

DPP® Micro Reader

Read this User Guide completely before using the product.

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

For use under Emergency Use
Authorization (EUA) only.

For *In Vitro* Diagnostic Use.

NAME AND INTENDED USE

The DPP® Micro Reader –is for use with the DPP® Zika IgM Assay System Devices.

SUMMARY AND EXPLANATION

The DPP® Micro Reader is a reflectance reader used to obtain test results from DPP® Zika IgM Assay System assay cassettes. The DPP Micro Reader minimizes human errors due to subjective visual interpretation; therefore, the results of DPP Zika IgM Assay System Devices made specifically to be read with a DPP Micro Reader 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 Zika IgM RFID sticker
 - 3 Lithium-ion, type CR2032 (3 V/230 mAh), coin cell batteries (installed)
- 1 Custom power adapter cable (USB to 2.0 mm jack)
- 1 Power plug adaptor
- 1 DPP Cartridge Holder
- 1 Microfiber cloth
- 1 User Manual

WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic Use.
- Where indicated, DPP Zika IgM Assay System test results **must be read using the DPP Micro Reader** and cannot be visually interpreted.
- The DPP Micro Readers are 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 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 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 Micro Reader is brought to operating temperature before use.
- Protect the DPP Micro Reader from liquids. Any liquid entering the Micro Reader may damage it permanently.

- Please follow the instructions in the product insert provided with the test kit regarding the disposal of DPP 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.

