ABBOTT PRISM®
Positive Run Control Kit
List No. 3E60-11
34-3827/R7

ABBOTT PRISM
Positive Run Control Kit

Customer Service
United States: 1-877-4ABBOTT

ABBOTT LABORATORIES
Diagnostics Division
Abbott Park, Illinois 60064
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NAME AND INTENDED USE
The ABBOTT PRISM Positive Run Control Kit contains a multi-constituent positive control for use as a 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:

- 6 Bottles (10 mL each) Positive Control (Human). Purified anti-HBc IgG (Concentration: 0.3 - 2.6 PEI* Units/mL) and recalified, 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)

*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, anti-HBC, 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)

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.

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. 3E60-11 ABBOTT PRISM Positive Run Control Kit
- No. 6A36-31 ABBOTT PRISM Run Control Adapters
- No. 6D18-68 ABBOTT PRISM HIV O Plus Assay Kit
- No. 6D19-68 ABBOTT PRISM HBsAg Assay Kit
- No. 6E50-68 ABBOTT PRISM HTLV-I/HTLV-II Assay Kit

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

<table>
<thead>
<tr>
<th>ABBOTT PRISM Positive Run Control Specifications</th>
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<tbody>
<tr>
<td><strong>S/CO Ranges</strong></td>
</tr>
<tr>
<td>HBsAg</td>
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<tr>
<td>Positive Control</td>
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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 (CHIA).

BIBLIOGRAPHY


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.


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