**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**
K032330

**B. Analyte:**
*Chlamydia trachomatis* (CT) antigen

**C. Type of Test:**
Immunochromatographic membrane assay

**D. Applicant:**
Thermo Electron Corporation

**E. Proprietary and Established Names:**
CT OIA®

**F. Regulatory Information:**

1. Regulation section:
   866.3120
2. Classification:
   I
3. Product Code:
   LJC
4. Panel:
   Microbiology (83)

**G. Intended Use:**

1. Intended use(s):
   The Thermo Electron CT OIA assay is an Optical ImmunoAssay (OIA) test for the rapid, qualitative detection of chlamydial antigen from female endocervical swab specimens. This test is intended for *in vitro* diagnostic use as an aid in identifying the presence of *Chlamydia trachomatis* antigen. The assay is intended for *in vitro* diagnostic use with symptomatic females in populations at risk for sexually transmitted diseases.
   CT OIA test results are presumptive evidence for either the presence or absence of *C. trachomatis*. Definitive laboratory evidence for the presence/ absence of *C. trachomatis* would need additional testing. CT OIA test results should not preclude empiric treatment of women with overt symptoms of PID. Performance for use in asymptomatic male and female populations has not been established.

2. Indication(s) for use:
   NA
3. Special condition for use statement(s):

Prescription Use

4. Special instrument Requirements:
   NA

**H. Device Description:**

The CT OIA test involves the extraction and detection of an antigen unique to the *Chlamydia* genus. The Optical ImmunoAssay technology enables the direct visual detection of a physical change in the optical thickness of molecular thin films. This change is a result of antigen-antibody binding on an optical surface (silicon wafer).

**I. Substantial Equivalence Information:**

1. Predicate device name(s):
   Chlamydia OIA
2. Predicate K number(s):
   K951010
3. Comparison with predicate:

| Similarities | | |
|---|---|---|
| **Item** | **Device** | **Predicate** |
| Analyte | Chlamydia antigen | same |
| Technology | Optical ImmunoAssay | same |
| | | |

**J. Standard/Guidance Document Referenced:**

NA

**K. Test Principle:**

The Optical ImmunoAssay technology enables the direct visual detection of a physical change in the optical thickness of molecular thin films. This change is a result of antigen-antibody binding on an optical surface (silicon wafer). When an extracted specimen is placed directly on the optical surface, the antigen binds to the biological attachment coating. Next, an antibody conjugated to horseradish peroxidase is added, forming a "sandwich" of coating-antigen-antibody-enzyme on the coated silicon surface. After washing, the substrate is added, increasing the thickness (mass enhancement) of the molecular thin film. This change in thickness alters the reflected light path and this alteration is visually perceived as a color change. Slight changes in optical thickness produce a distinct visible color change. A positive result appears as a purple spot on the gold background. When antigen is not present in the specimen, no binding takes place. Therefore, the optical thickness remains unchanged and the surface retains the original gold color indicating a negative result.

**L. Performance Characteristics:**

1. Analytical performance:
   *a. Precision/Reproducibility:*

Reproducibility testing was conducted at two hospitals and one physician office laboratory (POL) on three days with nine blinded swab samples each day. Two levels of positive swabs were produced by spiking clean swabs with aliquots of cultured CT. Low-level antigen swabs were spiked with the minimum CT concentration necessary to produce a consistent weak-positive OIA signal. Moderate-positive swabs were spiked with 2x the amount of antigen used in the low-positive swabs. The negative swabs contained no CT antigen. Overall reproducibility of the testing using these swab panels was 87.7%.

b. *Linearity/assay reportable range:*
NA

c. *Traceability (controls, calibrators, or method):*
NA

d. *Detection limit:*
The analytical sensitivity of the CT OIA test was determined using serial dilutions of cultured chlamydia in buffer. Fifteen serovars of *C. trachomatis* were tested by pipeting directly into the extraction tube, and the limit of detection (LOD) ranged from 150 EBs - 1400 EBs per sample for the various serovars. When samples were absorbed onto dry swabs and passed through a freeze/thaw cycle, the limit of detection was 40,000 EBs per sample.

e. *Analytical specificity:*
NA

f. *Assay cut-off:*
NA

2. Comparison studies:
   a. *Method comparison with predicate device:*
   NA
   b. *Matrix comparison:*
   NA
3. Clinical studies:
   a. *Clinical sensitivity:*
   NA
   b. *Clinical specificity:*
   NA
   c. *Other clinical supportive data (when a and b are not applicable):*
   The performance characteristics of the CT OIA assay were determined by comparing assay results to results of LCR (Ligase Chain Reaction) and positives were confirmed by PCR (Polymerase Chain Reaction) for *Chlamydia trachomatis*.

   A total of 499 female specimens were collected from four clinical trial sites representing locations in the Eastern, Southern, and Northwest regions of the United States. Symptomatic female patients were enrolled at all four clinical trial sites. All specimens were tested by LCR for *Chlamydia trachomatis* and the CT OIA

test. The positive percent agreement was 69.6% (95% CI 57.3-80.1) and the negative percent agreement was 98.0% (95% CI 96.2-99.1)

4. Clinical cut-off:
   NA
5. Expected values/Reference range:
   Hypothetical Negative and Positive Predicative Values as a Function of Prevalence

| Hypothetical Prevalence | NPV | PPV |
|---|---|---|
| 5% | 98.6% | 66.0% |
| 15% | 95.5% | 80.4% |
| 10% | 97.1% | 86.7% |
| 20% | 97.8% | 90.2% |

**M. Conclusion:**

The Thermo Electron CT OIA assay is substantially equivalent to the Thermo Electron Chlamydia OIA assay for the rapid, qualitative detection of chlamydial antigen from female endocervical swab specimens. The labeling has been agreed upon and will be sent as amendment 2.