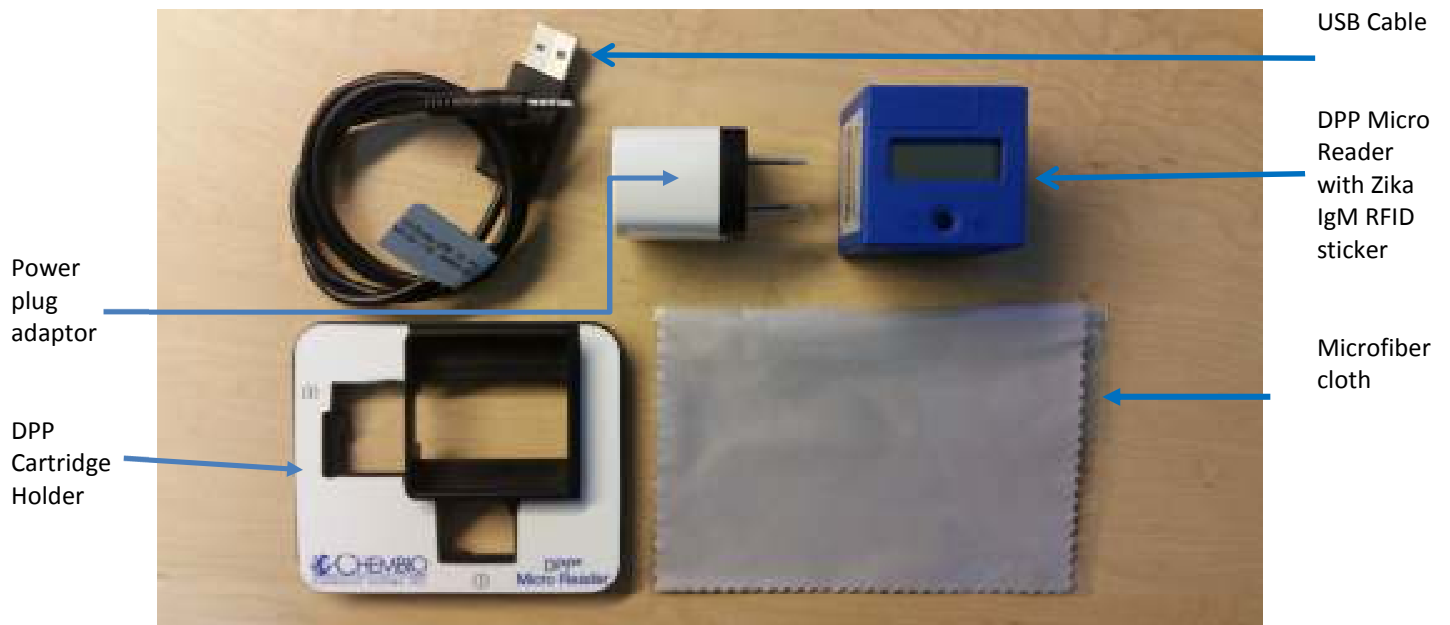
BATTERY LIFE

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

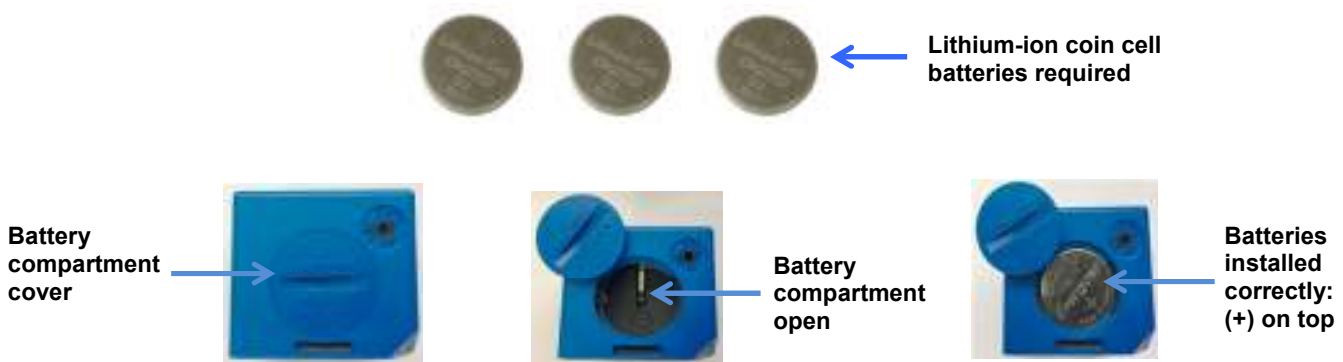


BATTERIES INSTALLATION AND REPLACEMENT

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



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.



Using the DPP Micro Reader

The DPP Micro Reader has 3 components: The DPP Micro Reader with Zika IgM RFID sticker, the holder for use with DPP® Zika IgM Assay System Test Device, and a USB Cable.

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).
- b) Place the DPP Micro Reader 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 Microreader in the holder socket.

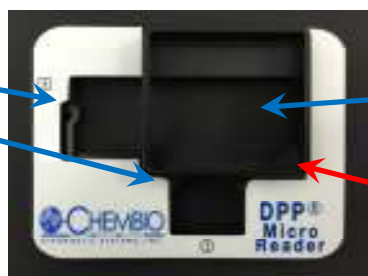


Zika IgM RFID Sticker



DPP Micro Reader

Openings for Wells 1 and 2
Angled Edge



Holder for Reader

Reader Opening
Angled Corner



DPP Micro Reader in Holder

- c) To read a test, place the DPP® Micro Reader-holder assembly on top of the testing device. Make sure the rectangular test window on the testing 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 holder on top of testing device

Reading a test:

- a) Between 10 to 15 minutes after the addition of the Buffer to Well 2 as per STEP 3 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 numerical value for the IgM result is displayed followed by either “R” for Reactive or “NR” for Non-reactive. **Record the IgM result according to the laboratory policy (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 IgM 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 the enclosed microfiber cloth lightly moistened with 70% isopropyl alcohol (IPA), 10% bleach solution, or mild soap 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 the provided dry microfiber cloth, or the 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 product 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 allow the reader to obtain assay information. Press the button and the 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 card 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

ORDERING INFORMATION

- REF 65-9560-0 Chembio DPP® Zika IgM Assay System
- REF 62-1001-1 Chembio DPP® Zika IgM Control Pack
- REF 61-1070-0 Chembio DPP® Micro Reader

For Product Information please email info@chembio.com













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Web Site: www.chembio.com

SYMBOL LEGEND

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