For use under the Emergency Use Authorization only
For in vitro diagnostic use
For Prescription Use Only
STORAGE: Store at 2 to 30°C (36 to 86°F)

Instructions for Use

DPP® Ebola Antigen System
Cat. No. 61-1013-0 **20 Test Kit**

A qualitative test kit with 20 devices for the rapid detection of antigen specific to Ebola virus (species *Zaire ebolavirus*) in capillary "fingerstick" whole blood, EDTA venous whole blood and EDTA plasma.

1. Intended Use

The DPP Ebola Antigen System is a rapid, single-use immunochromatographic test intended for the qualitative detection of VP40 protein from Ebola virus (species *Zaire ebolavirus* and hereafter referred to as Ebola virus) in capillary "fingerstick" whole blood, EDTA venous whole blood, and EDTA plasma.

The DPP Ebola Antigen System is for the presumptive detection of Ebola virus in individuals with signs and symptoms of Ebola virus disease (EVD) in conjunction with epidemiological risk factors (including geographic locations with high prevalence of EVD). The DPP Ebola Antigen System is intended for circumstances when use of a rapid Ebola test is determined to be more appropriate than use of an Ebola nucleic acid test, which has been demonstrated to be more sensitive in detecting the Ebola virus. The DPP Ebola Antigen System is not intended for use for general EVD screening, such as airport screening or contact tracing of individuals without signs and symptoms of EVD. The DPP Ebola Antigen System is intended for use in laboratories or facilities adequately equipped, trained and capable of such testing (including treatment centers and public health clinics).

Testing with the DPP Ebola Antigen System should not be performed unless the patient meets clinical and epidemiologic criteria for testing suspect specimens. Negative results do not preclude EVD and should not be used as the sole basis for patient management decisions. The definitive identification of EVD requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reporting is required. The diagnosis of EVD must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of Ebola virus.

The level of Ebola virus antigens that would be present in the clinical specimen from individuals with early systemic infection is unknown. The DPP Ebola Antigen System was evaluated in a limited clinical study using retrospective clinical specimens from individuals with EVD confirmed by RT-PCR.

2. Test Principle

The DPP Ebola Antigen System is composed of

1. A single-use immuno-chromatographic, rapid test developed on Chembio's patented DPP® technology (US/7189522 and WO/2006/099191).
2. The DPP® Micro Reader which is used to interpret test results.

The DPP® Ebola Antigen System is a qualitative test for the detection of VP40 antigen specific to Ebola Virus in capillary "fingerstick" whole blood, EDTA venous whole blood and EDTA plasma. The DPP Ebola Antigen System

employs a unique combination of antibodies, specific to Ebola virus antigens, which are conjugated to colloidal gold dye particles and bound to the membrane solid phase. To perform the test, the device should be removed from its pouch and placed on a flat surface. A blue test line and green control line should be noted in the device's rectangular TEST and CONTROL window. If the blue test line and green control line are absent (partially or completely) or defective (scratched), the test device should be discarded and replaced with a new one. 50uL of sample is obtained from the patient and added to the SAMPLE + BUFFER Well 1 of the device. Immediately following sample addition, 3 drops of buffer are added to the SAMPLE + BUFFER Well 1. In a properly performing device, when the sample and buffer are added to the SAMPLE + BUFFER Well 1 of the test device, upon the sample/buffer migration along the test strip to the test site (i.e. the rectangular TEST and CONTROL window), the blue and green dye at the test site becomes diluted and invisible to the naked eye, thereby indicating that the sample and buffer have properly migrated across the TEST and CONTROL areas, allowing for the capture of Ebola virus antigens, if present in the sample. After the sample and buffer have migrated onto the test strip (after 5 minutes), 6 drops of buffer are added to the BUFFER Well 2. The buffer solubilizes the gold nanoparticles conjugated to mouse antibodies against Ebola virus antigen and carries the conjugate across the TEST and CONTROL areas. The test results are interpreted using the DPP Micro Reader between 10 and 15 minutes after Running Buffer is added to BUFFER Well 2. The DPP Micro Reader is a reflectance reader for use with the DPP Ebola Antigen System that uses assay-specific algorithms to analyze the test and control line reflectance to determine the presence or absence of VP40 antigen specific to Ebola virus in the sample. The reader verifies the presence of the control line and measures color intensity at each of the test line positions; it interprets the results using an algorithm including assay-specific cut-off values, and reports a reactive (EVD+), non-reactive (EVD-), or invalid (INV) result after approximately 3 seconds. The results are displayed through a 14-segment liquid crystal display (LCD) on the top of the instrument.

3. Kit Contents

Each kit contains the items to perform 20 tests:

- 20 DPP Ebola Antigen System Test Devices - Individually Pouched
    - Each DPP® Ebola Antigen System Test Device contains membrane immobilized with a capture antibody raised against Ebola Virus VP40 antigen in the TEST (T) area and IgG antibody in the CONTROL (C) area; one clinical specimen result per test device.
    - 1 Desiccant Pouch, 1 gram
- 20 Disposable Microsafe® Tubes (50 µL)
- 20 Sterile Safety Lancets (for fingerstick whole blood samples)
- 20 Adhesive Bandages
- 20 Sterile Alcohol Swabs
- 1 DPP® Ebola Antigen System Buffer (7 mL) – Green Cap
- 1 Product Insert
- 1 Quick Reference Instructions
- 1 Fact Sheet for Healthcare Providers
- 1 Fact Sheet for Patients

4. Accessories that are available and required include

- DPP® Micro Reader (Catalog # 61-1050-0)
  Each contains:
    - 1 Chembio DPP Micro Reader with Ebola RFID sticker (includes 3 Lithium-ion, type CR2032 (3 V/230 mAh) coin cell batteries)
    - 1 DPP Cartridge Holder for use with DPP Ebola Antigen Test Device
    - 1 Custom Power Cable (USB)
    - 1 Power plug adapter
    - 1 Microfiber Cloth

- 1 User Manual for the DPP Micro Reader

- DPP® Ebola Rapid Test Control Pack (Catalog #60-9554-0)
  Each contains:
  - DPP® Ebola Reactive Control (0.5mL)
    - Lyophilized heat inactivated Recombinant Ebola virus VP40 protein (600 ng/ mL) in normal human serum negative for HBsAg, HCV Ab, HIV 1/2 ag, HBV DNA, HCV RNA, HIV RNA, RPR (syphilis) and preservative (0.09% sodium azide).
  - DPP® Ebola Non-Reactive Control (0.5mL)
    - Lyophilized normal human serum negative for HBsAg, HCV Ab, HIV 1/2 ag, HBV DNA, HCV RNA, HIV RNA, RPR (syphilis) and preservative (0.09% sodium azide).

5. Materials Required But Not Provided

- Clock, watch or other timing device
- Disposable gloves
- Sterile gauze (for fingerstick samples only)
- Collection devices (for venous whole blood or serum/plasma specimens)
- Biohazard disposal containers
- Pipettor capable of delivering 20-200µL of sample (for other than fingerstick specimens)
- Pipette tips

6. Storage and Shelf Life

- The DPP® Ebola Antigen System should be stored in unopened pouches at 2 °C to 30 °C (36 °F to 86 °F). **Do <u>not</u> freeze**.
- **Do not** use beyond the indicated expiration date. Test devices are stable until the expiration date marked on the pouch, when stored as indicated.
- DPP® Ebola Antigen System Buffer bottles should be stored at 2 °C to 30 °C (36 °F to 86 °F) in the original vial.
- **Do not** open the pouch until ready to perform the test.

7. Precautions and Warnings

- For In Vitro Diagnostic Use under Emergency Use Authorization only.
- Samples positive for Rheumatoid Factor, *Plasmodium malariae* or *Plasmodium ovale* may yield erroneous results.
- Local, state, and national public health agencies (for example, county and state health departments or the U.S. Centers for Disease Control and Prevention (CDC) or World Health Organization (WHO) should be notified of any patient suspected to have EVD. Confirmatory testing at the state/local public health laboratory or at CDC/WHO is necessary for positive detection results and may be necessary for negative detection results. Laboratories should consult with local, state or national public health officials on any positive detection OR no detection (negative) EVD test result on the need for additional testing and appropriate transportation of specimens.
- Use of this assay should be limited to designated, trained personnel.
- All personnel who are involved in collecting, processing, handling, or transporting specimens from a patient with suspected Ebola virus disease (EVD) should take appropriate precautions following the procedures recommended by Centers for Disease Control and Prevention (CDC).[1,2,3]
- All persons entering the patient room should wear at least: Gloves, Gown (fluid resistant or impermeable), Eye Protection (goggles or face shield) and Facemask. Additional PPE might be required in certain situations (e.g., copious amounts of blood, other body fluids, vomit, or feces present in the environment), including but not limited to: double gloving, disposable shoe covers and leg coverings.

- **Do not** eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact between hands, eyes or mouth during specimen collection and testing.
- Dispose of all specimens and materials used in the test procedure including the Quick Reference Guides in a biohazard waste container. Lancets should be placed in a sealed, puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121 ºC. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination (preferably overnight). Use 10% bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh daily. **NOTE: Do not autoclave solutions that contain bleach.**
- Avoid Aerosol Generating Procedures (AGPs) for patients with EVD.
- Patients should be placed in single patient room (containing a private bathroom) with the door closed.
- Dedicated medical equipment (preferably disposable, when possible) should be used for the provision of patient care.
- **Do not** use any device if the pouch has been perforated.
- Each device is for single use only.
- Always check expiration date prior to testing. **Do not** use the test beyond the expiration date printed on the pouch.
- If desiccant packet is missing, **Do not** use, discard and use a new test device.
- **Do not** mix reagents from different lot numbers of kits.
- Adequate lighting is required to read the test results.

8. Sample Collection

- The DPP Ebola Antigen System is intended for the qualitative detection of VP40 antigen specific to Ebola virus in capillary "fingerstick" whole blood, EDTA venous whole blood, and EDTA plasma.
- Shipping should be performed according to the policies of the shipping performer, customs regulations, and the requirements of the receiving laboratory.
- Follow the recommended infection control precautions for Ebola or other hemorrhagic fever viruses in handling all specimens.

For Fingerstick Whole Blood:

Following laboratory procedures, clean the finger of the person being tested with the Sterile Alcohol Swab. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Using the Sterile Safety Lancet, puncture the skin just slightly off the center of the finger and wipe away the first drop of blood with sterile gauze. Avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid. Without squeezing the bulb, hold the Microsafe® Tube (Figure 1) in a horizontal position and touch the tip of the tube to the blood sample (Figure 2). Capillary action will draw the sample to the black fill line (50 uL). Be sure the tube is completely filled to the black line and there are no air bubbles (Figure 2).

Figure 1:

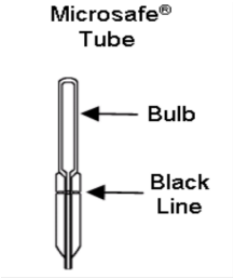
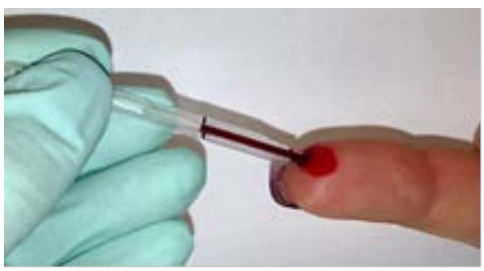


Figure 2: Blood Filled Microsafe Tube



CAUTION: When drawing sample with the Microsafe Tube **DO NOT** squeeze the bulb at the top of the tube. Capillary action will draw the sample to the black fill line.

