ABBOTT PRISM Run Control Kit

Customer Service
United States: 1-877-4ABBOTT

ABBOTT LABORATORIES
Diagnostics Division
Abbott Park, Illinois 60064

List No. 3E60-10
Printed in U.S.A.

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:

- 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, anti-HIV-1, and anti-HTLV-I. Plasma is also tested for HIV-1 by either HIV-1 Ag and is nonreactive, or by HIV-1 NAT, and may be reactive. Positive Control may be cross-reactive with antibody to HTLV-II. Preservative: 0.1% sodium azide. (Symbol: POS)
- 1 Bottle (10 mL) Supplemental Positive Control (Human). Recalcified, inactivated plasma reactive for anti-HIV-2 and anti-HTLV-II, nonreactive for HBsAg, anti-HCV and HIV-1 Ag or HIV-1 NAT. Supplemental Positive Control may be cross-reactive with antibody to HTLV-I. Preservative: 0.1% sodium azide. (Symbol: SUP)
- 2 Bottles (10 mL each) Negative Control (Human). Recalcified plasma nonreactive for HBsAg, HIV-1 Ag or HIV-1 NAT, anti-HCV, anti-HIV-1/HIV-2, anti-HBc, anti-HBs, and anti-HTLV-I/HTLV-II. Preservative: 0.1% sodium azide. (Symbol: NEG)

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

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use.

This kit is a quality control for ABBOTT PRISM Assay Kits.

Safety Precautions

CAUTION: This product contains human sourced and/or potentially infectious components. Some components sourced from human blood have been tested and found to be reactive for HBsAg, anti-HCV, anti-HIV-1/HIV-2, anti-HBc, and anti-HTLV-I/HTLV-II, by FDA licensed tests. Refer to the REAGENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources will not transmit infection. Therefore, all human sourced materials must 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 these materials are handled.
- Clean and disinfect all spills of specimens or reagents using a tuberculocidal disinfectant, such as 0.5% sodium hypochlorite, or other suitable disinfectants.[5,6]
- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.[7,8]

- All components of this product contain sodium azide. Sodium azide has been reported to form lead or copper azide in laboratory plumbing. These azides may explode upon percussion, such as hammering. To prevent formation of lead or copper azide, flush drains thoroughly with water after disposing of solutions containing sodium azide. To remove contamination from old drains suspected of azide accumulation, the National Institute for Occupational Safety and Health recommends the following: (1) siphon liquid from trap using a rubber or plastic hose, (2) fill drain with 10% sodium hydroxide solution, (3) allow to stand for 16 hours, and (4) flush well with water.
- All components of this product contain sodium azide and are classified per applicable European Community (EC) Directives as: Harmful (Xn). The following are the appropriate Risk (R) and Safety (S) phrases for these components.

R22 Harmful if swallowed.
R32 Contact with acids liberates very toxic gas.
S35 This material and its container must be disposed of in a safe way.
S36 Wear suitable protective clothing.
S46 If swallowed, seek medical advice immediately and show this container or label.

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.

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

- No. 3E60-10 ABBOTT PRISM Run Control Kit

Materials Required but not Provided

- No. 6A36-31 ABBOTT PRISM Run Control Adapters

For use with

- No. 6E66-68 ABBOTT PRISM HBcore Assay Kit
- No. 6D19-68 ABBOTT PRISM HBsAg Assay Kit
- No. 3D17-68 ABBOTT PRISM HIV O Plus Assay Kit
- No. 6D18-68 ABBOTT PRISM HCV Assay Kit

- No. 6E50-68 ABBOTT PRISM HTLV-I/HTLV-II Assay Kit
- No. 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	N/A	N/A	N/A	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.

BIBLIOGRAPHY

1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*, Fourth Edition. Washington, DC: US Government Printing Office, May 1999.
3. World Health Organization. *Laboratory Biosafety Manual*. 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.
5. CDC, Guidelines for the Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers. *MMWR* 1989,38, (S-6);16S.
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.
7. National Committee for Clinical Laboratory Standards. *Clinical Laboratory Waste Management*: Approved Guideline-Second Edition. NCCLS Document GP5-A2. Wayne, PA: NCCLS, 2002;22(3):1-23, 32-44.
8. US Environmental Protection Agency. *EPA Guide for Infectious Waste Management*. Publication No. EPA/530-SW-86-014. Washington, DC: US Environmental Protection Agency, 1986: 1-1–5-5, R1–R3, A1–A24.

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