# Loa Antibody Rapid Test

**Prototype — For Research Use Only (RUO)**
**Not for use in diagnostic procedures**

For the detection of antibodies against *Loa loa* SXP-1 antigen.

Loiasis, also known as African eye worm, is a disease caused by the parasitic worm *Loa loa*. Loiasis affects over 10 million people, predominantly in forested areas of West and Central Africa. The disease is transmitted to humans by day-biting flies and can lead to the presence of a 1–2 cm long adult worm under the skin or in the eye. The adult worms produce embryos, called microfilariae, which circulate in the blood stream during the day. Loiasis can be accompanied by transient swellings on the skin known as Calabar swellings, severe itching, joint pain, and fatigue. There is growing evidence that loiasis is associated with renal, cardiac, and neurological problems and with a shorter life expectancy.

Certain people with *L. loa* infections are at risk of brain inflammation (encephalopathy) when treated with ivermectin or diethylcarbamazine, two deworming drugs used in mass drug administration programs for the elimination of onchocerciasis and lymphatic filariasis. The encephalopathy can cause coma and sometimes death. Treatment for loiasis exists but must be given by experienced medical doctors, especially in cases of high levels of microfilariae where incorrect chemotherapy is potentially lethal.

## Intended Use

The Loa Antibody Rapid Test is a Research Use Only (RUO) device. It is intended for epidemiology purposes and as a population surveillance tool. It should not be used to establish a definitive diagnosis or as a basis to recommend a treatment to an individual person. This prototype is a model product specifically built for initial field-testing and to receive feedback from end-users in view of enhancing the design of future versions. The Loa Rapid Antibody Test only detects if a person has been exposed to *L. loa* in his or her lifetime; it cannot distinguish previous from current infections.

## Principles of the Procedure

When a person is infected with *L. loa*, he or she will produce antibodies against the parasite. Studies have shown that the human antibody response to the *L. loa* protein LI-SXP-1 is a sensitive and specific marker for exposure to loiasis. The Loa Antibody Rapid Test contains black nanoparticles and a membrane strip with a test and a control line. The test and control lines in the result window have been labelled with embossed “T” and “C” letters, respectively. When a sample and eluent are added to the sample port, red blood cells (if present) are retained by a filter while the antibodies can pass through. The antibodies-eluent mixture comes in contact with the nanoparticles located under the port and migrates by capillarity towards the test and control lines. The nanoparticles and test line are pre-coated with reagents such that the nanoparticles will bind to the test line only if antibodies to SXP-1 are present. In contrast, the control line will bind the nanoparticles regardless of the presence or absence of antibodies to SXP-1.

## Reagents and Materials

**Provided**

The Loa Antibody Rapid Test kit contains the following items:

- 25 test devices with indicating desiccant packets in individual pouches
- 1 vial of assay eluent
- Instructions for use

**Required for finger prick but not provided**

- Lancet
- Alcohol wipe or swab
- Calibrated micropipette (ideally 10 µL) with disposable tips

**Recommended but not required nor provided**

- Smartphone reader [Cat # 63-0001]

## Safety and Handling Precautions

1. For Research Use Only.
2. Follow instructions exactly.
3. All blood products are potentially infectious and should be handled by trained personnel only.
4. Keep test away from children.
5. Do not use the test kit if the pouch is damaged or the seal is broken.
6. Do not use the test kit past its expiration date.
7. Do not reuse the test device.
8. Do not reuse blood collection devices or pipette tips.
9. Perform the test immediately after opening the foil pouch. The beads in the silica gel pillow pack should be dark blue; partially or completely purple or pink beads indicate moisture and the test should be discarded.
10. The assay eluent contains ProClin300, a preservative which may be slightly irritating to the skin, eyes and digestive tract. Material Safety Data Sheets for this product are available upon request.
11. Indicating silica gel pillow pack contains cobalt dichloride. Cobalt dichloride is toxic and should be handled carefully, avoiding ingestion or skin contact. Material Safety Data Sheets for this product are available upon request.
12. Decontaminate and dispose of all specimens, reaction kits, and potentially contaminated materials in a biohazard container as if they were infectious waste. Follow your national, regional, and local ordinances accordingly for waste disposal regulations.