For Venous Whole Blood:

Draw blood following laboratory procedure for obtaining venous blood. Depending on use, collect sample in a tube containing citrate, heparin or EDTA. Be sure the tube of blood is well mixed before sampling. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18 to 30°C (64 to 86°F).

For Plasma:

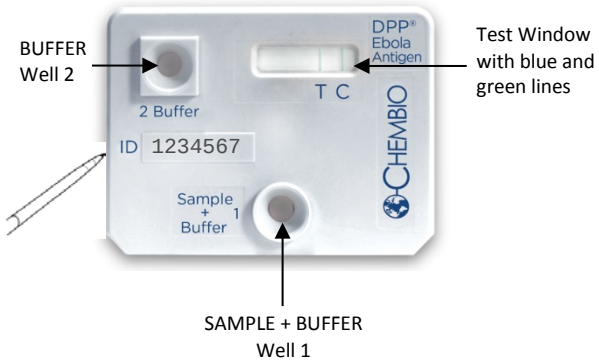
Collect plasma in a tube containing EDTA following standard laboratory procedures. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18 to 30°C (64 to 86°F).

9. Testing Procedure

1. Remove the DPP® Ebola Antigen System Test Device from its pouch and place it on a flat surface (it is not necessary to remove the Desiccant Packet from the pouch). Note: If Desiccant Packet is missing, DO NOT USE, discard Test Device and a new Test Device should be used.

   Label the Test Device with patient ID or identification number. Note that the DPP® Ebola Antigen System Test Device has 2 colored lines in the Test Window; one is blue and the other is green. If the 2 colored lines are absent, DO NOT USE, discard Test Device and a new Test Device should be used.

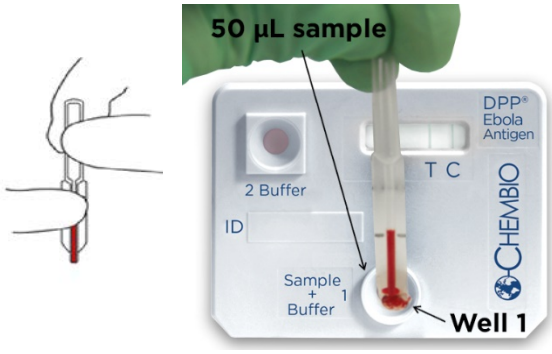
   IMPORTANT: When adding the Sample into Well 1, be sure to dispense onto the white absorbent pad.



2. ***For Fingerstick Whole Blood:***

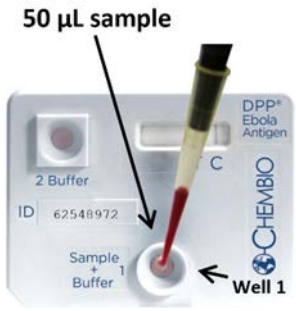
   Holding the Microsafe Tube vertically over the SAMPLE+BUFFER Well 1, squeeze the bulb to release 50 µL sample into the well. Immediately continue onto Step 3.

   IN THE EVENT THAT THE SAMPLE DOES NOT COME OUT OF THE TUBE, hold the tube vertically and slide a finger over the vent hole near the black mark. Then line up the Microsafe Tube tip with Well 1 and squeeze the bulb.

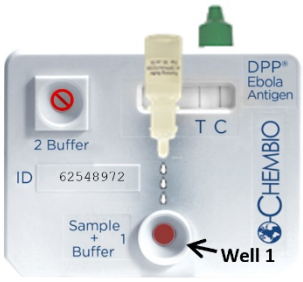


For Venous Whole Blood or Plasma:

Using a calibrated pipette, add 50 µL of the sample to Sample + Buffer Well 1.



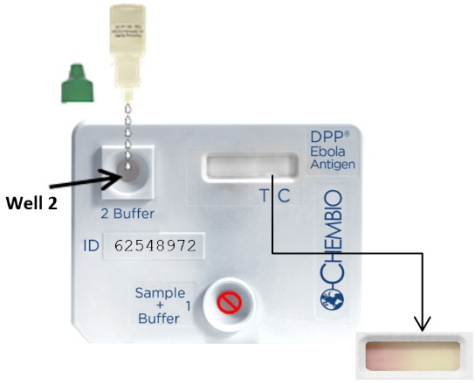
3. Immediately after the addition of the sample, add 3 drops of DPP Ebola Antigen System Buffer (Green Cap) into the same well (Well 1). To add the buffer, invert the DPP Ebola Antigen System Buffer bottle (Green Cap) and hold it vertically (not at an angle) over Well 1. Squeeze the bottle to slowly **add 3 drops**.



4. **Wait 5 minutes.** The blue colored line should have disappeared from the rectangular TEST and CONTROL window. If not, DO NOT USE, discard Test Device and use a new Test Device. The green colored line may or may not disappear.

   Invert the DPP Ebola Antigen System Buffer bottle (Green Cap) and hold it vertically (not at an angle) over BUFFER Well 2. **Add 6 drops** of Buffer (Green Cap) slowly, dropwise, into BUFFER Well 2.

   A pink color should begin to flow across the strip within 2-3 minutes. If NO PINK flow is present, repeat with a new device.



5. **Wait 10 minutes**. Read the test result (see INTERPRETATION OF RESULTS section) 10-15 minutes from the addition of DPP Ebola Antigen System Buffer into Well 2. DO NOT read results after 15 minutes from the addition of DPP Ebola Antigen System Buffer into Well 2.

   NOTE: The test result should be manually recorded immediately after the test is complete as the reader will turn off automatically after approximately 50 seconds of inactivity. The DPP Micro Reader device does not store or recall previous results.

Test Results are read using the DPP Micro Reader.
DO NOT ATTEMPT TO INTERPRET THE RESULTS VISUALLY.
ALWAYS USE THE DPP MICRO READER TO OBTAIN THE RESULTS.

Using the DPP Micro Reader

DPP Micro Reader

Components of the DPP Micro Reader

- DPP Micro Reader with Ebola RFID sticker
- Cartridge Holder for use with the DPP Ebola Antigen System Test Device
- USB Cable
- 1 Power plug adapter
- 1 Microfiber Cloth
- 1 User Manual for the DPP Micro Reader

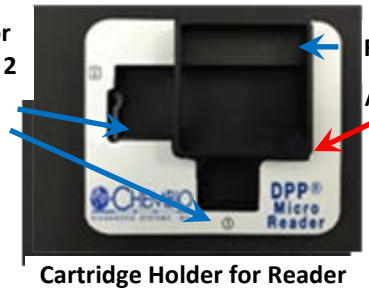
Assemble the DPP Micro Reader

a) Check to make sure that the window at the bottom of the reader is clean of finger marks and dust or lint before using the reader. Use enclosed microfiber cloth to wipe free of marks, dust or debris following the Chembio Ebola Micro Reader User Manual instructions.

Make sure the RFID Sticker refers to Ebola VP40.

Place the Cartridge Holder on a flat surface. Align the angled edge in the bottom of the DPP Micro Reader with the corresponding angled corner of the holder socket and place the DPP Micro Reader in the holder socket.

DPP Micro Reader



Cartridge Holder for Reader

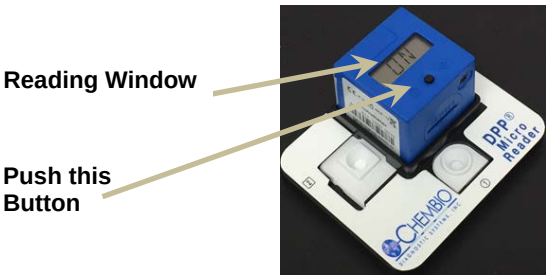
DPP Micro Reader in Holder

b) To read a test, place the DPP® Micro Reader in Cartridge Holder on top of the Test Device. Make sure the rectangular test window on the Test Device is aligned with the reading window of the reader. At the end of assembly, the black button, battery compartment and Buffer Well 1 on the test device should be facing the user and Buffer Well 2 should be to the left of the user.

DPP Micro Reader with Cartridge Holder on top of testing device

Reading the test:

a) 10 to 15 minutes after the addition of the DPP Ebola Antigen System Buffer to Well 2 as per STEP 4, push the operating button. "ON" should appear in the reading window.



b) Press the Operating Button again; the display will read "RFID".

c) "TEST" will appear in the display window.

d) Press the Operating Button and "RUN" will appear in the display window.

After approximately 3 seconds, a result for the DPP Ebola Antigen System Test Device will appear across the display. **Record the result (refer to INTERPRETATION OF TEST RESULTS) as the reader does not record results**.

If the DPP Micro Reader does not detect a line in the CONTROL (C) area, then it will display "INV", indicating that the test is INVALID. An INVALID result indicates a problem with running the test, either related to the specimen, the device, or the procedure followed. An INVALID test cannot be interpreted; it is recommended that the INVALID test be repeated with a new device.

10. Interpretation of Test Results

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

Interpretation of Internal and External Controls

Internal Control

• Upon opening of test pouch, user should see a blue and green line printed in the test window. If lines are not present, user should discard device and use a new Test Device.

• When sample and buffer is added to well #1, these lines should disappear from the test window. If they do not, the user is to discard the Test Device and use a new Test Device.
• Regardless if a line develops in the test area (T), a line must develop in the CONTROL area (C). If a line does not develop in the CONTROL area, the test is not performing correctly and is INVALID. An invalid test cannot be interpreted; it is recommended that the invalid test be repeated with a new device. The reader will display "INVALID" and not give a result.

External Control

The DPP Ebola Rapid Test Control Pack is a set of external controls. The DPP Ebola Rapid Test Control Pack is manufactured specifically for use with the DPP Ebola Antigen System. One package of the DPP Ebola Rapid Test Control Pack contains 1 DPP Ebola Reactive Control (lyophilized), 1 DPP Ebola Non-Reactive Control (lyophilized), and 1 Product Insert for external controls.

Run the External Controls under the following circumstances:

- Each new operator prior to performing tests on patient samples
- 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 (36 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 dictated by local, state and country laws and by the user facility.

If external controls do not produce expected results as stated in the section 13 below "External Quality Control" on page 11, patient testing should not be performed. Contact Chembio Diagnostic Systems' Customer Service at 1-844-CHEMBIO (243-6246) if the Kit Control reagents do not produce the expected results.

INTERPRETATION	DISPLAY ON READER
NON-REACTIVE (EVD -) A NON-REACTIVE Test Result means that Ebola virus VP40 antigen was not detected in the specimen. The Test Result is interpreted as NEGATIVE. **A NON-REACTIVE result does not exclude possible infection with Ebola virus.** As with any test, providers must consider the patient's likelihood of exposure and the possibility of false laboratory results when making treatment or other patient management decisions.	
REACTIVE (EVD +) A REACTIVE Test Result means Ebola virus VP40 antigen has been detected in the specimen. The Test Result is interpreted as Presumptive POSITIVE for possible infection with Ebola virus. Individuals with a reactive DPP Ebola Antigen System Test Result should undergo appropriate clinical follow-up which may include supplemental PCR testing.	

INVALID (INV)

An INVALID test cannot be interpreted. It is recommended that the INVALID test be repeated with a new Test Device. If results are still invalid collect a fresh sample or test by another method.

