The OnSite Chlamydia Rapid Test is a lateral flow immunoassay for the qualitative detection of Chlamydia trachomatis (C. trachomatis) antigen in endocervical or endourethral swab specimens. It is intended to be used as a screening test and as an aid in the diagnosis of the infection of C. trachomatis. Any reactive specimen with the OnSite Chlamydia Rapid Test must be confirmed with alternative testing method(s).

**REAGENT PREPARATION AND STORAGE INSTRUCTIONS**

1. All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to 15°C-30°C before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

**SPECIMEN COLLECTION AND HANDLING**

1. Consider any materials of human origin as infectious and handle them using standard biosafety procedures.
2. Swab specimen should be collected by standard male or female specimen collection methods.
3. Swabs should be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed into a dry, sterile, tightly capped tube or bottle and stored in refrigerator (2°C-8°C) for up to 5 days, preferably in a transportation tube.
4. A specimen swab which contains too much blood may cause weak false positive results. Therefore, bloody swabs should be avoided.
5. Do not freeze the swab.
6. Swabs may be transported to the test site under ambient conditions. Transport media should not be used.

**ASSAY PROCEDURE**

1. **Procedure Notes**
   1. 1. Bring all samples and controls to room temperature (15°C-30°C) prior to testing.
   2. All drops must be free falling with the reagent bottles held vertically. In order to avoid contamination of reagents. Do not allow the tips of the bottles to come in contact with the extraction cups.

2. **Extraction:**
   1. Label an extraction tube for each patient and place in a tube holder or rack.
   2. Add 4 drops (200 µL) of Extraction buffer A to the extraction tube containing the specimen and twirl briefly to mix the reagent. Incubate at room temperature (15°C-30°C) for 5 minutes, but no longer than 10 minutes.
   3. Add 4 drops (200 µL) of Extraction buffer B to extraction tube containing the swab. Twirl the swab vigorously for 10 seconds and incubate for 1 minute, but no longer than 10 minutes.

3. **Perform Assay**
   1. Remove a Chlamydia Rapid Test device from its protective pack. Place the test device on a clean, flat surface.
   2. Be sure to label the device with specimen’s ID number.
   3. Dispense 2 drops (100 µL) of liquid from the extraction tube to the sample pad. Don’t over load samples.

**SPECIMEN INTERPRETATION**

- **Negative**
  - No lines are visible on the test strip.

- **Positive**
  - A red line appears on the test pad.
3.4 Set up timer.
3.5 Read the result within 15 minutes. Depending on the number of the C. trachomatis organisms on the swab, some positive results may be visible as soon as 1 minute. However, to confirm negative results the complete reaction time of 15 minutes is required.

Don’t read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

### QUALITY CONTROL

Using individual OnSite Chlamydia Rapid Test cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:

1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit falls outside of 2°C -30°C.
5. The temperature of the test area falls outside of 15°C -30°C.

Expected results are as follows:

**Negative Control**

Only the C band shows color development. The T band shows no color development.

**Positive Control**

Both C and T bands show color development.

The appearance of any burgundy color in the T band, regardless of intensity, must be considered as presence of the band.

### INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT:** If only the C band is developed, the test indicates that no detectable C. trachomatis is present in the specimen. The result is negative.

2. **POSITIVE RESULT:** If both C and T bands are developed, the test indicates for the presence of C. trachomatis in the specimen. The result is positive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID:** If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.

### PERFORMANCE CHARACTERISTICS

**Clinical Performance**

A total of 110 samples from susceptible subjects were tested by the OnSite Chlamydia Rapid Test and by a commercial latex rapid test. Comparisons for all subjects are showed in the following table:

<table>
<thead>
<tr>
<th>OnSite Chlamydia Rapid Test</th>
<th>Latex rapid test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Negative</td>
</tr>
</tbody>
</table>
| 32                          | 2
| 3                            | 74
| 34                          | 77
| 110                         |                |

Relative Sensitivity: 94.1%, Relative Specificity: 97.4%, Overall Agreement: 96.4%

### REFERENCES