## Storage and Stability

Store the test kit between 4°C and 40°C. Do not freeze the kit or its components. The Loa Antibody Rapid Test kit and reagents are stable until the expiration date marked on their outer packaging when stored as specified.

## Specimen Collection and Handling

**Capillary Blood Collected by Finger Prick**

- The side of the fourth finger of the non-dominant hand is recommended to minimize discomfort. Clean the area to be lanced with an alcohol wipe or swab (not provided). Squeeze the end of the fingertip and pierce with a sterile lancet (not provided). Wait until a drop of blood has collected on the finger, squeezing the fingertip if necessary to accelerate its formation.

**Blood, Plasma, or Serum Collected by Venipuncture**

- **Blood:** Collect whole blood into a collection tube containing heparin, EDTA or sodium citrate as anticoagulants.
- **Plasma:** Collect whole blood into a collection tube containing heparin, EDTA or sodium citrate as anticoagulants. Centrifuge the tube to get the plasma specimen.
- **Serum:** Collect whole blood into a collection tube without anticoagulants. Leave to settle for 30 minutes for blood coagulation to proceed and then centrifuge blood to get the serum specimen.
- Blood, plasma, and serum specimen can be refrigerated at 2–8°C for up to 3 days; longer storage can cause a non-specific reaction. Additionally, plasma and serum (but not blood) specimen can be frozen for longer periods.
- Plasma or serum specimens containing a precipitate may yield inconsistent test results and should be clarified prior to testing.

## Test Procedure (See Figure)

1. Bring all kit components and specimen to room temperature prior to testing.
2. Remove the test device from the foil pouch and place it on a flat, dry surface.
3. Verify that the desiccant is still dark blue. If not, discard the test.
4. Using a micropipette, dispense 5.0 µl of whole blood, serum, or plasma specimen into the sample port.
5. Immediately dispense 2 drops of assay eluent vertically into the port. The dropper bottle opens by slightly squeezing the sides of the cap.
6. Interpret test results after 20 minutes and while the test is still wet.
7. The test can be interpreted up to 60 minutes after addition of the sample, provided that the membrane strip is still wet.

D|D|T|D Drugs & Diagnostics for Tropical Diseases
4898 Ronson Court, Suite C
San Diego, CA 92111, USA

Date issued: 2017/02

## Test Interpretation (See Figure)

A black control line will appear in the result window in front of the embossed letter “C” to show that the assay is working properly. The embossed “T” indicates the area where the test band should appear in case of a positive sample. We highly recommend using the test in conjunction with the smartphone Rapid Diagnostic Reader (Cat. # 63-0001).

1. **Negative Result**
   The presence of only the control line (C) within the result window indicates a negative result.
2. **Positive Result**
   The presence of both the control line (C) and the Test line (T) within the result window indicates a positive result.
3. **Résultat invalide**
   If the control line (C) is absent, abnormally weak, or smudgy, the results are invalid and cannot be interpreted. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

**Important:** This Prototype has not been fully evaluated. In some cases, a weak test line may not be due to exposure to *L. loa*, but to other pathogens such as *O. volvulus* (river blindness) or *W. bancrofti* (lymphatic filariasis). The optional smartphone Rapid Diagnostic Reader or Visual Scorecard may help assess the probability of such occurrences. We strongly recommend that positive subjects consult a doctor for further confirmation of the test result.

## Quality Control

The Loa Antibody Rapid Test has the letters “T” (test line) and “C” (control line) on the surface of the device. Neither the test line nor the control line is visible within the result window before applying a sample. The control line is used for procedural control. A quality control test ran with eluent alone should only show the control line (C), and not the test line. The presence of a test line, even if faint, would indicate that the test has deteriorated and should be discarded. If this is the case, please email us at: quality@ddtd.org.