11. Assay Limitations

- All results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors.
- Interpretation of results from the *DPP Ebola Antigen System* must account for the possibility of false-negative and false-positive results.
- Negative results do not preclude infection with Ebola virus and should not be the sole basis of a patient treatment/management or public health decision.
- False positive results may occur from cross-contamination by target organisms or other pathogens.
- Failure to follow the assay procedures may lead to false negative results.
- Improper collection, storage, or transport of specimens may lead to false negative results.
- Inhibitors present in the samples may lead to false negative results.
- Reading test results earlier than 10 minutes or later than 15 minutes after the addition of Running Buffer to Well 2 may yield erroneous results.
- **Do not** open the sealed foil pouch until just prior to use.
- **Do not** use kit contents beyond labeled expiration date.
- Performing fingerstick sample collection when the finger is not completely dry could result in the contamination or dilution of the sample.
- Results should be read in a well-lit area.
- Results must be read with the DPP Micro Reader.
- The test is not validated as a quantitative test for treatment monitoring.
- Performance of this assay has only been established for EDTA venous whole blood and Fingerstick whole blood or EDTA plasma. Performance with other specimen types has not been evaluated.
- This test should not be used to test specimens from asymptomatic individuals.
- The definitive identification of Ebola virus disease (EVD) requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reporting is required.
- The diagnosis of EVD must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of Ebola virus.
- Samples positive for *Plasmodium malariae* or *Plasmodium ovale* may yield erroneous results.
- Concentrations of Rheumatoid Factor above 125 IU/mL in the sample may cause interference in the assay.
- Cross-reactivity with organisms other than those tested in the Cross-reactivity Study has not been assessed and may lead to erroneous results.

12. Built-In Control Feature

The control line serves as a built-in internal control and gives confirmation of sample addition and proper test performance. A pink/purple line will appear in the CONTROL (C) area if the test has been performed correctly and the device is working properly (Please see: Interpretation of Test Results). If the DPP Micro Reader does not detect a line in the CONTROL (C) area, then it will display "INV", indicating that the test is INVALID.

13. External Quality Control

The DPP Ebola Rapid Test Control Pack (Catalog #:60-9554-0) is available separately for use with the DPP Ebola Antigen System. The controls are used to verify the operator's ability to properly perform the test and to interpret the results. The DPP Ebola Reactive Control will produce a reactive test result and has been manufactured to produce a faint line in the TEST (T) area. The DPP Ebola Non-Reactive Control will produce a non-reactive test result. Run the controls as described in the Test Procedure section for a plasma sample and follow the directions in the Interpretation of Test Results section of this product insert. It is the responsibility of each facility using the DPP® Ebola Antigen System to establish an adequate quality assurance program to ensure the performance of the device under specific locations and conditions of use.

RUN THE KIT CONTROLS UNDER THE FOLLOWING CIRCUMSTANCES:

- Each new operator prior to performing tests on patient samples
- 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 (36 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

If the Ebola Control reagents do not produce the expected results, contact Chembio Diagnostic Customer Service at 1-631-924-1135.

14. Conditions For Authorization For Laboratories and Facilities

The DPP® Ebola Antigen System Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website: https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm. Use of the DPP Ebola Antigen System must follow the procedures outlined in these manufacturer's Instructions for Use and the conditions of authorization outlined in the Letter of Authorization. Deviations from the procedures outlined are not permitted under the Emergency Use Authorization. To assist clinical laboratories and facilities running the DPP Ebola Antigen System, the relevant Conditions of Authorization are listed verbatim below.

- Authorized laboratories and facilities will include with reports of the results of the DPP Ebola Antigen System the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

- Authorized laboratories and facilities will perform the DPP Ebola Antigen System as outlined in the DPP Ebola Antigen System Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the DPP Ebola Antigen System are not permitted.

- Authorized laboratories and facilities must read the results of the DPP Ebola Antigen System on the DPP Micro Reader or on other authorized instruments. Authorized laboratories and facilities must not attempt to interpret the results of the DPP Ebola Antigen System visually.

- Authorized laboratories and facilities will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[1]

- Authorized laboratories and facilities will collect information on the performance of the DPP Ebola Antigen System and report to DMD/OIR/CDRH (*via* email CDRH-EUA-Reporting@fda.hhs.gov) and Chembio any suspected occurrence of false negative and false positive results and significant deviations from the established performance characteristics of which they become aware.

- All personnel using the assay must be appropriately trained in performing and interpreting immunochromatographic techniques, use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling. All personnel using the assay must also be trained in and be familiar with the interpretation of results of the DPP Ebola Antigen System.

- Chembio, its authorized distributor(s), and authorized laboratories and facilities will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

15. Performance Characteristics

Analytical testing of the DPP Ebola Antigen System was conducted in BSL-4 (Center for Disease Control and Prevention, Atlanta, Georgia, USA) and BSL-2 (Chembio Diagnostic Laboratories, Medford, NY, USA) laboratories in 2015.

Analytical Sensitivity/ Limit of Detection (LoD)

A Limit of Detection (LoD) range finding study in venous whole blood identified 9.88 x 10^5 $TCID_{50}$/ mL as the tentative LoD for Ebola Inactivated Virus [Gamma irradiated Ebola virus from a West African isolate Ebola virus Makona strain variant 2014 (Spec.no. 812572, Liberia, 2014)]. The LoD was confirmed to be 1.23 x 10^5 $TCID_{50}$/ mL in EDTA Whole Blood by all 20 replicates testing positive with the same Ebola Inactivated Virus at this concentration. In EDTA Plasma, the LoD was confirmed to be 2.47 x 10^5 $TCID_{50}$/ mL by all 20 replicates testing positive with the same Ebola Inactivated Virus at this concentration.

Additionally, a LoD range finding study was performed using recombinant VP40 antigen spiked into EDTA venous whole blood and EDTA plasma. The LoD of the DPP Ebola Antigen System in EDTA plasma and EDTA venous whole blood with recombinant VP40 antigen was determined to be 250 ng/ mL or 12.5 ng/test. The LoD of the DPP Ebola Antigen System in serum with recombinant VP40 antigen was determined to be 150 ng/ mL or 7.5 ng/test.

LoD for the CDC inactivated Ebola virus slurry SPR582 was determined to be 1:128 in EDTA Whole Blood and EDTA Plasma and 1:256 in serum.

Table 1: Summary Table Comparing the Final LoD Determined in All Matrices Claimed for the DPP Ebola Antigen System for the Inactivated Ebola Virus Makona Strain Variant 2014 (Spec.no. 812572, Liberia, 2014), rVP40, and Ebola Virus Slurry SPR582

Matrix	Final LoD		
	Inactivated Ebola Virus Makona Strain (812572:	rVP40	Ebola Virus Slurry SPR582

[1] According to CDC, EVD is a nationally notifiable condition (see https://www.cdc.gov/vhf/ebola/index.html).

	Liberia, 2014) ($TCID_{50}$/ mL)		
EDTA Plasma	1:64 (2.47×10^5)	250 ng/ mL or 12.5 ng/test	1:128
EDTA Whole Blood	1:128 (1.23×10^5)	250 ng/ mL or 12.5 ng/test	1:128
Serum*	N/A	150 ng/ mL or 7.5 ng/test	1:256

N/A: Not Available

* Serum LoD studies are provided only to support some of the cross-reactivity studies

Field Samples

The clinical performance of the DPP® Ebola Antigen System was assessed in three separate studies using retrospective samples. In the first study conducted with thirty (30) frozen archived natural EDTA plasma samples collected in Liberia, the overall Positive Percent Agreement against the comparator (CDC Ebola Virus VP40 Real-time RT-PCR Assay) was 85.0% (17/20) with 95% CI 64.0 –94.8%. The Negative Percent Agreement was 90.0% (9/10) with 95% CI 59.6% - 98.2% (**Table 2**).

Table 2: Percent Positive Agreement for select CT Value Ranges

PCR CT Value Ranges	Percent Agreement	95% CI*
Negative	90.0% (9/10)	59.6%-98.2%
15-25	100.0% (9/9)	70.1-100.0%
15-30	82.4% (14/17)	59.0-93.8%
15-34	85.0% (17/20)	64.0-94.8%

* Calculated using score method

Table 3: DPP Ebola Antigen System & Comparator Results Stratified by CT Value Ranges

		Comparator RT-PCR Results											
		15- 20		21-<25		≥25-<30		≥30-34		Overall		Comparator RT-PCR Results	
												Ebola not detected	
		+	-	+	-	+	-	+	-	+	-	+	-
DPP Ebola Results	+	4	0	5	0	5	0	3	0	17	0	0	1
	-	0	0	0	0	3	0	0	0	3	0	0	9

In the second study, the performance of the DPP Ebola Antigen System was evaluated using a blinded panel comprised of 100 EDTA plasma samples. The panel consisted of 50 negative frozen archived EDTA plasma samples from individuals from West Africa collected from 2001 to 2006, prior to the 2014 Ebola Outbreak, and 50 individual negative frozen EDTA plasma samples from individuals from Colombia with symptoms of febrile illness that also tested IgM positive for Dengue fever and IgG positive for Chikungunya. Samples were tested once and read in a blinded fashion by one operator with the DPP Micro reader. Fifty (50) individual samples (from Africa) were tested neat as negative samples on the DPP Ebola Antigen Assay. Twenty-five (25) of the febrile samples were tested after being spiked with the inactivated Ebola virus Makona strain variant 2014 (Spec.no. 812572, Liberia, 2014) at the Limit of Detection (LoD; i.e. 1:64) into clinical matrix, and the remaining 25 contrived febrile samples were tested after being spiked with the inactivated Ebola virus Makona strain variant 2014 at serial dilutions above and below the LoD. Of the 50 positive samples, 10 were below the detectable limit of the Assay (1:64). None of these samples were detected by the assay. The DPP Ebola Antigen System found 49 negative samples non-reactive (49/50 = 98.0% with 95% CI extending from 89.5 to 99.7%). Of the 40 positive samples within the detectable limits of the

assay, the DPP Ebola Antigen System found 37 out of 40 to be reactive: 37/40 = 92.5% with 95% CI extending from 80.1 to 97.4%. See **Table 4.**

Table 4: EDTA Plasma-Blinded Panel in Relation to LoD of Assay

DPP Ebola Antigen System	Percent	95% CI*
Negative	98.0% (49/50)	89.5 – 99.7%
Percent positive above LoD	100.0% (15/15)	79.6% - 100.0%
Percent positive at LoD	88.0% (22/25)	70.1 % - 95.8%

* Calculated using the score method

A third study was conducted with a blinded panel of 100 EDTA whole blood samples. The panel consisted of 100 individual negative EDTA whole blood samples from individuals from Africa with fever symptoms that also tested positive for malaria and in some cases specifically *P.falciparum*. Fifty (50) individual samples were tested neat as negative samples on the DPP Ebola Antigen Assay. Twenty (20) of the samples were tested after first being prepared by spiking the inactivated Ebola Virus (Ebola Slurry; Lot SPR852) at what at the time was thought to be the Limit of Detection (LoD; i.e. 1:256) into clinical matrix, and the remaining 30 contrived samples were tested after first being prepared by spiking the inactivated Ebola Virus at serial dilutions above and below the LoD (i.e 1:16; 1:32; 1:64; 1:128; 1:512 with n=5 for each). After completion of the study, it was discovered that the LoD of inactivated Ebola Virus (Ebola Slurry; Lot SPR852) in EDTA Whole Blood was at the one-fold higher concentration of 1:128.

