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## ABBOTT PRISM **Chagas**

### Run Control Kit

**REF** 6L86-10

**G1-0299/R05**

# Trypanosoma cruzi (E coli, Recombinant) Antigen



Read Highlighted Changes  
Revised June 2014

**Customer Service: Contact your local representative or find country specific contact information on [www.abbottdiagnostics.com](http://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			
<b>LOT</b>	Lot Number		Manufacturer
<b>REF</b>	List Number		
<b>IVD</b>	In Vitro Diagnostic Medical Device	<b>CONTROL +</b>	Positive Control
	Consult instructions for use	<b>CONTROL -</b>	Negative Control
	Caution	<b>PRODUCT OF USA</b>	Product of USA
	Store at 2-8°C	<b>RUN CONTROL ADAPTERS</b>	Run Control Adapters
	Expiration Date	<b>WARNING: SENSITIZER</b>	Warning: May cause an allergic reaction
<b>EC REP</b>	Authorized Representative in the European Community		

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



## NAME AND INTENDED USE

The ABBOTT PRISM Chagas Run Control Kit contains a positive control and a negative control for use as quality controls with the ABBOTT PRISM Chagas assay. The 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 negative control can be used at any point in a batch as a quality control.

## SUMMARY AND EXPLANATION OF THE TEST

Refer to the ABBOTT PRISM Chagas package insert.

## REAGENTS

Kit contains:

- **CONTROL +** 2 Bottles (10 mL each) Positive Control. Recalcified, human plasma reactive for antibodies to *T. cruzi*. Minimum activity: 1.02 sample/cutoff (S/CO). Preservatives: 0.1% ProClin 300 and 0.01% gentamicin sulfate. (Symbol: **POS**)
- **CONTROL -** 2 Bottles (10 mL each) Negative Control. Recalcified, human plasma. Preservatives: 0.1% ProClin 300 and 0.01% gentamicin sulfate. (Symbol: **NEG**)

## WARNINGS AND PRECAUTIONS

- **IVD**
- **For In Vitro Diagnostic Use**
- This kit is a quality control for the ABBOTT PRISM Chagas assay kit.
- 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<sup>1</sup>. Biosafety Level 2<sup>2</sup> or other appropriate biosafety practices<sup>3,4</sup> 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.<sup>5,6</sup>
  - Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.<sup>7,8</sup>
- The human plasma used in the negative control is nonreactive for antibodies to *T. cruzi*, HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.
- The human plasma used in the positive control is reactive for antibodies to *T. cruzi*. 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 these components:

- Negative Control
- Positive Control



**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.

- Safety Data Sheets are available at [www.abbottdiagnostics.com](http://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 this package insert may result in erroneous test results.
- Use caution when handling samples, control bottles, and control caps to prevent cross contamination.

## Storage Instructions



- 2°C Store the ABBOTT PRISM Chagas Run Control Kit at 2-8°C.

- When stored and handled as directed, controls are stable until the expiration date.

## Indications of Instability or Deterioration of Controls

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

## SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Not applicable. Refer to the **ABBOTT PRISM Chagas Assay Procedure** and **QUALITY CONTROL PROCEDURES** sections of the ABBOTT PRISM Chagas package insert for details.

## PROCEDURE

### Materials Provided

- **REF** 6L86-10 ABBOTT PRISM Chagas Run Control Kit

### Materials Required but not Provided

- **REF** 6A36-31 ABBOTT PRISM **RUN CONTROL ADAPTERS**

### For use with

- **REF** 7K35-68 ABBOTT PRISM Chagas Assay Kit

Refer to the **ABBOTT PRISM Chagas Assay Procedure** and **QUALITY CONTROL PROCEDURES** sections of the ABBOTT PRISM Chagas package insert 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 Chagas Assay Procedure** and **QUALITY CONTROL PROCEDURES** sections of the ABBOTT PRISM Chagas package insert for details.

## RESULTS

### 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 Chagas Positive and Negative Controls. Refer to the **Interpretation of Results** section of the ABBOTT PRISM Chagas package insert for details.

ABBOTT PRISM Chagas Run Control Specifications

Control	S/CO Range
Positive	1.02 - 6.00
Negative	0.02 - 0.98

## LIMITATIONS OF THE PROCEDURE

Refer to the ABBOTT PRISM Chagas package insert.

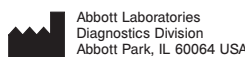
## EXPECTED VALUES

The positive control is designed to yield a reactive result and the negative control a nonreactive result with the ABBOTT PRISM Chagas assay.

## BIBLIOGRAPHY

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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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