seroconversion panels. Each specimen was tested with the ABBOTT PRISM HIV O Plus assay, which detected the presence of HIV antibody at the same time or earlier than an FDA-licensed HIV-1/HIV-2 assay (Table VIII).

Table VIII
Performance of the ABBOTT PRISM HIV O Plus Assay on Seroconverting Donors Compared to an FDA-licensed HIV-1/HIV-2 Assay

Panel	Number Tested	ABBOTT PRISM HIV O Plus Number RR	FDA-licensed HIV-1/HIV-2 Assay Number RR
9077	28	14	14
BCP6243	10	3	3
PRB910	7	5	5
PRB916	6	2	2
PRB923	13	5[a]	4
PRB924	8	3	3
PRB925	6	2	2
PRB926	6	2	2
PRB928	5	4	4
PRB931	9	4	4
PRB932	8	5	5
PRB940	8	6	6
PRB941	6	3	3
PRB944	6	2	2
PRB947	4	3	3
PRB951	6	1	1
PRB955	5	2	2
PRB959	7	5	5
SV0321	5	3	3
SV0401	7	4	4
Total	160	78	77

RR = Repeatedly Reactive

[a] One of the 5 reactive specimens was negative with an FDA-licensed HIV-1/HIV-2 assay and a Western blot. It was positive with both an HIV-1 antigen and a PCR assay.

PERFORMANCE CHARACTERISTICS OF CADAVERIC SERUM TESTING

Reproducibility

Twenty-four postmortem serum specimens, collected up to 18.2 hours after death, and 30 living donor serum specimens were spiked with human plasma reactive for anti-HIV-1 or anti-HIV-2 to create low-level reactive specimens. Each specimen was tested once per day over 6 different days with each of 3 ABBOTT PRISM HIV O Plus reagent lots. Inter-assay and total %CV values were determined (Table IX).

Table IX
ABBOTT PRISM HIV O Plus Assay Reproducibility

Specimen Category	Number of Replicates	Mean S/CO	Between-Specimen SD	Between-Specimen %CV	Total[a] SD	Total[a] %CV
Postmortem	432	4.64	0.506	10.9	0.717	15.4
Living Donor	540	4.11	0.454	11.0	0.688	16.8

[a] Total variability includes within-specimen, between-specimen, between-lot, and specimen-lot interaction variance components.

Specificity

Assay specificity was determined by testing postmortem serum specimens, collected up to 18.8 hours after death, and living donor serum specimens. Each specimen was tested once. Three ABBOTT PRISM HIV O Plus reagent lots were used (Table X).

Table X
ABBOTT PRISM HIV O Plus Assay Reactivity

Specimen Category	Number of Specimens	Median S/CO	Nonreactive (% of Total)	Initial Reactive (% of Total)
Postmortem	56	0.35	56 (100.00)	0 (0.00)
Living Donor	60	0.25	60 (100.00)	0 (0.00)

The ABBOTT PRISM HIV O Plus assay has an estimated specificity of 100.00% (56/56) (95% binomial confidence interval of 93.62% - 100.00%) for postmortem serum specimens.

Sensitivity

Postmortem specimens, collected up to 20.5 hours after death, and living donor specimens were spiked with human plasma reactive for anti-HIV-1 or anti-HIV-2 to create low-level reactive specimens.[a] Each specimen was tested once on each of 3 ABBOTT PRISM HIV O Plus reagent lots (Table XI).

Table XI
ABBOTT PRISM HIV O Plus Assay Reactivity

Specimen Category	Number of Specimens	Mean S/CO	Nonreactive (% of Total)	Initial Reactive (% of Total)
Postmortem	59	4.08	0 (0.00)	59 (100.00)
Living Donor	60	3.10	0 (0.00)	60 (100.00)

The ABBOTT PRISM HIV O Plus assay has an estimated sensitivity of 100.00% (95% binomial confidence interval of 93.94% - 100.00%) for postmortem serum specimens.

[a] Spiked reactive samples were initially tested within 24 hours of spiking.

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ABBOTT PRISM
Run Control Kit

REF 3E60-10

G1-0321/R10

Revised June 2014

ABBOTT PRISM
Run Control Kit

Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to Symbols

LOT	Lot Number		Manufacturer
REF	List Number	CONTROL +	Positive Control
IVD	*In Vitro* Diagnostic Medical Device	CONTROL −	Negative Control
	Consult instructions for use	CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
	Caution	PRODUCT OF USA	Product of USA
2°C 8°C	Store at 2-8°C	RUN CONTROL ADAPTERS	Run Control Adapters
	Expiration Date		

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

Abbott

NAME AND INTENDED USE

The ABBOTT PRISM Run Control Kit contains multi-constituent positive controls and a negative control for use as quality controls with the ABBOTT PRISM Assay Kits. The ABBOTT PRISM Positive Control is required as a release control and must be tested as the last sample in each batch to validate system function and release sample results. The ABBOTT PRISM Supplemental Positive and Negative Controls can be used at any point in a batch as a quality control.