## Performance

The latest data for this Prototype, including sensitivity and specificity, are posted at www.ddtd.org/specs.

## Add-on Accessories

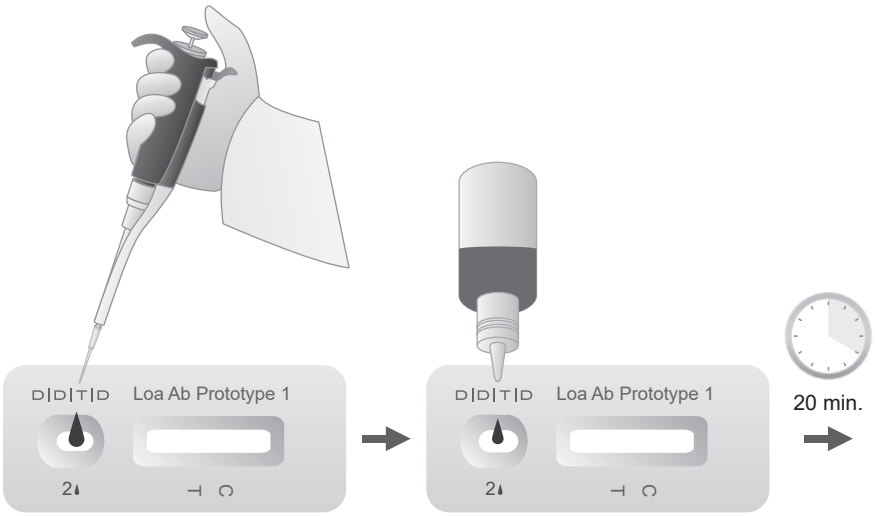
The following items are available upon request at www.ddtd.org:

- Positive sample control [Cat # 60-0031]
- Visual Scorecard [Cat # 63-0036]
- Rapid Diagnostic Reader [Cat # 63-0001]

**Environmental factors and user error:** While every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the manufacturer and distributor and test results may accordingly be affected by environmental factors and/or user error.

**Warning:** The manufacturer and distributor of this product shall not be liable for any direct, or consequential losses, liability, claims, costs or damages arising from or related to an incorrect positive or negative diagnosis using this product.

# TEST PROCEDURE

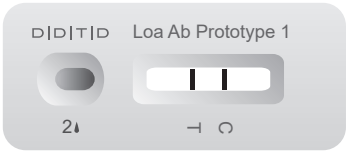



5 µl of whole blood, serum, or plasma into the port

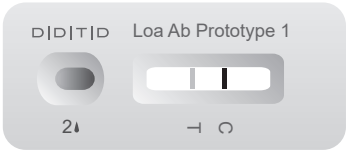
2 drops of assay eluent into the port

# TEST INTERPRETATION

**Positive**

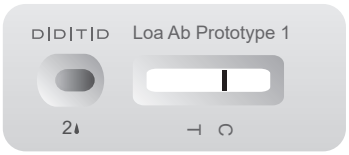



Two black lines “C” and “T” in the result window



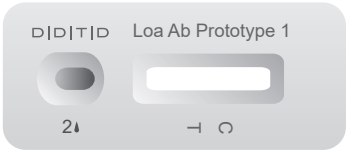

The test is positive even if the “T” line is weak

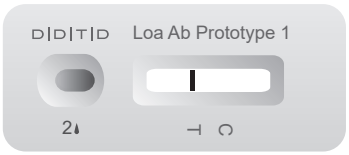
**Negative**




One black line “C” in the result window

**Invalid**




No control “C” line in the result window

D|D|T|D
Drugs & Diagnostics for Tropical Diseases
4898 Ronson Court, Suite C
San Diego, CA 92111, USA

Date issued: 2017/02