The DPP Ebola Antigen System identified 49 of the 50 negative whole samples to be non-reactive (49/50 = 98.0% with 95% CI extending from 89. 5 to 99.7%). Of the 20 positive samples within the detectable limits of the assay (LoD of 1:128 and above), the DPP Ebola Antigen System found 20 out of 20 to be reactive: 20/20 = 100% with 95% CI extending from 83.9 to 100.0%). Thirty of the positive samples were below the limit of detection, with 23/30 (76.7% CI extending from 59.1 to 88.2%) detected by DPP. See **Table 5.**

Table 5: EDTA Whole Blood Clinical Performance in relation to LoD of Assay[1]

DPP Ebola Antigen System	Percent	95% CI*
Negative	98% (49/50)	89.5 to 99.7 %
Percent positive above LoD	100% (15/15)	79.62% - 100.0%
Percent positive at LoD	100% (5/5)	56.56 to 99.3 %

* Calculated using score method

[1] These results were read at 20 minutes after addition of buffer to Well 2, which is outside the normal range of the assay time reading. However, the average values obtained were similar to those measured on time at similar dilutions.

High-Dose Hook Effect

Studies were conducted to evaluate if a hook effect occurs for the DPP Ebola Antigen System by testing increasing purified recombinant VP40 antigen concentrations in serum from 0 ng/ mL up to 0.1 mg/ mL This concentration range is based on LoD studies on the DPP® Ebola Antigen System where the assay was found to have a confirmed LoD of 250 ng/ mL or 12.5 ng/ test and measurement of virus load in clinical specimens by Q-RT-PCR assay and plaque assay[4]. There was no decrease in the test line intensity by the reader for a VP40 antigen concentration from 0 to 400 times the established LoD. This demonstrates that the DPP® Ebola Antigen System does not generate High-dose Hook or Prozone effect within the range of the assay.

Clinical Specificity

The clinical specificity of the DPP Ebola Antigen System with samples negative for Ebola virus species and strains was assessed by testing two-hundred and thirty-eight (238) plasma samples and two-hundred and fifty (250) whole blood samples over a series of experiments. All samples were collected from asymptomatic individuals from an area non-endemic for Ebola. In brief, for EDTA plasma specimens the clinical specificity was found to be 98.7%

(235/238 = 98.7% with 95% CI from 96.4 to 99.6%). For EDTA whole blood the clinical specificity was found to be 98.2% (245.5/250 = 98.2% with 95% CI 95.7 to 99.3%).

To support a fingerstick whole blood claim, a specificity study was carried out by testing fingerstick whole blood specimens collected from fifty-five (55) asymptomatic U.S. volunteers on the DPP Ebola Antigen System. Fifty-four (54) of the 55 fingerstick whole blood specimens tested in this study were negative; one specimen generated a trace signal, resulting in a percent negative agreement against the expected negative results of 54/55= 98.2% (95% CI 90.4 to 99.7 %).

A summary of the clinical specificity of the DPP® Ebola Antigen System can be found in **Table 6** below.

Table 6: Clinical Specificity of the DPP Ebola Antigen System

Matrix	Percent	95% CI*
EDTA plasma	98.7% (235/238)	96.4 to 99.6%
EDTA venous whole blood	98.2% (245.5/250)	95.7 to 99.3%
Fingerstick (capillary) blood	98.2% (54/55)	90.4 to 99.7 %

* Calculated using score method

^ Measured with opTricon opTrilyzer, conversion factor used to obtain the Micro Reader values.

Cross Reactivity

Cross-reactivity of the DPP Ebola Antigen System was evaluated by testing additional viral, bacterial, or parasitic pathogens. In one study three (3) replicates were tested with the pathogens spiked into serum (Tables 7, 8, and 9) and three (3) or 20 replicates were tested in whole blood (Tables 10 and 11) at the concentrations listed in the tables below. *P. ovale*, showed cross-reactivity in serum in concentrations of 2.41×10^4 parasites/uL. Cross-reactivity was observed in a single specimen of *Plasmodium malariae* tested at 1.3×10^4 and 7×10^3 parasites/ uL in serum and whole blood respectively. Other two specimens with the highest and the lowest concentrations of *Plasmodium malariae* tested negative in whole blood.

Table 7: Cross-Reactant Testing (where # reactive/# tested)

Organism	Strain	Format tested	Testing Concentration	Organism + Negative Serum + Saline	Organism + Negative Serum	Organism + Negative Serum + rVP40 (500 ng/ mL) in Saline
Adenovirus	Type 5	Heat-inactivated	1.51 x10^6 $TCID_{50}$/ mL	0/3	0/3	3/3
Chikungunya	R80422	Heat-inactivated	2.82 x10^7 $TCID_{50}$/ mL	0/3	0/3	3/3
Dengue Virus-Serotype 1	Hawaii	Heat-inactivated	7.24 x10^5 $TCID_{50}$/ mL	0/3	0/3	3/3
Dengue Virus-Serotype 2	New Guinea C	Heat-inactivated	1.05 x10^6 $TCID_{50}$/ mL	0/3	0/3	3/3
Dengue Virus-Serotype 3	H87	Heat-inactivated	2.09 x10^6 $TCID_{50}$/ mL	0/3	0/3	3/3
Dengue Virus-Serotype 4	H241	Heat-inactivated	1.26 x10^6 $TCID_{50}$/ mL	0/3	0/3	3/3
Enterovirus	Type 68 (2007 Isolate)	Heat-inactivated	1.95 x10^7 $TCID_{50}$/ mL	0/3	0/3	3/3
HIV-1 (Subtype B)	IIIB	Heat-inactivated	3.39 x10^7 $TCID_{50}$/ mL	0/3	0/3	3/3
HIV-1 (Subtype O)	Subtype O	Live virus	9.35 x10^6 $TCID_{50}$/ mL	0/3	0/3	3/3
HIV2	NIH-Z	Heat-inactivated	2.19 x10^6 $TCID_{50}$/ mL	0/3	0/3	3/3
Hepatitis B	N/A	Live virus	1.08 x10^9 mLU/ mL	0/3	0/3	3/3
Hepatitis C	N/A	Live virus	6.05 x10^6 mIU/ mL	0/3	0/3	3/3
Influenza virus A	A/New Cal/20/99/H1N1	Heat-inactivated	4.57 x10^6 $TCID_{50}$/ mL	0/3	0/3	3/3
Influenza virus B	B/Florida/04/2006	Heat-inactivated	4.57 x10^6 $TCID_{50}$/ mL	0/3	0/3	3/3
Rotavirus	WA	Heat-inactivated	1.15 x10^7 $TCID_{50}$/ mL	0/3	0/3	3/3
RSV A	2006 Isolate	Heat-inactivated	3.16 x10^6 $TCID_{50}$/ mL	0/3	0/3	3/3
Yellow Fever	17D	Heat-inactivated	1.26 x10^6 $TCID_{50}$/ mL	0/3	0/3	3/3
Yersinia Pestis	Colorado 92	Heat-inactivated	3.01 x10^9 CFU/ mL	0/3	0/3	3/3
Yersinia Pestis[1]	A1122	Live virus	2.2 x10^8 CFU/ mL	0/3	0/3	3/3
Yersinia enterocolitica	Z036	Live	5.8 x 107 CFU/ mL	0/3	0/3	3/3

[1] Yersinia Pestis strain A1122 was spiked with recombinant Ebola VP40 protein at a final concentration of 300 ng/ mL as this cross-reactant alone was conducted separately.

Table 8: Cross-Reactant Testing (where # reactive/# tested)

Organism	Strain	Format tested	Testing Concentration	Organism + Negative Serum + Saline	Organism + Negative Serum	Organism + Negative Serum + rVP40 (500 ng/ mL) in Saline
Salmonella enterica	Tryphimurium	Live	1.19 x10^{10} CFU/ mL	0/3	0/3	3/3
Salmonella typhi	Zi52	Live	1.89 x10^{9} CFU/ mL	0/3	0/3	3/3
Shigella sonnei	Z004	Live	2.29 x10^{9} CFU/ mL	0/3	0/3	3/3
Pseudomonas aeruginosa	Clinical isolate	Live	3.93 x10^{9} CFU/ mL	0/3	0/3	3/3
Vibrio cholera	Z132 toxigenic	Live	1.8 x10^{10} CFU/ mL	0/3	0/3	3/3
Haemophilus influenzae B	Eagan	Live	7.6 x10^{8} CFU/ mL	0/3	0/3	3/3
Neisseria meningitidis	Serogroup A	Live	7.07 x10^{8} CFU/ mL	0/3	0/3	3/3

Table 9: Cross-Reactant Testing (where # reactive/# tested)

Organism	Strain	Format tested	Testing Concentration	Organism + Negative Serum + Saline	Organism + Negative Serum	Organism + Negative Serum + rVP40 (750 ng/ mL) in Saline
Plasmodium	*Vivax*	Live	See note below±	0/3	0/3	3/3
	Falciparum	Live	Unknown*	0/3	0/3	3/3
	Ovale	Live	2.41 x10^{4} parasites/ uL	0/3	1/3	3/3
	Malariae	Live	1.3 x10^{4} parasites/ uL$^{\pm}$	0/3	1/3	3/3
Trypanosoma	cruzi	Live	See note below^	0/3	0/3	3/3

* EDTA Whole blood patient sample collected in Cameroon tested positive for Malaria on the BIOCREDIT Rapid Test Malaria Ag Pf (HRP II)

± On Abcam Malaria IgG/M, Sample had OD value 1.184 with index of 2.812. Positive for Malaria SD BIOLINE Malaria Ag P.f/ Pv test with visual value of 3. Patient had symptoms of fever, headache, nausea and vomiting

^ On Wiener Laboratories Chagas test ELISA, Sample had OD value was 1.68

Table 10: Cross-Reactant Testing in EDTA Whole Blood,

300 ng VP40 in Saline	**300 ng VP40 in Whole Blood**	***Plasmodium malariae* in whole blood**	***Plasmodium malariae* in whole blood + saline**	***Plasmodium malariae* in whole blood + 300 ng VP40 in Saline**
NT	3/3= 100% R	**Estimated Testing Concentration 5.8 x10^4 parasites/ uL** 0/20=0% R	**Estimated Testing Concentration 5.8 x10^4 parasites/ uL** NT	**Estimated Testing Concentration 5.8 x10^4 parasites/ uL** 20/20=100% R
20/20=100% R	NT	**Estimated Testing Concentration 7.0 x10^3 parasites/ uL[1]** 1/20=5% R	**Estimated Testing Concentration 7.0 x10^3 parasites/ uL[1]** 2/20=10% R	**Estimated Testing Concentration 7.0 x10^3 parasites/ uL[1]** 20/20=100% R
NT	NT	**Estimated Testing Concentration 1.8 x10^3 parasites/ uL** 0/20=0% R	**Estimated Testing Concentration 1.8 x10^3 parasites/ uL** NT	**Estimated Testing Concentration 1.8 x10^3 parasites/ uL** 20/20=100% R
300 ng VP40 in Saline	**300 ng VP40 in Whole Blood**	***S. pneumoniae* in Whole Blood[2]**	***S. pneumoniae* in Whole Blood[2] + saline**	**S. pneumoniae in Whole Blood[2] + 300ng/mL VP40**
3/3= 100% R	3/3= 100% R	0/20=0% R	NT	20/20=100% R

R = Reactive; NT=Not Tested

[1] Based on original material having a parasite level of 2.8 x 10^4 parasite/ uL. The material used for this study contained dead malaria parasites and was diluted 4-fold.

[2]No concentration available.

