**QUALITATIVE – BASIC PROCEDURE**

**1. Add 1 drop of specimen diluent**

**2. Add 40 µL of specimen**

**3. Insert strip**

**4. Incubate 10 min**

**5. Line = negative**

**6. 2 lines = positive**

**WARRIORS AND PRECAUTIONS**

1. Use this kit with samples other than human serum, plasma, CSF and whole blood is not recommended.

2. Wear protective clothing, including lab coat, eye/face protection, and/ or micro-titer plate, etc.). It is also good practice to label the strip, prior to inserting it into sample.

3. Add 2 drops or pipette 40 µl of LF Titration Diluent (REF EI0010) to each of the tubes labeled 2-10.

4. Add 40 µl of specimen to tube #1 and mix well.

5. Transfer 80 µl of specimen from tube #1 to tube #2 and mix well.

6. Provide the test strip to the control. If a delay is encountered in specimen processing, storage at 2-8°C for up to 72 hours is permissible, CSF, plasma, and serum may be stored for a longer period.

7. Refer to Hazards and Precautionary Information section for hazards after use.

**MATERIALS NOT PROVIDED**

1. Pipette (40-µl and 60-µl) or disposable 40 µl plastic Pettes.

2. Timer

3. Disposable, flat-bottom micro-centrifuge tubes, test tubes, or a micro-titer plate that can hold the test strip.

**REAGENT PREPARATIONS**

- LF Titration Diluent (6.0 mL, REF EI0010): Glycine-buffered saline

- LF Specimen Diluent (4.0 mL, REF GLF025): Glycine-buffered saline

- LF Test Strip (60 stripes in desiccant vial, REF LFCR60): Strips are 0.4 cm wide by 7.6 cm tall

**REAGENT STABILITY AND STORAGE**

- The entire kit should be stored at the stated temperature before and during use. If the kit is stored at or below 4°C, allow the kit to come to room temperature before opening.

- The stability of the control and test lines beyond the reading time (10 minutes) has not been validated.

**SUMMARY and EXPLANATION of the Test**

Cryptococcal antigen is caused by two species of the Cryptococcus species complex (Cryptococcus neoformans and Cryptococcus gattii) and is widely employed when cryptococcal disease is suspected. A single control line indicates a negative result. If the control line does not appear, the results are invalid and the test should be repeated. Faint line intensity could be indicative of a high titer specimen. The semi-quantitative procedure should be run to rule out high titer inhibition of test line. The control line is a migration control and not intended as a specimen addition control.
The results of this testing are shown in the table below.

### REPRODUCIBILITY AND PRECISION

The CrAg Latex Assay was evaluated for reproducibility and precision by spiking serum with cryptococcal antigen to produce a panel consisting of a negative sample, a high-positive (H), a moderate-positive sample. This panel was tested twice per day at three sites over a total of 100 tests and the inter-lab and the intra-lab reproducibility and precision of the assay were determined. The results of this study are shown in the table below.

### HAZARDS & PRECAUTIONARY INFORMATION

There are no known hazards associated with the reagents in this kit.

### BIBLIOGRAPHY