alethia™

Malaria External Control

RESEARCH USE ONLY

External Control Material for use with
Research Use Only Alethia Malaria DNA Amplification Assays

REF **479970RUO** RUO

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

INTENDED USE
The Research Use Only (RUO) Alethia Malaria External Control Kit contains Positive and Negative Control Reagents for use with the Research Use Only Alethia Malaria or Research Use Only Alethia Malaria PLUS DNA Amplification Assays. External controls are used as part of a routine quality control program to aid the user in detection of unexpected conditions that may lead to test errors.

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
1. **RUO Alethia Malaria Positive Control:** Tris-buffered solution with plasmid containing DNA inserts (*Plasmodium sp.* and human mitochondrial DNA inserts) and azide (0.09%) as a preservative.
2. **RUO Alethia Malaria Negative Control:** Tris-buffered solution with plasmid containing human mitochondrial DNA inserts and azide (0.09%) as a preservative.

MATERIALS PROVIDED SEPARATELY
1. **RUO Alethia Malaria PLUS DNA Amplification Test Kit**, Meridian Bioscience, Inc. Catalog Number 481125RUO
2. **RUO Alethia Malaria DNA Amplification Test Kit**, Meridian Bioscience, Inc. Catalog Number: 480925RUO

MATERIALS NOT PROVIDED
1. Disposable latex gloves, powder free
2. DNAse/RNAse free, aerosol resistant pipette tips

EQUIPMENT NOT PROVIDED
1. Interval timer
2. Vortex Mixer (optional)
3. Micropipette capable of dispensing 50 µL
4. Micropipette capable of dispensing 250 µL (catalog number 481125RUO only)
5. Research Use Only Alethia Incubator/Reader™, Meridian Bioscience, Inc. Catalog Number: 610189RUO

PRECAUTIONS
1. **All reagents are For Research Use Only. Not for use in diagnostic procedures.**
2. This is a quality control reagent and is used to evaluate the performance of the **RUO** Alethia Malaria and **RUO** Alethia Malaria PLUS DNA Amplification Assays. It is not directly used to test patient samples.
3. Do not eat, drink or smoke in areas where specimens or kit reagents are handled.
4. Wear disposable gloves while handling specimens and thoroughly wash hands afterwards.
5. Quality Control Programs for Molecular Testing Laboratories should be employed.
6. The **RUO** Alethia Malaria Test Devices contain lyophilized reagents. The protective pouch should not be opened until ready to perform the assay.
7. The **RUO** Alethia Malaria Test Devices include a latch feature that is designed to prevent contamination of the test area with amplification product. Do NOT use Test Devices with broken latches.
8. Dispose of used **RUO** Alethia Test Devices, ***M-prep*** Columns, and tubes immediately after processing, leaving the device latch securely in place. Opening the device after amplification may result in contamination of the test area with amplification product.

HAZARD AND PRECAUTIONARY STATEMENTS
There are no known hazards associated with this product.

SHELF LIFE AND STORAGE
The expiration date is indicated on the kit label. Store the kit components at the temperature indicated on the label.

REAGENT PREPARATION
1. Bring RUO Alethia Malaria External Positive and Negative Controls, and all RUO Alethia Malaria kit components to room temperature (19-30 C) before use. Incorrect results may be obtained if control materials and components are not brought to room temperature prior to use.
2. Use one RUO Alethia Malaria Test Device for each Positive Control and Negative Control to be tested.

For controls to be processed by RUO Alethia Malaria PLUS: Refer to the RUO Alethia Malaria Package Insert (SN11035_RUO) for information regarding column preparation, orientation and use. Use 1 RUO ***M-prep*** column per sample. Remove the column top cap, followed by the bottom twist-off tip, and place the column tip into an ST tube to drain. Drained RUO ***M-prep*** columns should be used within 1 hour.

QUALITY CONTROL SAMPLE PREPARATION
NOTE: Ensure that the **RUO** Alethia Incubator/Reader is powered and the required performance verifications have been completed prior to initiation of Quality Control Sample Preparation. Refer to the **RUO** Alethia Incubator/Reader Operator's Manual for further information regarding instrument set-up and operation.

1. Preparation of controls using RUO Alethia Malaria (Catalog number 480925RUO)
Note: The Positive and Negative Control require separate Buffer tubes and SMP PREP IV.
a. Mix Positive Control by inversion 5 times or by vortexing 10 seconds. Using a micropipette, add 50 µL of the appropriate Positive or Negative Control to one Buffer I tube. Mix by inversion 5 times or by vortexing for approximately 10 seconds. Incubate the sample for 2 minutes.
b. Mix by inversion 5 times or by vortexing for approximately 10 seconds. Using a micropipette, immediately transfer 50 µL of prepared sample into SMP PREP IV. Mix by inversion 5 times or vortex for 10 seconds.
c. Gently squeeze the SMP PREP IV and slowly collect 5 to 10 drops into a clean Tube I. Proceed to Quality Control Test Procedure.