Table 11: Cross-Reactant Testing (where # reactive/# tested)

Organism	**Titer**	**Organism + Negative Whole Blood + Saline**	**Organism + Negative Whole Blood**	**Organism + Negative Whole Blood + Inactivated Ebola Virus Makona Strain Variant 2014 (Liberia, 2014) (1:64) in Saline**
Ebola Bundibugyo	5x10^6 $TCID_{50/}$ mL	0/3	0/3	3/3
Ebola Ivory Coast	N/A	0/3	0/3	3/3
Ebola Reston	1x$10^{7.5}$ pfu/ mL	0/3	0/3	3/3
Ebola Sudan Gulu	5.6x10^5 pfu/mL	0/3	0/3	3/3
Ebola Sudan Boniface	1x10^6 pfu/ mL	0/3	0/3	3/3
Marburg Angola	N/A	0/3	0/3	3/3
Marburg Musoke	1x$10^{7.5}$ pfu/ mL	0/3	0/3	3/3
Marburg Ravn	2.85x10^6 $TCID_{50/}$	0/3	0/3	3/3

	mL			
Marburg Voege	3.6×10^7 pfu/ mL	0/3	0/3	3/3

Interfering Substances

Controlled studies of potentially interfering substances were performed on negative and positive whole blood samples near the clinical decision points. Testing was performed as per CLSI guidelines EP7-A2 and EP37. Rheumatoid Factor showed interference on the DPP Ebola Antigen System at concentrations above 125 IU/mL. No interference was seen at the testing concentrations listed below.

Table 12: Interfering Substances for the DPP Ebola Antigen System in Whole Blood (where # reactive/# tested)

Interferent	Testing Concentration	Interferent + Negative Whole Blood + Saline	Interferent + Negative Whole Blood	Interferent + Negative Whole Blood + rVP40 (300 ng/mL) in Saline
Serum proteins	11 g/ dL or 110 mg/ mL	0/3	0/3	3/3
HAMA	663 ng/mL	0/3	0/3	3/3
Rheumatoid Factor	125 IU/ mL	0/5	0/5	5/5
Bilirubin conjugated	0.4 mg/ mL	0/3	0/3	3/3
Bilirubin unconjugated	0.4 mg/ mL	0/3	0/3	3/3
Cholesterol	4 mg/mL	0/3	0/3	3/3
Glucose	10 mg/mL	0/20	0/20	20/20
Hemoglobin	10 mg/ mL	0/3	0/3	3/3

Reading Reproducibility Study

The reproducibility of reading the DPP Ebola Antigen System was evaluated using blinded EDTA venous whole blood samples and blinded EDTA plasma samples spiked with various levels of inactivated Ebola Virus slurry. A total of 300 measurements per sample matrix were obtained. The calculated reproducibility of the DPP Ebola Antigen System was 94.3% (283/300 = 94.3% with 95% CI 91.1 to 96.4%) for EDTA whole blood and 93.0% (279/300 = 93.0% with 95% CI 89.5 to 95.3%) for EDTA plasma.

WHO International Reference Panel for Ebola virus VP40 antigen

In support of the World Health Organization's (WHO) ongoing activities related to Ebola virus, The National Institute for Biological Standards Control (NIBSC) conducted an international collaborative study to develop a standardized Ebola virus VP40 protein preparation to serve as WHO International Reference Reagents (IRR) for use in monitoring the performance of POC tests for the detection of VP40. Chembio Diagnostic Systems was invited to participate and provided kits of the DPP Ebola Antigen System for assessment as part of this study.

Nine study samples were formulated by dilution in a pool of thrombinized and declotted plasma screened negative for HBsAg, anti-HIV and anti-HCV. Three sets of nine samples were provided to Chembio freeze-dried, coded and blinded. The coded samples included both negative and positive samples. Directions for reconstitution of the freeze-dried materials were given in the instructions for use included with the study samples. Results using three lots total of the DPP Assay, one per panel set, are summarized in Table 13 below.

Table 13: Ebola VP40 in DPP Ebola Antigen System Results Using the WHO International Reference Panel

	Sample #								
	1	2	3	4	5	6	7	8	9
	VP 40 (high)	VP 40 (medium)	VP40 (medium)	VP40 (low)	VP40 (low)	VP 40 (high)	VP40-GP-NPs-VLPs (high)	Negative	VP40-GP-NPs- (medium)
DPP Ebola, Lot 1	292 (R)	168 (R)	69 (R)	98 (R)	17 (R)	167 (R)	194 (R)	7 (NR)	223 (R)
DPP Ebola, Lot 2	298 (R)	195 (R)	109 (R)	107 (R)	22 (R)	166 (R)	194 (R)	6 (NR)	220 (R)
DPP Ebola, Lot 3	300 (R)	226 (R)	114 (R)	107 (R)	25 (R)	162 (R)	194 (R)	6 (NR)	207 (R)

NR = Non-Reactive; R = Reactive

Notes: # High, medium, and low indicate the relative amounts antigen present as assessed during formulation of the study samples.

In a separate LoD determination study, three vials of sample 3 from the WHO Ebola QC Material (as described above) were obtained from WHO/NIBSC. After reconstitution with distilled water, the samples were pooled. From the pool, sample was prepared and tested as the undiluted material plus serial dilutions at 1:3, 1:6, 1: 9, 1:12, 1:24, and 1:48 (diluted in EDTA whole blood) on the DPP Ebola Antigen System. For all dilutions, five independent replicates (not five samplings from a single series) were prepared and assayed. Due to volume limitations, the undiluted material was only tested in duplicate. As can be seen from the results below (Table 14), the EDTA whole blood used as diluent before spiking sample 3 gave a negative result on the DPP Ebola Antigen System (3 replicates). The last dilution at which no signal is detected by the DPP Ebola Antigen System is 1:48. At the 1:9 dilution, 5 of 5 replicates were reactive. At the 1:12 dilution, 4 of the 5 replicates were reactive. There was not enough material to ascertain if further independent replicates at the 1:12 dilution would continue to be reactive on the DPP Assay.

Table 14. Serial Dilutions of WHO Ebola QC Material Sample 3 on the DPP Ebola Antigen System.

		DPP Ebola Antigen System				
Negative Blood		**Rep 1**	**Rep 2**	**Rep 3**		
		10	8	10		
WHO Panel CS 571, Member 3,		**DPP Ebola Antigen System**				
		Rep 1	**Rep 2**	**Rep 3**	**Rep 4**	**Rep 5**
Undiluted	**0**	ND	81 (R)	ND	ND	54 (R)
Dilution	**1:3**	36 (R)	35 (R)	27 (R)	23 (R)	22 (R)
	1:6	17 (R)	14 (R)	21 (R)	12 (R)	21 (R)
	1:9	15 (R)	18 (R)	13 (R)	12 (R)	12 (R)
	1:12	**8.5 (NR)**	17 (R)	16 (R)	14 (R)	13 (R)
	1:24	**11 (NR)**	14 (R)	**10 (NR)**	**10 (NR)**	**10 (NR)**
	1:48	**7.6 (NR)**	**10 (NR)**	**8.3 (NR)**	**8.1 (NR)**	**8.5 (NR)**

ND= Not Done; NR = Non-Reactive; R = Reactive

Due to volume limitations, the undiluted sample was only tested in duplicate.

16. References

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5. CLSI. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition.* CLSI Document EP17-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.

ORDERING INFORMATION

REF 61-1013-0 Chembio DPP® Ebola Antigen System

REF 61-1050-0 Chembio DPP® Micro Reader

REF 60-9554-0 Chembio DPP® Ebola Rapid Test Control Pack

For Product Information, Literature and/or SDS please email info@chembio.com

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MEDFORD, NY 11763 USA

Tel: 1-844-CHEMBIO (844-243-6246)

Email: info@chembio.com
Web Site: www.chembio.com

SYMBOL LEGEND	
	CONSULT THE MANUAL BEFORE USE
	CAUTION, CONSULT THE ACCOMPANYING DOCUMENTS
	DO NOT RE-USE
	FOR USE WITHIN TEMPERATURE LIMITS
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	BATCH CODE
REF	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
Rx Only	PRESCRIPTION DEVICE
	USE BY DATE
	CONTAINS SUFFICIENT FOR 20 TESTS

CHEMBIO DIAGNOSTIC SYSTEMS, INC.

For use under the Emergency Use Authorization (EUA) only | For prescription use only | For *In Vitro* diagnostic Use Only

DPP® Ebola Antigen System: Quick Reference Instructions

Cat No. 61-1013-0

Before you begin

These instructions are only a Reference Guide. Read the complete DPP® Ebola Antigen System Product Instructions and the DPP® Micro Reader User Manual before performing the test.

- Gather the material you will need.
- Cover your work station with a clean, disposable absorbent workplace cover.
- Wear disposable gloves, gown (fluid resistant or impermeable), and eye protection (goggles or face shield).
- Let the test reach room temperature (between 8-30°C or 64-86°F) before opening the pouch.

For problems or questions, please contact:

Chembio Diagnostic Systems
Customer Services -
844-CHEMBIO (243-6246)

Materials included

- 20 DPP® Ebola Antigen Individually Pouched Test Devices
- 20 Microsafe Tubes (50uL)
- 20 Sterile Safety Lancets (for fingerstick whole blood samples)
- 20 Adhesive Bandages
- 20 Sterile Alcohol Swabs
- 1 DPP® Ebola Antigen System Buffer (7 mL) with GREEN Cap
- 1 Product Insert
- 1 Quick Reference Instructions
- 1 Fact Sheet for Healthcare Providers
- 1 Fact Sheet for Patients

Materials required but not included

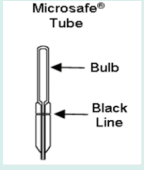
- DPP® Ebola Rapid Test Control Pack (Catalog #60-9554-0)
- Clock, watch or other timing device
- Disposable gloves
- Sterile gauze (for fingerstick samples only)
- Biohazard disposal containers
- Pipettor capable of delivering 20-200µL of sample (for other than fingerstick specimens)
- Pipette tips
- DPP® Micro Reader (Catalog #61-1050-0)

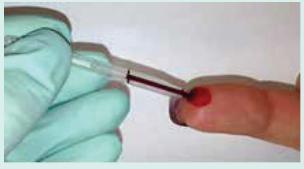
  Each kit contains:
  - 1 DPP® Micro Reader with Ebola RFID sticker (includes 3 batteries)
  - 1 DPP® Cartridge Holder for use with DPP® Test Device
  - 1 USB adapter (will only transmit power)
  - 1 Power plug adapter
  - 1 Microfiber Cloth
  - 1 User Manual for the DPP® Micro Reader

DPP® Ebola Antigen System: Quick Reference Instructions

For *In Vitro* diagnostic use

1 COLLECTION: FINGERSTICK WHOLE BLOOD

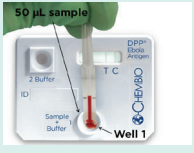




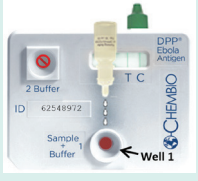
Collect 50µL of Sample by holding **Microsafe® Tube** horizontally. Ensure Tube is filled to the black line. **DO NOT squeeze the bulb at the top of the tube.** Capillary action will draw the sample to the black fill line.

2 SAMPLE + BUFFER DELIVERY INTO WELL 1

Holding the **Microsafe® Tube** vertically over the **SAMPLE+BUFFER** Well 1, squeeze the bulb to release 50µL sample into the well.



Immediately add 3 drops of **DPP® Ebola Antigen System Buffer (Green Cap)** into Well 1.



