

DPP HIV-Syphilis Rapid Test Control Pack
Chembio DPP HIV-Syphilis Reactive/Nonreactive Controls
 FOR *IN VITRO* DIAGNOSTIC USE
 FOR PROFESSIONAL USE ONLY

Read this Product Insert and the DPP® HIV-Syphilis System Product Insert completely before using this product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate Test Results. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other blood borne pathogens. [1]

STORAGE: Store at 2 to 8°C (36 to 46°F)

INTENDED USE

The Chembio DPP HIV-Syphilis Reactive/Nonreactive Controls are quality control reagents for use with the Chembio DPP HIV-Syphilis System only.

Run the Kit Controls under the following circumstances:

- Each new operator prior to performing tests on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test storage area falls outside of 2 to 30°C (46 to 86°F),
- If the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F),
- At periodic intervals as indicated by the user facility.

It is the responsibility of each laboratory using the DPP HIV-Syphilis System to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

SUMMARY AND EXPLANATION OF HIV REACTIVE AND NONREACTIVE CONTROLS

Chembio DPP HIV-Syphilis Reactive/Nonreactive Controls are human, plasma-based reagents. The Controls are specifically formulated and manufactured to ensure performance of the test and are used to verify the user's ability to properly perform the test and interpret the results. The Chembio HIV-1/Syphilis Reactive Control will produce an HIV and treponemal antibody REACTIVE Test Result. The Chembio HIV-2 Reactive Controls will produce an HIV REACTIVE Test Result and treponemal antibody NONREACTIVE Test Result. The Chembio Nonreactive Control will produce a NONREACTIVE Test Result for HIV and treponemal antibodies. Use of Control Reagents manufactured by another source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the Chembio DPP HIV-Syphilis System.

MATERIALS PROVIDED

Each DPP HIV-Syphilis Rapid Test Control Pack contains a Product Insert and three (3) Vials (one HIV-1/Syphilis Reactive Control, one HIV-2 Reactive Control, and one Nonreactive Control) as described.

HIV-1/Syphilis Reactive Control

One Vial containing 0.5mL of heat inactivated human plasma positive for antibodies to HIV-1 and *T. pallidum*, diluted in normal human plasma. Negative for Hepatitis B surface antigen, Hepatitis C antibody and HTLV I/II antibodies.

HIV-2 Reactive Control

One Vial containing 0.5mL of heat inactivated human plasma positive for antibodies to HIV-2, diluted in normal human plasma. Negative for Hepatitis B surface antigen, Hepatitis C antibody, HTLV I/II antibodies and treponemal antibodies.

Nonreactive Control

One Vial containing 0.5mL of normal human plasma negative for antibodies to HIV-1, HIV-2 and *T. pallidum*. Negative for Hepatitis B surface antigen, Hepatitis C antibody and HTLV I/II antibodies.

EXPECTED RESULTS

HIV-1/Syphilis Reactive Control:

The HIV-1/Syphilis Reactive Control will produce an HIV and SYPHILIS REACTIVE Test Result. The following should scroll across the reader display:

H V • R

T P • R

This indicates an HIV and TREPONEMAL REACTIVE Test Result.

HIV-2 Reactive Control:

The HIV-2 Reactive Control will produce an HIV REACTIVE Test Result. The following should scroll across the reader display:

H V • R

T P • NR

This indicates an HIV REACTIVE Test Result.

Nonreactive Control:

The Nonreactive Control will produce a NONREACTIVE Test Result. The following should scroll across the reader display:

H V • NR

T P • NR

This indicates a NONREACTIVE Test Result.

NOTE: If the Test Result for the HIV-1/Syphilis Reactive Control, HIV-2 Reactive Control, or Nonreactive Control, is not as expected, the test should be repeated using a new Test Device and Control Specimen. If the Control Reagents do not produce the expected results, contact Chembio Diagnostic Systems Customer Service Toll Free at 1-844-CHEMBIO (1-844-243-6246) if you are unable to obtain a valid Test Result upon repeat testing.

LIMITATIONS

The Chembio DPP HIV-Syphilis Reactive/Nonreactive Controls are quality control reagents for use **ONLY** with the Chembio DPP HIV-Syphilis System.

REFERENCES

1. Centers for Disease Control and Prevention (CDC). Universal Precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. *MMWR* 1988; 37(24):377-388.

2. Centers for Disease Control (CDC): Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis. MMWR 2005; 54(RR09): 1-17.
3. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

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ORDERING INFORMATION

REF 60-9555-0
Chembio DPP HIV-Syphilis Rapid Test Control Pack

AVAILABLE ACCESSORIES

REF 65-9502-0
Chembio DPP HIV-Syphilis System, 20 Test Kit

REF 70-1056-0
Chembio DPP Micro Reader for use with the DPP HIV-Syphilis System, 1 Unit

SYMBOL LEGEND

	CONSULT THE MANUAL BEFORE USE
	BATTERY LEVEL
	CAUTION, CONSULT THE ACCOMPANYING DOCUMENTS
	FOR USE WITHIN TEMPERATURE LIMITS
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	BATCH CODE
REF	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	DATE OF MANUFACTURE
	USE BY DATE
	THIS DEVICE SHOULD BE TREATED AS WASTE EQUIPMENT AND DISPOSED OF AT DESIGNATED COLLECTION POINT
	READER POWER ACTUATION (ON/OFF)
SN	READER SERIAL NUMBER (11 DIGITS)
IP20	PROTECTION CLASS OF ELECTRONIC EQUIPMENT