SUMMARY AND EXPLANATION OF THE TEST

Refer to the ABBOTT PRISM assay package inserts.

REAGENTS

Kit contains:

- CONTROL + 2 Bottles (10 mL each) Positive Control (Human). Purified anti-HBc IgG (Concentration: 0.9 - 2.6 PEI* Units/mL) and recalcified inactivated plasma reactive for HBsAg (Concentration: 0.10 - 0.40 ng/mL), anti-HCV (Minimum activity: 1.02 sample to cutoff [S/CO]), anti-HIV-1 (Minimum activity: 1.02 S/CO) and anti-HTLV-I (Minimum activity: 1.02 S/CO). Plasma is also tested for HIV-1 either by an HIV-1 antigen test and is nonreactive, or by an HIV-1 NAT, and may be reactive. Positive Control may be cross-reactive with HTLV-II antigens. Preservative: 0.1% sodium azide. (Symbol: POS)
- SUP CONTROL + 1 Bottle (10 mL) Supplemental Positive Control (Human). Recalcified inactivated plasma reactive for anti-HIV-2 (Minimum activity: 1.02 S/CO) and anti-HTLV-II (Minimum activity: 1.02 S/CO). Supplemental Positive Control may be cross-reactive with HTLV-I antigens. Preservative: 0.1% sodium azide. (Symbol: SUP)
- CONTROL – 2 Bottles (10 mL each) Negative Control (Human). Recalcified plasma. Preservative: 0.1% sodium azide. (Symbol: NEG)

*Concentration standardized against the reference standard of the Paul Ehrlich Institute (PEI), Langen, Germany.

WARNINGS AND PRECAUTIONS

- IVD
- **For *In Vitro* Diagnostic Use.**
- This kit is a quality control for ABBOTT PRISM Assay Kits.
- Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Safety Precautions

- ⚠ **CAUTION: This product contains human-sourced and/or potentially infectious components. Refer to the REAGENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens.[1] Biosafety Level 2[2] or other appropriate biosafety practices[3,4] should be used for materials that contain or are suspected of containing infectious agents. These precautions include, but are not limited to, the following:**
  - Wear gloves when handling specimens or reagents.
  - Do not pipette by mouth.
  - Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where specimens or reagents are handled.
  - Clean and disinfect all spills of specimens or reagents using an appropriate disinfectant such as 0.1% sodium hypochlorite, or other suitable disinfectant.[5,6]
  - Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.[7,8]
- The human plasma used in the positive control is reactive for HBsAg, anti-HCV, anti-HIV-1, and anti-HTLV-I. Plasma is also tested for HIV-1 either by an HIV-1 antigen test and is nonreactive, or by an HIV-1 NAT, and may be reactive. Positive Control may be cross-reactive with HTLV-II antigens.
- The human plasma used in the supplemental positive control is reactive for anti-HIV-2 and anti-HTLV-II. Plasma is nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, and anti-HCV. Supplemental Positive Control may be cross-reactive with HTLV-I antigens.
- The human plasma used in the negative control is nonreactive for anti-HBc, anti-HBs, anti-HTLV-I/HTLV-II, HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.
- This product contains sodium azide; for a specific listing, refer to the **REAGENTS** section of this package insert. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.
- Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

Handling Precautions

- Do not use controls beyond the expiration date.
- Do not mix controls from different bottles.
- Do not freeze controls.
- Failure to adhere to instructions in the ABBOTT PRISM Operations Manual or package insert may result in erroneous test results.
- Use caution when handling samples, control bottles, and control caps to prevent cross contamination.

Storage Instructions

- The ABBOTT PRISM Positive, Supplemental Positive, and Negative Controls must be stored at 2-8˚C.
- When stored and handled as directed, controls are stable until the expiration date.

Indications of Instability or Deterioration of Reagents

The presence of precipitates or particulate matter may indicate instability or deterioration of reagents, and those reagents should not be used.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Not applicable. Refer to the **ABBOTT PRISM ASSAY PROCEDURE** and **QUALITY CONTROL PROCEDURES** sections of the ABBOTT PRISM assay package inserts for details.