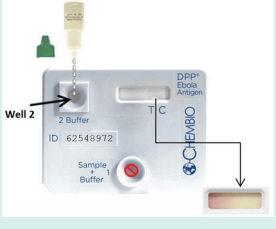
3

WAIT **5** MINUTES

The blue colored line should have disappeared. If not, DO NOT USE, discard test device and use a new Test Device.

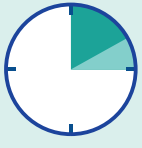
4 RUNNING BUFFER DELIVERY INTO WELL 2

Add 6 drops of **DPP® Ebola Antigen System Buffer (Green Cap)** slowly, dropwise, into BUFFER Well 2.



A PINK flow should begin across the strip within **2-3 minutes of buffer addition**. If NO PINK flow is present, repeat with a new device.

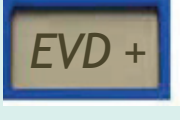
5 RESULTS INTERPRETATION



Read results **10-15 min** AFTER addition of Buffer into Well 2.

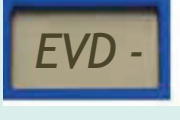
The **Chembio DPP® Micro Reader** must be used for all interpretation of test results. **Do not attempt to interpret the results visually.**

DO NOT ATTEMPT TO INTERPRET RESULTS VISUALLY. ALWAYS USE THE DPP® MICRO READER TO OBTAIN RESULTS.



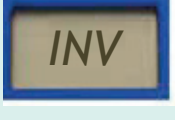
REACTIVE

A Reactive test result means that Ebola antigen has been detected in the specimen.



NONREACTIVE

A non-reactive test result means that Ebola antigen was not detected in the specimen.



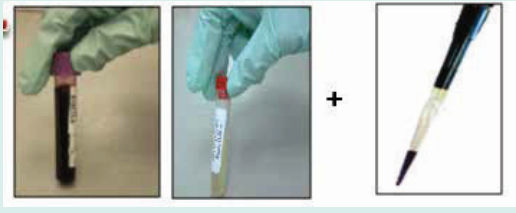
INVALID

An INVALID test cannot be interpreted.

DPP® Ebola Antigen System: Quick Reference Instructions

For *In Vitro* diagnostic use

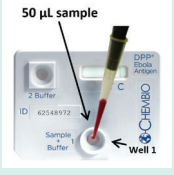
1 COLLECTION: VENOUS BLOOD/PLASMA



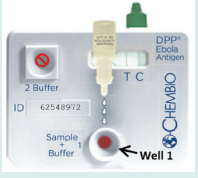
Using a calibrated pipette, collect 50µL of Sample.

2 SAMPLE + BUFFER DELIVERY INTO WELL 1

Using a calibrated pipette, add 50µL of the sample to **SAMPLE + BUFFER** Well 1.



Immediately add 3 drops of **DPP® Ebola Antigen System Buffer (Green Cap)** into Well 1.



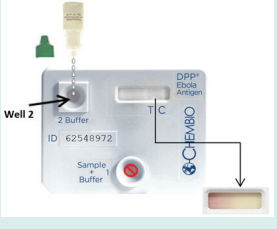
3

WAIT **5** MINUTES

The blue colored line should have disappeared. If not, DO NOT USE, discard test device and use a new Test Device.

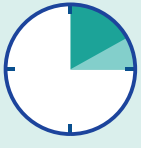
4 RUNNING BUFFER DELIVERY INTO WELL 2

Add 6 drops of **DPP® Ebola Antigen System Buffer (Green Cap)** slowly, dropwise, into BUFFER Well 2.



A PINK flow should begin across the strip within **2-3 minutes of buffer addition**. If NO PINK flow is present, repeat with a new device.

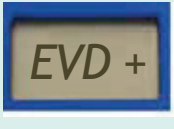
5 RESULTS INTERPRETATION



Read results **10-15 min** AFTER addition of Buffer into Well 2.

The **Chembio DPP® Micro Reader** must be used for all interpretation of test results. **Do not attempt to interpret the results visually.**

DO NOT ATTEMPT TO INTERPRET RESULTS VISUALLY. ALWAYS USE THE DPP® MICRO READER TO OBTAIN RESULTS.

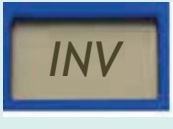


REACTIVE

A Reactive test result means that Ebola antigen has been detected in the specimen.

NONREACTIVE

A non-reactive test result means that Ebola antigen was not detected in the specimen.



INVALID

An INVALID test cannot be interpreted.

**DO NOT ATTEMPT TO INTERPRET RESULTS VISUALLY.
ALWAYS USE THE DPP® MICRO READER TO OBTAIN RESULTS.**

Using the Chembio DPP® Micro Reader

These instructions are only a Reference Guide. Read the complete User Manual before using the DPP® Micro Reader.

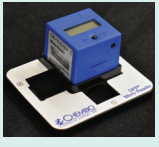
A

Ensure that the reader and components are clean. Remove any dust or debris. Connect the DPP® Micro Reader to the supplied cartridge holder as shown.

DPP® Micro Reader

Cartridge Holder

CORRECT Reader Placement



DPP® Micro Reader correctly seated in holder

INCORRECT Placement

Reader is **NOT** seated properly

B

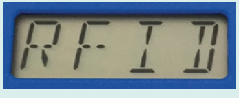
Reading window

Push this button

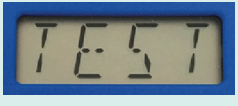
At the time indicated for reading the test results, place the reader and holder onto the top of the cassette and push the operating button. "**ON**" should appear in the reading window.

C

Press the operating button again and the display will read "**RFID**".



The display will read "**TEST**".



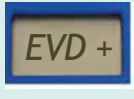
D

Press the operating button and "**RUN**" will appear in the display window.

After approximately 3 seconds, a result for the DPP® Ebola test device will appear across the display

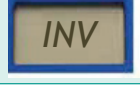
NOTE: As soon as the test is complete, the user should manually record the result. The reader will turn off automatically after approximately 50 seconds of inactivity. There is no active function to shut off the DPP® Micro Reader or to recall the last test results.

E



A Reactive test result means that Ebola antigen has been detected in the specimen. The patient is presumed Positive for Ebola antigen. Follow up testing with PCR to confirm test result.

A non-reactive test result means that Ebola antigen was not detected in the specimen. The test result is interpreted as not having detected Ebola antigen. The patient is presumed Negative for Ebola antigen.



An INVALID test cannot be interpreted. It is recommended that the INVALID test be repeated with a new device.

Ordering Information:

Cat No.	Description
61-1050-0	DPP® Micro Reader

CHEMBIO DIAGNOSTIC SYSTEMS, INC.
Tel: (631) 924-1135 | Email: info@chembio.com | www.chembio.com

For use under the Emergency Use Authorization only

REF 60-9554-0

DPP® Ebola Rapid Test Control Pack
Chembio DPP Ebola Reactive Control and DPP Ebola Non-Reactive Control

For in vitro diagnostic use

For Prescription Use Only

STORAGE: Store at 25 °C

Read this Product Insert and the DPP® Ebola Antigen 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 MUST read and become familiar with Universal Precautions for prevention of transmission of blood borne pathogens in Health-Care Settings and the CDC's guidance on how to safely manage specimens from persons under investigation for Ebola Virus Disease. [1]

INTENDED USE

The Chembio DPP Ebola Reactive control and DPP Ebola Non-Reactive Control are quality control reagents for use with the Chembio DPP Ebola Antigen 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 (36 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 Ebola Antigen 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 EBOLA REACTIVE AND NONREACTIVE CONTROLS

Chembio DPP Ebola Reactive control and DPP Ebola Non-Reactive Control are human, serum-based reagents. The Controls are specifically formulated and manufactured to ensure performance of the DPP® Ebola Antigen System test, and are used to verify the user's ability to properly perform the test and interpret the results. The Chembio DPP Ebola Reactive Control will produce a REACTIVE (EVD+) Test Result and have been manufactured to produce a faint Test "T" line. The Chembio DPP Ebola Non-Reactive Control will produce a NONREACTIVE (EVD-) Test Result. 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 Ebola Antigen System.

MATERIALS PROVIDED

Each DPP Ebola Rapid Test Control Pack contains a Product Insert and two Vials (one DPP Ebola Reactive Control and one DPP Ebola Non-Reactive Control) as described.

DPP Ebola Reactive Control

One Vial containing 0.5mL of lyophilized heat inactivated Recombinant Ebola virus (species *Zaire ebolavirus*) VP40 protein (600 ng/ml) in normal human serum negative for HBsAg, HCV Ab, HIV 1/2 ag, HBV DNA, HCV RNA, HIV RNA, RPR (syphilis) and preservative (0.09% sodium azide).

DPP Ebola Non-Reactive Control

One Vial containing 0.5mL of lyophilized normal human serum negative for HBsAg, HCV Ab, HIV 1/2 ag, HBV DNA, HCV RNA, HIV RNA, RPR (syphilis) and preservative (0.09% sodium azide).

MATERIALS REQUIRED AND PROVIDED
in the Chembio DPP Ebola Antigen System (Cat# 61-1013-0)

Each kit contains the items to perform 20 tests:

- 20 DPP Ebola Antigen System Test Devices - Individually Pouched
- 20 Disposable Microsafe® Tubes (50µL)
- 20 Sterile Safety Lancets (for fingerstick whole blood samples)
- 20 Adhesive Bandages
- 20 Sterile Alcohol Swabs
- 1 DPP Ebola Antigen System Buffer (7mL) – Green Cap
- 1 Product Insert
- 1 Quick Reference Instructions
- 1 Fact Sheet for Health Care Providers
- 1 Fact Sheet for Patients

ACCESSORIES THAT ARE AVAILABLE AND REQUIRED INCLUDE THE

Chembio DPP Micro Reader (Catalog # 61-1050-0)
Each kit contains:

- 1 Chembio DPP Micro Reader with Ebola RFID sticker (includes 3 Lithium-ion, type CR2032 (3 V/230 mAh) coin cell batteries)
- 1 DPP Cartridge Holder for use with DPP Ebola Antigen Test Device
- 1 Custom Power Cable (USB)
- 1 Power plug Adapter
- 1 Microfiber Cloth
- 1 User Manual for the DPP Micro Reader

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, watch or other timing device
- Disposable gloves
- Sterile gauze (for fingerstick samples only)
- Collection devices (for venous whole blood or serum/plasma specimens)
- Biohazard disposal containers
- Pipettor capable of delivering 20-200µL
- Pipette tips

WARNINGS
For *IN VITRO* diagnostic use

1. Read this Product Insert and the DPP Chembio Ebola Antigen System Product Insert completely before using this product. Follow the instructions carefully as not doing so may result in inaccurate Test Results.
2. Users of this test MUST read and become familiar with the CDC's "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Setting" [1], the CDC's guidance on "Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals" [2], and the CDC's guidance on "How U.S. Clinical Laboratories Can Safely Manage Specimens from Persons Under Investigation for Ebola Virus Disease" [3]
3. Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact with hands, eyes or mouth during specimen collection and testing.
4. Put on disposable Gloves, Gown (fluid resistant or impermeable), Eye protection (goggles or face shield) and Facemask. Additional PPE might be required in certain

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Nov 9, 2018

situations (e.g., copious amounts of blood, other body fluids, vomit, or feces present in the environment), including but not limited to: Double gloving, Disposable shoe covers and leg coverings.

5. Dispose of all specimens and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121ºC. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination.
   NOTE: Do not autoclave solutions that contain bleach.
6. Use 10% bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh each day.
7. Use of Kit 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 Ebola Antigen Assay.

