REF B11187

PK7400 TP HA CONTROLS
Instructions for Use
Controls for the PK7400 TP HA REAGENT (Ref B11186)
Using the Beckman Coulter PK7400 Automated Microplate System

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I. INTENDED USE

PK7400 TP HA CONTROLS is intended for use with the PK7400 TP HA REAGENT (B11186) for the qualitative screening of blood and plasma donors for the detection of *Treponema pallidum* IgG and IgM antibodies in human serum, EDTA plasma or CPDA plasma[a] using the Beckman Coulter PK7400 Automated Microplate System.

II. SUMMARY OF THE TEST

Refer to the PK7400 TP HA REAGENT (B11186) Instructions For Use for a complete description of the test system. For complete details on the setup and operation of the BECKMAN COULTER PK7400 refer to the Beckman Coulter PK7400 Instructions for Use.

III. REAGENTS

The PK7400 TP HA CONTROLS contains REACTIVE and NONREACTIVE CONTROLS. The REACTIVE CONTROL has been designed to produce a positive (+) result. The NONREACTIVE CONTROL has been designed to produce a negative (-) result.

Name	Symbol	Description	
REACTIVE CONTROL (Red Cap)	CONTROL +	Each tube contains liquid human serum with antibodies to *Treponema pallidum* antigen in phosphate buffered saline, and 0.09% sodium azide as a preservative.	8 tubes containing 5.0 mL each
NONREACTIVE CONTROL (White Cap)	CONTROL -	Each tube contains normal rabbit serum with no detectable antibodies to *Treponema pallidum* in phosphate buffered saline, and 0.09% sodium azide as a preservative.	8 tubes containing 5.0 mL each

IV. WARNINGS AND PRECAUTIONS

1. The PK7400 TP HA CONTROLS is for *in vitro* diagnostic use only and designed for use only with the PK7400 TP HA REAGENT.
2. REACTIVE and NONREACTIVE Controls contain sodium azide (< 0.1% w/v) as a preservative, which can accumulate in lead or copper pipes to form potentially explosive azides. To prevent azide build-up, flush with large volumes of water after disposing of solutions containing azide in the sink.
3. Do not freeze CONTROLS.
4. CONTROLS showing visible signs of microbial growth or gross turbidity may indicate degradation and should be discontinued from use.
5. Do not use reagents or controls after the expiration date.
6. Do not pool or transfer CONTROLS from one tube to another.
7. Do not interchange caps between the REACTIVE and NONREACTIVE CONTROL tubes. CONTROLS are differentiated by color coded caps and the vial label. If caps are inadvertently switched, the CONTROL tubes should be discarded.
8. **Caution:** CONTROLS contain material of human or animal origin. All human origin material in the PK7400 PK TP HA CONTROLS has been tested and found negative or nonreactive for HBsAG, HIV 1 Ag [or HIV PCR(NAT)], HIV 1/2 antibody, HCV antibody, and HCV PCR (NAT) as required at the time of collection using FDA licensed test kits. No known test methods can offer total assurance that products derived from human origin will not transmit HIV, hepatitis or other potentially infectious agents. Therefore, the CONTROLS and all specimens should be handled as potentially infectious. See guidelines for "Biosafety in Microbiological and Biomedical Laboratories[1] or follow local guidance.
9. Clean, dry microplates must be used for testing. Improper washing of the microplate can adversely affect the test results. The recommended washing procedure is found in the Beckman Coulter PK7400 Instructions for Use.
10. Deviations from the Beckman Coulter PK7400 Instructions for Use can lead to erroneous results.
11. Deviations from the PK7400 TP HA REAGENT or the PK7400 TP HA CONTROLS Instructions for Use can lead to erroneous results.

12. Dispose of leftover controls in a safe manner, in accordance with local regulations.

V. REAGENT PREPARATION

REACTIVE and NONREACTIVE CONTROLS are liquid and require no reagent preparation. The CONTROLS are supplied in ready to use tubes, which can be placed directly into the PK7400 sample racks. Open tubes are stable for up to 2 months when stored at 2–8°C.
Note: All CONTROLS should be equilibrated to room temperature (18–28°C) prior to use.