PROCEDURE

Materials Provided

- REF 3E60-10 ABBOTT PRISM Run Control Kit

Materials Required but not Provided

- REF 6A36-31 ABBOTT PRISM RUN CONTROL ADAPTERS

For use with

- REF 6E66-68 ABBOTT PRISM HBcore Assay Kit
- REF 6D19-68 ABBOTT PRISM HBsAg Assay Kit
- REF 3L68-68 ABBOTT PRISM HIV O Plus Assay Kit
- REF 6D18-68 ABBOTT PRISM HCV Assay Kit
- REF 6E50-68 ABBOTT PRISM HTLV-I/HTLV-II Assay Kit
- REF 6E51-68 ABBOTT PRISM HBsAg Confirmatory Kit

Refer to the **ABBOTT PRISM ASSAY PROCEDURE** and **QUALITY CONTROL PROCEDURES** sections of the ABBOTT PRISM assay package inserts for details.

Instructions For Use

1. Before use, thoroughly mix the contents of the run control bottle by gently inverting several times. Avoid foaming. It is not necessary to bring the material to room temperature prior to placing on the instrument.
2. Refer to the **ABBOTT PRISM ASSAY PROCEDURE** and **QUALITY CONTROL PROCEDURES** sections of the ABBOTT PRISM assay package inserts for details.

INTERPRETATION OF RESULTS

Control results are interpreted in the same manner as sample results. The following table details the acceptable Sample to Cutoff ratio (S/CO) specifications for the ABBOTT PRISM Positive, Negative, and Supplemental Positive Controls for each assay. Refer to the **Interpretation of Results** section of the ABBOTT PRISM assay package inserts for details.

ABBOTT PRISM Run Control Specifications
S/CO Ranges

	HBsAg	HBcore	HCV	HIV O Plus	HTLV-I/ HTLV-II
Positive Control	1.02 to 6.00	0.20 to 0.98	1.02 to 6.00	1.02 to 6.00	1.02 to 6.00
Negative Control	0.02 to 0.98	1.02 to 4.00	0.02 to 0.98	0.02 to 0.98	0.02 to 0.98
Supplemental Positive Control	Not applicable	Not applicable	Not applicable	1.02 to 6.00	1.02 to 6.00

LIMITATIONS OF THE PROCEDURE

Refer to the ABBOTT PRISM assay package inserts.

EXPECTED VALUES

The ABBOTT PRISM Positive Control is designed to yield a reactive result and the ABBOTT PRISM Negative Control a nonreactive result with each ABBOTT PRISM chemiluminescent immunoassay (ChLIA). The ABBOTT PRISM Supplemental Positive Control is designed to yield a reactive result with the ABBOTT PRISM HIV O Plus and HTLV-I/HTLV-II assays.

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3. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
4. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline—Third Edition*. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute, 2005.
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7. Clinical and Laboratory Standards Institute. *Clinical Laboratory Waste Management: Approved Guideline—Second Edition*. CLSI Document GP5-A2. Wayne, PA: Clinical and Laboratory Standards Institute, 2002;22(3):1–23, 32–44.
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June 2014

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ABBOTT PRISM
Positive Run Control Kit
REF 3E60-11
G1-0322/R10

ABBOTT PRISM
Positive Run Control Kit

Revised June 2014

Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to Symbols

LOT	Lot Number		Expiration Date
REF	List Number		Manufacturer
IVD	*In Vitro* Diagnostic Medical Device	CONTROL +	Positive Control
	Consult instructions for use	CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
	Caution	PRODUCT OF USA	Product of USA
2°C 8°C	Store at 2-8°C	RUN CONTROL ADAPTERS	Run Control Adapters

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

Abbott

NAME AND INTENDED USE

The ABBOTT PRISM Positive Run Control Kit contains a multi-constituent positive control for use as quality control with the ABBOTT PRISM Assay Kits. The ABBOTT PRISM Positive Control is required as a release control and must be tested as the last sample in each batch to validate system function and release sample results.

SUMMARY AND EXPLANATION OF THE TEST

Refer to the ABBOTT PRISM assay package inserts.

REAGENTS

Kit contains:

- CONTROL + 6 Bottles (10 mL each) Positive Control (Human). Purified anti-HBc IgG (Concentration: 0.9 - 2.6 PEI* Units/mL) and recalcified inactivated plasma reactive for HBsAg (Concentration: 0.10 - 0.40 ng/mL), anti-HCV (Minimum activity: 1.02 sample to cutoff [S/CO]), anti-HIV-1 (Minimum activity: 1.02 S/CO) and anti-HTLV-I (Minimum activity: 1.02 S/CO). Plasma is also tested for HIV-1 either by an HIV-1 antigen test and is nonreactive, or by an HIV-1 NAT, and may be reactive. Positive Control may be cross-reactive with HTLV-II antigens. Preservative: 0.1% sodium azide. (Symbol: POS)

*Concentration standardized against the reference standard of the Paul Ehrlich Institute (PEI), Langen, Germany.