STORAGE AND STABILITY

The Chembio DPP Ebola Reactive Control and DPP Ebola Non-Reactive Control can be stored at 25 ± 5°C/ 77± 9°F if unopened. Once opened and rehydrated, these Ebola control reagents should be stored at 2 to 8°C (36 to 46°F) for no more than 30 days. Do not use beyond the indicated expiration date on the vial. Open the Control Vials only when you are performing tests. Recap and store the Control Vials in their original container at 2 to 8°C (36 to 46°F) after use. The test devices should be stored in its unopened pouch at 2 to 30°C (36 to 86°F). Do not freeze. Do not open the pouch until you are ready to perform a test. When stored as indicated, Test Devices are stable until the expiration date marked on the pouch. The Running Buffer (for Chembio DPP Ebola Antigen System) should also be stored at 2 to 30°C (36 to 86°F) in its original Vial.

TEST PROCEDURE

All components for the Chembio DPP Ebola Antigen System are ready to use as supplied. Instructions for use are given in the Chembio DPP Ebola Antigen System Product Insert. Follow directions as indicated. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18 to 30°C (64 to 86°F) prior to testing.

Procedure for Using Controls with Chembio DPP Ebola Antigen System

First Use of Chembio DPP Ebola Reactive Control and DPP Ebola Non-Reactive Control

1. Open a Control Vial containing the Control Reagent.
2. Using a calibrated pipettor capable of delivering 100-1000µL, add 500µL of deionized water to each of the Control Vials.
3. Mix on a rocker for 15-20 min until material is in a solution.

To Run Controls on Assay

4. Open a Control Vial containing the Control Reagent.
5. Remove the Chembio DPP Ebola Antigen System Test Device from its pouch and place it on a flat surface (It is not necessary to remove the desiccant from the pouch).
6. Label the Test Device with Control Reagent name or identification number.
7. Note that the DPP test device has 2 colored lines in the Test Window; one is blue and the other is green. If the 2 colored lines are absent, DO NOT USE. Discard the test device and use a new test device.
8. Use a laboratory pipet to withdraw 50µL of the control sample.
9. Pipette the sample into Sample + Buffer Well 1 of the DPP Test Device,
10. Test immediately, following Test Procedure instructions.
    a. Immediately after the addition of the control material, add 3 drops of DPP® Ebola Antigen System Buffer (Green Cap) into the same well (Well 1). To add the buffer, invert the DPP Ebola Antigen System Buffer (Green Cap) and hold it vertically (at a 90º) over Well 1. Squeeze the bottle to slowly add 3 drops.
       NOTE: The Control Reagents are clear to straw-colored.
    b. Wait 5 minutes. The blue and green colored lines should have disappeared from the rectangular TEST and CONTROL window. If not, discard the test device and repeat the procedure with a new DPP test device.
    c. Invert the DPP Ebola Antigen System Buffer (Green CAP) and hold it vertically (not at an angle) over BUFFER Well 2. Slowly add 6 drops of DPP Ebola Antigen System Buffer (GREEN CAP) to BUFFER Well 2.
    d. Read the test result 10 to 15 minutes after the addition of the DPP Ebola Antigen System Buffer to BUFFER Well 2. In some cases, a test line may appear in less than 10 minutes however, 10 minutes are needed to report a nonreactive result. Read results in a well-lit area. Do not read results after 15 minutes from the addition of the Running Buffer to BUFFER Well 2.
11. Discard the used pipet tips, Test Device and any other test materials into a biohazard waste container.
12. Reseal the Control Reagent Vials and store them in their original container at 2 to 8°C (36 to 46°F).

QUALITY CONTROL

Built-in Control Feature

The control line serves as a built-in internal control and gives confirmation of sample addition and proper test performance. A pink/purple line will appear in the CONTROL area if the test has been performed correctly and the Device is working properly (Please see section: Interpretation of Test Results).

INTERPRETATION OF TEST RESULTS

Read the test result between 10 to15 minutes after the addition of the running buffer to well 2 of the DPP® device (see interpretation of results section 3 below). Follow the DPP Micro Reader instruction manual.

EXPECTED RESULTS

1. DPP Ebola Non-Reactive Control:

The DPP Ebola Non-Reactive Control will produce a NONREACTIVE (EVD-) Test Result. The reader will display the following result:

2. DPP Ebola Reactive Control:

The DPP Ebola Reactive Control will produce a REACTIVE (EVD+) Test Result. The reader will display the following result:

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3. INVALID –

.An INVALID (INV) test cannot be interpreted. It is recommended that the INVALID test be repeated with a new device. If results are still invalid collect a fresh sample or test by another method.

NOTE: If the Test Result for the DPP Ebola Non-Reactive Control or DPP Ebola Reactive Control is not as expected, the test should be repeated using a new Test Device and Control Specimen. If the Ebola control reagents do not produce the expected results and you are unable to obtain a valid Test Result upon repeat testing contact Chembio Diagnostic Systems Customer Service at 1-631-924-1135 ext. 112.

LIMITATIONS

The Chembio DPP Ebola Reactive Control and DPP Ebola Non-Reactive Controls are quality control reagents for use **ONLY** with Chembio DPP Ebola Antigen Assay.

REFERENCES

1. CDC's 2014 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Setting Available from: http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html

2. August 1, 2014 CDC released guidance titled, "Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals." Available from: http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html

3. Centers for Disease Control and Prevention, How U.S. Clinical Laboratories Can Safely Manage Specimens from Persons Under Investigation for Ebola Virus Disease Available from: http://www.cdc.gov/vhf/ebola/hcp/safe-specimen-management.html

ORDERING INFORMATION

REF 61-1013-0 Chembio DPP® Ebola Antigen Assay System

REF 61-1050-0 Chembio DPP® Micro Reader

REF 60-9554-0 Chembio DPP® Ebola Rapid Test Control Pack

CHEMBIO DIAGNOSTIC SYSTEMS, INC.
3661 HORSEBLOCK ROAD
MEDFORD, NY 11763 USA

Tel: 1-844-CHEMBIO (844-243-6246)
Fax: 1-631-924-2065
Email: info@chembio.com
Web Site: www.chembio.com

SYMBOL LEGEND

- CONSULT THE MANUAL BEFORE USE
- CAUTION, CONSULT ACCOMPANYING DOCUMENTS.
- DO NOT REUSE
- 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

CHEMBIO
DIAGNOSTIC SYSTEMS, INC.

REF 61-1050-0
1 Unit

DPP® Micro Reader

For use under the Emergency Use Authorization (EUA) only.

For *In Vitro* Diagnostic Use.

Read this User Guide completely before using the product.

Storage conditions: Store between -20 to 80°C (-4 to 176°F)

NAME AND INTENDED USE

The DPP® Micro Reader –is for use with the DPP® Ebola Antigen System test device.

SUMMARY AND EXPLANATION

The DPP Micro Reader is a reflectance reader used to obtain test results from DPP Ebola Antigen System test device. The DPP Micro Reader minimizes human errors due to subjective visual interpretation; therefore, the results of the DPP Ebola Antigen System test devices are made specifically to be read with the DPP Micro Reader. Results must be read exclusively with the DPP Micro Reader.

PRINCIPLES OF THE PROCEDURE

The DPP Micro Reader is a portable, battery-powered instrument that captures an image of the test strip surface, verifies the presence and intensity of the control line and measures the line intensity at each of the test line positions; it interprets the results using a scoring algorithm, and reports a REACTIVE, NON-REACTIVE or INVALID result after approximately 3 seconds. A 14-segment liquid crystal display (LCD) on the top of the instrument shows the status of the instrument and displays the test results to the operator.

The DPP Micro Reader is maintenance-free, not configurable by the user, and is operated with a single, multi-function button.

MATERIALS PROVIDED

Each kit contains:

1 DPP Micro Reader with Ebola RFID sticker (includes 3 Lithium-ion, type CR2032 (3 V/230 mAh), coin cell batteries)
1 DPP Cartridge Holder for use with DPP Ebola Antigen Test Device
1 Custom Power Cable (USB)
1 Power plug adapter
1 Microfiber Cloth
1 User Manual for the DPP Micro Reader

WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic Use.
- Where indicated, DPP Ebola Antigen System test results **must be read using the DPP Micro Reader** and cannot be visually interpreted.
- The DPP Micro Reader is calibrated and checked before shipping under strict quality control measures in order to guarantee a high degree of quality. **Do not attempt** to open, re-configure or re-calibrate the DPP Micro Reader.
- Protection provided by this instrument may be impaired if the equipment is used in a manner not consistent with the instructions in this manual.
- The DPP Micro Reader requires three (3) CR2032 (3 V/230 mAh) batteries to operate or must be plugged in through the power cable using the port located above the battery compartment and connecting it to a powered USB adapter or a powered USB hub.
- **Do not** use the DPP Micro Reader in direct sunlight or exposed to bright light while reading results.
- The DPP Micro Reader is designed for use on a clean, flat, horizontal surface.
- Always ensure that the DPP Micro Reader is positioned correctly in the DPP Cartridge Holder. Incorrect positioning may lead to incorrect results.
- The DPP Micro Reader can be operated at temperatures between 10 and 35°C (50 to 95°F) and between 20% and 85% humidity. Ensure that the DPP Micro Reader is brought to operating temperature before use.
- Protect the DPP Micro Reader from liquids. Any liquid entering the DPP Micro Reader may damage it permanently.
- Please follow the instructions in the product insert provided with the test kit regarding the disposal of test devices containing hazardous or infectious material.

- The DPP Micro Reader itself contains no biological hazards. However, contamination during use with biological hazards is possible. For cleaning and maintenance, refer to section **CLEANING AND MAINTENANCE.**

STORAGE AND STABILITY

The DPP Micro Reader should be stored at temperatures between -20 and 80°C (-4 to 176°F) and between 20% and 85 % humidity. It can be operated at temperatures between 10 and 35°C (50 to 95°F) and between 20% and 85% humidity.