VI. STORAGE

1. Store at 2–8°C. DO NOT FREEZE.
2. After opening, CONTROLS are stable for up to 2 months, when stored at 2–8°C.
3. Do not use after the expiration date.
4. Visible signs of microbial growth or gross turbidity in the CONTROL tube may indicate degradation and should be discontinued from use.
5. After opening, CONTROL tubes should be stored covered, when not in use.
6. After placing on the PK7400, the REACTIVE and NONREACTIVE CONTROLS can be left on board the instrument for up to 12 hours.

VII. MATERIALS

Materials provided:	PK7400 TP HA CONTROLS – REACTIVE (Red Cap) PK7400 TP HA CONTROLS – NONREACTIVE (White Cap)
Materials required but not provided:	Beckman Coulter 16µm terraced microplates P3 or P4 Beckman Coulter PK7400 Automated Microplate System PK7400 TP HA REAGENT (Ref B11186): REAGENT SAMPLE DILUENT PK REAGENT VIALS – barcoded

VIII. DIRECTIONS FOR USE

PK7400 TP HA CONTROLS, REACTIVE and NONREACTIVE CONTROLS must be tested at the beginning and end of each test run of samples, after the addition of reagents and sample diluents, and after interruption or delays in processing.

Perform the test as described under Section X, DIRECTIONS FOR USE, in the PK7400 TP HA REAGENT (B11186) Instructions for Use using the REACTIVE and NONREACTIVE CONTROLS as the specimens. The REACTIVE CONTROL should produce a positive (+) result and the NONREACTIVE CONTROL should produce a negative (-) result with the test. If the appropriate results are not obtained with the CONTROLS, all assay results within that test run are invalid and must be retested. Repeat testing making sure that the volumes of CONTROLS are sufficient for adequate instrument sampling (>1.5 mL). When control material repeatedly fails to perform as expected contact your local Beckman Coulter Representative.

IX. INTERPRETATION

In a negative reaction, no agglutination occurs, and the cells settle to the bottom of the well to form a compact dense button surrounded by a clear zone. In the presence of antibodies to *Treponema pallidum,* agglutinated cells form a lattice that appears as a homogeneous layer in the microplate well.

The PK7400 employs assessment parameters, referred to as image analysis measurements (IAM) for each microplate well expected to contain reagent and test sample. When the image is read by the camera, data is obtained for the following.

SPC	Sharpness at the edge of the cell button at the border of the peripheral (P) and the central (C) part of the well
LIA	Low intensity area which indicates the size and density of the cell button
P/C	Ratio of transmitted light between the peripheral (P) and central (C) parts of the well

When the data for the SPC, LIA, and P/C are compared to the associated thresholds, a reagent result interpretation of either +, -, or ? is made. SPC is the predominant value used to establish pattern interpretation with LIA and P/C used in support of SPC.

Refer to the PK7400 TP HA REAGENT (B11186) Instructions for Use and the Beckman Coulter PK7400 Instructions for Use for further information.

X. LIMITATIONS

The PK7400 TP HA CONTROLS should be used in conjunction with the PK7400 TP HA Reagent (B11186).

XI. FOOTNOTES

a. Citrate Phosphate Dextrose Adenine plasma

XII. REFERENCES

1. Biosafety in Microbiological and Biomedical Laboratories 5th Edition. HHS Publication No. (CDC) 21-1112 Revised December 2009

XIII. KEY TO SYMBOLS

REF	Catalogue number
	Manufactured by
	Temperature limitation
	Use by
LOT	Batch code
	Consult instructions for use
	Biological risk
Rx only	Prescription device symbol (US)

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For technical assistance, call your local Beckman Coulter Representative. For technical assistance in the US call 1-800-447-5852.	