WARNINGS AND PRECAUTIONS

- IVD
- **For *In Vitro* Diagnostic Use.**
- This kit is a quality control for ABBOTT PRISM Assay Kits.
- Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Safety Precautions

- **CAUTION: This product contains human-sourced and/or potentially infectious components. Refer to the REAGENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens.[1] Biosafety Level 2[2] or other appropriate biosafety practices[3,4] should be used for materials that contain or are suspected of containing infectious agents. These precautions include, but are not limited to, the following:**
  - Wear gloves when handling specimens or reagents.
  - Do not pipette by mouth.
  - Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where specimens or reagents are handled.
  - Clean and disinfect all spills of specimens or reagents using an appropriate disinfectant such as 0.1% sodium hypochlorite, or other suitable disinfectant.[5,6]
  - Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.[7,8]
- The human plasma used in the positive control is reactive for HBsAg, anti-HCV, anti-HIV-1, and anti-HTLV-I. Plasma is also tested for HIV-1 either by an HIV-1 antigen test and is nonreactive, or by an HIV-1 NAT, and may be reactive. Positive Control may be cross-reactive with HTLV-II antigens.
- This product contains sodium azide; for a specific listing, refer to the **REAGENTS** section of this package insert. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.
- Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

Handling Precautions

- Do not use controls beyond the expiration date.
- Do not mix controls from different bottles.
- Do not freeze controls.
- Failure to adhere to instructions in the ABBOTT PRISM Operations Manual or package insert may result in erroneous test results.
- Use caution when handling samples, control bottles, and control caps to prevent cross contamination.

Storage Instructions

- The ABBOTT PRISM Positive Control must be stored at 2-8˚C.
- When stored and handled as directed, controls are stable until the expiration date.

Indications of Instability or Deterioration of Reagents

The presence of precipitates or particulate matter may indicate instability or deterioration of reagents, and those reagents should not be used.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Not applicable. Refer to the **ABBOTT PRISM ASSAY PROCEDURE** and **QUALITY CONTROL PROCEDURES** sections of the ABBOTT PRISM assay package inserts for details.

PROCEDURE

Materials Provided

- REF 3E60-11 ABBOTT PRISM Positive Run Control Kit

Materials Required but not Provided

- REF 6A36-31 ABBOTT PRISM RUN CONTROL ADAPTERS

For use with

- REF 6E66-68 ABBOTT PRISM HBcore Assay Kit
- REF 6D19-68 ABBOTT PRISM HBsAg Assay Kit
- REF 3L68-68 ABBOTT PRISM HIV O Plus Assay Kit
- REF 6D18-68 ABBOTT PRISM HCV Assay Kit
- REF 6E50-68 ABBOTT PRISM HTLV-I/HTLV-II Assay Kit

Refer to the **ABBOTT PRISM ASSAY PROCEDURE** and **QUALITY CONTROL PROCEDURES** sections of the ABBOTT PRISM assay package inserts for details.

Instructions For Use

1. Before use, thoroughly mix the contents of the run control bottle by gently inverting several times. Avoid foaming. It is not necessary to bring the material to room temperature prior to placing on the instrument.
2. Refer to the **ABBOTT PRISM ASSAY PROCEDURE** and **QUALITY CONTROL PROCEDURES** sections of the ABBOTT PRISM assay package inserts for details.

INTERPRETATION OF RESULTS

Control results are interpreted in the same manner as sample results. The following table details the acceptable Sample to Cutoff ratio (S/CO) specifications for the ABBOTT PRISM Positive Control for each assay. Refer to the **Interpretation of Results** section of the ABBOTT PRISM assay package inserts for details.

ABBOTT PRISM Positive Run Control Specifications
S/CO Ranges

	HBsAg	HBcore	HCV	HIV O Plus	HTLV-I/ HTLV-II
Positive Control	1.02 to 6.00	0.20 to 0.98	1.02 to 6.00	1.02 to 6.00	1.02 to 6.00

LIMITATIONS OF THE PROCEDURE

Refer to the ABBOTT PRISM assay package inserts.

EXPECTED VALUES

The ABBOTT PRISM Positive Control is designed to yield a reactive result with each ABBOTT PRISM chemiluminescent immunoassay (ChLIA).

BIBLIOGRAPHY

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6. Sehulster LM, Hollinger FB, Dreesman GR, *et al*. Immunological and biophysical alteration of hepatitis B virus antigens by sodium hypochlorite disinfection. *Appl Envir Microbiol* 1981;42:762-767.
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