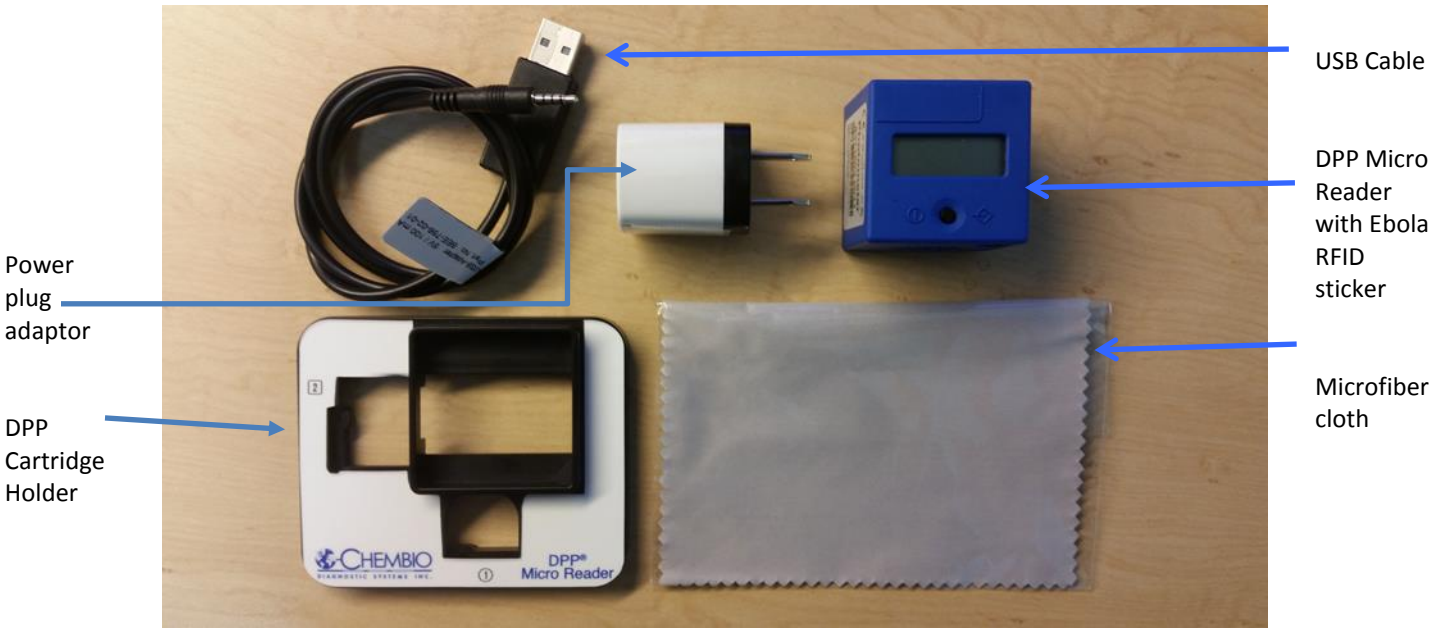
BATTERY LIFE

Under continuous use, one set of batteries will last for approximately 250- 300 reads (exact number may vary depending on battery quality, temperature, and length of storage between uses). The status of the batteries is being monitored and shown on the reader display every time the reader is turned ON. Verify that the battery symbol is not blinking nor has any bars left. Replace the batteries when the battery symbol starts to blink. The batteries cannot be recharged and have to be disposed according to local regulations. Always have a spare set of three batteries. Please see section on **BATTERY INSTALLATION** below. Alternatively, the DPP Micro Reader can be powered using the USB power cable connected to a power source.

UNPACKING AND SET-UP

1. Before using the DPP Micro Reader, visually inspect the contents for damage. If damage is apparent, contact Chembio Diagnostic Systems, Inc. (Figure 1).
2. Remove the reader from its protective wrapping. It is recommended that the packaging materials are retained for later use.
3. Ensure that the reader and components are clean. Remove any dust or debris with a smooth, dry cloth.

Figure 1: Package Content



BATTERIES INSTALLATION AND REPLACEMENT

The reader requires three (3) CR2032 (3 V/230 mAh) batteries, Lithium-ion Coin Cell batteries such as Energizer™ ECR2032 3V LITHIUM; DURACELL DL2032B4 Battery, 2032, Lithium, 3V or equivalent. Replace the batteries when the battery symbol starts to blink. To replace the batteries, turn the battery cover with a smooth-edged coin ¼ turn counterclockwise until it stops. Tilt the side with the battery cover down so it falls into your hand, as well as the batteries inside. Place three new Lithium-ion Coin Cell batteries with correct polarity orientation ('+' sign outward, see Fig. 2) into the battery compartment one by one. Replace the battery cover by pressing slightly with a coin and turning ¼ turn clockwise until it stops.

NOTE: If the reader does not start after installing new batteries, clean the batteries with a dry cloth and make sure they are installed with the + side directed outwards. If it still does not start, try a set of fresh batteries.

Figure 2: Battery Installation/Replacement

Lithium-ion coin cell batteries required

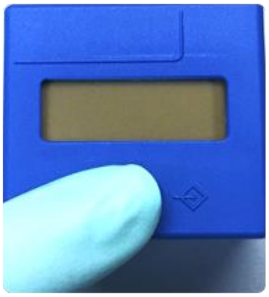
Battery compartment cover

Battery compartment open

Batteries installed correctly: (+) on top

After changing the batteries, perform the following steps Note: the date that appears in step 3 (below) represents the manufacture date of the DPP Micro Reader.

1. When the DPP® Micro Reader is off, the display is blank.



2. To turn on the device, press the button briefly (i.e. less than 1 second).

3. After activation, the buzzer sounds can be heard, and the display shows "Year – Date and time"

4. Press the button one more time (<1 second) and the display will show "ON" and is now ready to use

Using the DPP Micro Reader

DPP Micro Reader

The DPP Micro Reader has 3 components: The DPP Micro Reader with Ebola RFID sticker, the Cartridge Holder for use with DPP® Ebola Antigen System Test Device, and a USB Cable.

DPP Ebola Ag RFID Sticker

Assemble the DPP® Micro Reader:

a) Check to make sure that the window at the bottom of the reader is clean of finger marks and dust or lint before using the reader (see CLEANING AND MAINTENANCE Section below).Use enclosed microfiber cloth to wipe free of marks, dust or debris following the Chembio Ebola Micro Reader User Manual instructions.

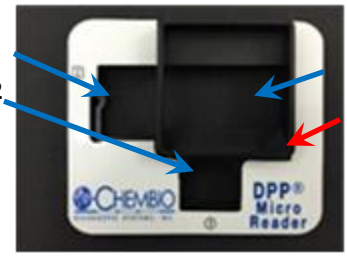
Make sure the RFID Sticker refers to Ebola VP40.

b) Place the Cartridge Holder on a flat surface. Align the angled edge on the bottom of the DPP Micro Reader with the corresponding angled corner of the holder socket and place the DPP Microreader in the holder socket.

Angled Edge

DPP Micro Reader

Openings for Wells 1 and 2



Reader Opening

Angled Corner

Cartridge Holder for Reader

DPP Micro Reader in Cartridge Holder

c) To read a test, place the DPP Micro Reader in Cartridge Holder on top of the test device. Make sure the rectangular test window on the test device is aligned with the reading window of the reader. At the end of assembly, the black button, battery compartment and Buffer Well 1 on the test device should be facing the user and Buffer Well 2 should be to the left of the user.

DPP Micro Reader with Cartridge Holder on top of testing device

Reading a test:

a) 10 to 15 minutes after the addition of the DPP Ebola Antigen System Buffer to Well 2 as per STEP 4 in the TEST PROCEDURE, push the operating button. "ON" should appear in the reading window.

Reading Window

Push this Button

b) Press the Operating Button again; the display will read “RFID”.

c) “TEST” will appear in the display window.

d) Press the Operating Button and “RUN” will appear in the display window.

After approximately 3 seconds, a result for the DPP Ebola Antigen System Test Device will appear across the display. **Record the result (refer to INTERPRETATION OF TEST RESULTS) as the reader does not record results**.

NOTE: The test result should be manually recorded immediately after the test is complete as the reader will turn off automatically after approximately 50 seconds of inactivity. The DPP Micro Reader device does not store or recall previous results.

If the DPP Micro Reader does not detect a line in the CONTROL (C) area, then it will display “INV”, indicating that the test is INVALID. An INVALID result indicates a problem with running the test, either related to the specimen, the device, or the procedure followed. An INVALID test cannot be interpreted; it is recommended that the INVALID test be repeated with a new device.

TURNING OFF THE READER

There is no active function to shut off the DPP Micro Reader; it will turn off automatically after approximately 50 seconds of inactivity.

CLEANING AND MAINTENANCE

The outer case and display may be cleaned with a microfiber cloth lightly moistened with 70% isopropyl alcohol (IPA) or 10% bleach solution. Do not introduce cleaning solution or any liquid into the unit. Do not use a saturated towel, which may leak liquid into the case or display seams. Ensure that the DPP Micro Reader is dry and the surface is free of fluid prior to returning to use.

Make sure that the window under the reader is clean of finger marks, dust and lint, which may interfere with the results. It can be wiped with a dry microfiber cloth, or a microfiber cloth lightly moistened with 70% isopropyl alcohol (IPA) to remove greasy or finger marks.

SERVICING AND RE-ORDERING

There are no user serviceable components in the unit with the exception of the replaceable batteries. For technical issues or questions, and to order a new reader, please contact Chembio Diagnostic Systems, Inc.

CUSTOMER SERVICE DEPARTMENT
Call: 1-844-CHEMBIO (844-243-6246)
Email: customerservice@chembio.com

DISPOSAL

As the DPP Micro Reader may be contaminated by infectious material, it should be disinfected according to the **CLEANING AND MAINTENANCE** section above before disposal. Remove the batteries before disposing of the expired device and dispose of the batteries in accordance with local regulations.

MESSAGES

Messages displayed by the DPP Micro Reader are described in the table below. For assay-specific messages, see the appropriate package insert.

Message	Type	Meaning	Action Recommended
ON	Status	Reader is ready for use.	None
RFID	Status	Reader is ready for RFID.	The RFID sticker is attached to the reader to obtain assay information. Press the button and reader will show TEST.
TEST	Status	Reader is ready to run a DPP test device.	Press the button and the reader will show RUN.
RUN	Status	Reader is reading test results.	None.
OK	Status	Reader has recorded date and time information.	Press the button one more time, the reader will show 'ON' and is now ready for use.
ERR	Error	The device could not read the information from the RFID sticker.	(1) Press the button briefly (<1 second), the display will show 'ON'. (2) Make sure the RFID sticker is attached to the side of the reader. After you press the button when the RFID word is in the display, the reader should show TEST. If the error occurs again, please contact Chembio Diagnostic Systems, Inc.
DATE	Error	An expiry date appears to be exceeded.	Check the expiration date of the reader, RFID sticker and the test device in use.

SPECIFICATIONS

Dimensions:	L x W x H: Approx. 1.6 x 1.6 x 1.6 in. (41 x 41 x 40 mm)
Weight:	Approx. 1.4 oz (40 g)
Operation:	One button operation
Display:	14-segment LCD
Storage capacity:	None
Device measurement period:	Approx. 3 second
Power supply:	3 batteries CR2032 (3 V/230 mAh) Or Micro-Reader specific power cord/USB cable
Interface:	4 pole – 0.1 in. (2.5 mm) jack plug for power supply (instead of battery
Configuration:	Specific configuration program; RFID technology
Measuring field:	Min. 0.2 in. (4 mm) width; Max. 0.7 in. (18 mm) length
Lighting:	Wavelength 525 nm
Signaling device:	Buzzer
Operating conditions:	Between 50°F (+10°C) and 95°F (+35°C); between +20 % and +85 % humidity
Storage conditions:	Between -22°F (-30°C) and 176°F (+80°C); between +20 % and 85 % humidity
Degree of protection:	IP 20
Lifetime:	3,000

REF 61-1050-0
1 Unit

ORDERING INFORMATION

REF 61-1013-0 Chembio DPP® Ebola Antigen System

REF 60-9554-0 Chembio DPP® Ebola Rapid Test Control Pack

REF 61-1050-0 Chembio DPP® Micro Reader

For Product Information please email info@chembio.com

CHEMBIO DIAGNOSTIC SYSTEMS, INC.
3661 HORSEBLOCK ROAD
MEDFORD, NY 11763 USA

Tel: 1-844-CHEMBIO (844-243-6246)

Email: info@chembio.com
Web Site: www.chembio.com

SYMBOL LEGEND	
	CONSULT THE MANUAL BEFORE USE
	CAUTION, CONSULT THE ACCOMPANYING DOCUMENTS
	FOR USE WITHIN TEMPERATURE LIMITS
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
REF	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	DATE OF MANUFACTURE
	THIS DEVICE SHOULD BE TREATED AS WASTE EQUIPMENT AND DISPOSED OF AT DESIGNATED COLLECTION POINT
	READER POWER ACTUATION (ON/OFF)
SN	READER SERIAL NUMBER (13 DIGITS)
IP20	PROTECTION CLASS OF ELECTRONIC EQUPMENT