2. Preparation using RUO Alethia Malaria PLUS (Catalog number 481125RUO)
Note: The Positive and Negative Control require separate Buffer I tube and M-*prep* Columns.
a. Mix Positive Control by inversion 5 times or by vortexing 10 seconds. Using a micropipette, add 50 µL of appropriate Positive or Negative Control to one Buffer I tube. Mix by inversion 5 times or by vortexing for approximately 10 seconds. Incubate the sample for 2 minutes.
b. Mix by inversion 5 times or by vortexing for approximately 10 seconds. Using a micropipette, immediately transfer 250 µL of the prepared sample to the top of an appropriately labeled and prepared ***M-prep*** Column. Wait approximately 2 minutes, or until the sample has been absorbed by the column and flow stops.
c. Using a micropipette, add 250 µL of ***M-prep*** Buffer II to the top of the ***M-prep*** Column. Discard the pipette tip. The column will have a red appearance after the addition of ***M-prep*** Buffer II. Wait approximately 2 minutes, or until the red-colored buffer is absorbed by the column and flow stops.
d. Remove the last drop of liquid from the column tip with the ST Tube. Discard the tube.
e. Place a clean ST Tube under the ***M-prep*** Column. Using a micropipette, add 250 µL of ***M-prep*** Buffer III to the top of the ***M-prep*** Column. Discard the pipette tip. Wait approximately 2 minutes or until flow stops.
f. Remove the last drop of liquid from the column tip with the ST Tube. Label the tube and proceed to the Quality Control Test Procedure.

QUALITY CONTROL TEST PROCEDURE
NOTE: A maximum of 10 samples can be processed in a single RUO Alethia Incubator/Reader run.
1. Remove 1 RUO Alethia Malaria Test Device from its protective pouch for the Negative Control. Carefully open the device, holding the chambers such that the lyophilized reagents will not fall out upon opening. Place the device on a flat surface or in a rack that can accommodate the device.
2. Using a micropipette, transfer 50 µL of the prepared Negative Control to both the TEST (Left/White Bead) and CONTROL (Right/Yellow Bead) chambers of the RUO Alethia Malaria Test Device. Take care to not introduce air to the reaction mixture. Do not mix reactions with pipette.
3. Close the RUO Alethia Test Device and fasten the latches securely.
4. Repeat Test Procedure Steps 1-3 for the prepared Positive Control sample to be tested.
5. Tap device(s) on the bench top or mix to remove air bubbles. Carefully examine the Test Device(s) for rehydration of the Control/Test Bead, for air bubbles left in the chamber and liquid in the top of the device. If undissolved beads, air bubbles or liquid in the top of the device are noted, tap the device on the bench top and repeat visual inspection. Amplification and detection should be initiated within 15 minutes.
6. Insert the RUO Alethia Test Devices into the RUO Alethia Incubator/Reader and initiate run **using the RUO Malaria Program.** Results will be displayed at the conclusion of the run.

INTERPRETATION OF RESULTS

Sample ID	Reported Result	Interpretation
Positive Control	POSITIVE	Valid positive control result. Reagents active at time of use, Alethia Incubator/Reader performing correctly.
	NEGATIVE	**Incorrect control result.** Repeat control testing as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.
	INVALID	**No reportable result. Repeat entire assay run using original samples.** Improper sample preparation, reagent failure, instrument failure or internal control failure.
Negative Control	POSITIVE	**Incorrect control result.** Repeat control testing as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.
	NEGATIVE	Valid negative control result. Reagents active at time of use, Alethia Incubator/Reader performing correctly.
	INVALID	**No reportable result. Repeat entire assay run using original samples.** Improper sample preparation, reagent failure, instrument failure or internal control failure.
EMPTY WELL	NONE	No Alethia Test Device in the Alethia Incubator/Reader Well. **OR** The Alethia Test Device present is compromised due to sample preparation failure, dirty device or improperly seated device. **Repeat the test using original sample.**

SN11038_RUO **REV. 10/15/2018**

Manufactured By

Meridian Bioscience, Inc.
Corporate Office
3471 River Hills Drive
Cincinnati, Ohio 45244 USA
Telephone: 513.271.3700
Orders/Customer Service:
800.543.1980
Technical Support Center:
800.343.3858
Information Fax: 513.272.5432
Ordering Fax: 513.271.0124

SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	RoHS	Restriction of Hazardous Substances
	Manufacturer		Caution, consult accompanying documents
	Single Use Only	STERILE R	Sterilization by gamma irradiation
	Female	STERILE EO	Sterilization by ethylene oxide
Σ	Contains sufficient for <n> tests	BUF RXN	Reaction Buffer
	Temperature limitation		ETL Registered Mark Certified
SN	Serial number		Recycle - do not dispose of as general waste
TEST	Test Device	HT TUBE	Heat Treatment Tube
	Date of manufacture		For IVD Performance Evaluation Only
	LASER RADIATION: Avoid Exposure to Beam		HOT SURFACE: Keep hands Away from Hot Surfaces
CAUTION	CAUTION: Laser Radiation	IPX-0	CAUTION: Protect from water
	CAUTION: Risk of Danger	CONTROL	Assay Control
BUF	Buffer	MIN OIL	Mineral Oil
MEDIA	Media		Warning
ST TUBE	Screw Top Tube	IUO	Investigational Use Only
RUO	Research Use Only	COL	Sample Preparation Column
BUF SMP	Sample Buffer	PRE REAG	Pretreatment Reagent
Rx Only	Prescription Use Only	SMP PREP	Sample Preparation
TUBE	Empty Tube		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.