# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY

## I Background Information:

### A 510(k) Number

K193081

### B Applicant

Rheonix, Inc

### C Proprietary and Established Names

Rheonix STI TriPlex Assay
Rheonix Encompass MDx Workstation

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| QEP | Class II | 21 CFR 866.3393 - Device To Detect Nucleic Acids From Non-Viral Microorganism(S) Causing Sexually Transmitted Infections And Associated Resistance Marker(S) | MI - Microbiology |
| NSU | Class II | 21 CFR 862.2570 - Instrumentation for clinical multiplex test systems | CH - Clinical Chemistry |
| LSL | Class II | 21 CFR 866.3390 - Neisseria spp. direct serological test reagents | MI - Microbiology |
| OUY | Class II | 21 CFR 866.3860 - Trichomonas vaginalis nucleic acid assay | MI - Microbiology |
| MKZ | Class I, reserved | 21 CFR 866.3120 - Chlamydia serological reagents | MI - Microbiology |

## II Submission/Device Overview:

### A Purpose for Submission:

To obtain clearance for a new device, Rheonix STI TriPlex Assay on Rheonix Encompass MDx Workstation.

### B Measurand:

*Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) DNA.

### C Type of Test:

Nucleic acid amplification assay (end point polymerase chain reaction)

## III Intended Use/Indications for Use:

### A Intended Use(s):

See Indications for Use below.

### B Indication(s) for Use:

The Rheonix STI TriPlex Assay, as performed on the Rheonix Encompass MDx Workstation, is an automated DNA extraction and multiplex PCR amplification test system intended for the direct, qualitative detection of DNA from *Chlamydia trachomatis* (CT), and/or *Neisseria gonorrhoeae* (NG), and/or *Trichomonas vaginalis* (TV) in male urine specimens collected with the Rheonix Urine Specimen Collection Kit. The test is indicated to aid in the diagnosis of chlamydial urogenital disease, gonococcal urogenital disease and trichomoniasis in asymptomatic or symptomatic male individuals.

### C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

### D Special Instrument Requirements:

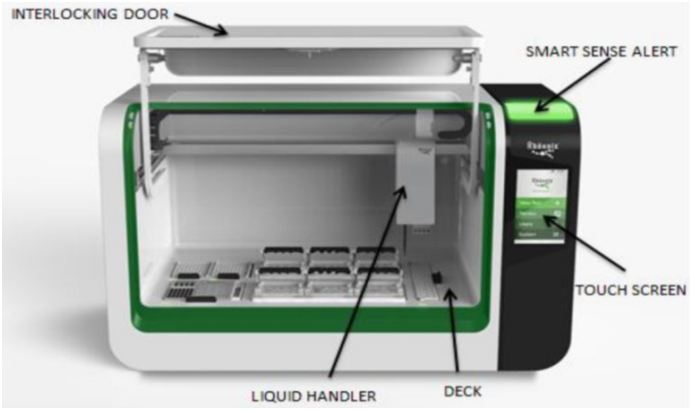
Rheonix Encompass MDx Workstation

## IV Device/System Characteristics:

### A Device Description:

The Rheonix Encompass MDx Workstation and the Rheonix STI TriPlex Assay are comprised of an instrument with associated hardware and accessories, disposable microfluidic CARD

cartridges, master mixes and reagent components used to extract, amplify and detect DNA using end point PCR. In addition, male urine specimens must be collected using the Rheonix Urine Specimen Collection Kit. The process is fully automated with the user intervention required only for loading and unloading the samples and disposable assay components. The Rheonix Encompass MDx Workstation's software automatically interprets test results which may be called as POS (positive), NEG (negative), or IND (indeterminate) for each of the assay's three targets. In addition, if the instrument encounters an error during the performance of the assay, it will report an ERR code. If either an IND or ERR code results, the same specimen should be reanalyzed for the presence of the target for which the indeterminate or error code occurred. Each assay has a built-in process control that assures that the individual steps of the entire process occurred properly. The user may also include external positive and/or negative controls.



Rheonix Encompass MDx Workstation

## B Principle of Operation:

The Rheonix STI TriPlex Assay, as performed on the Rheonix Encompass MDx Workstation, consists of automated DNA extraction and end-point PCR for the qualitative detection of CT/NG/TV DNA from male urine specimens. The specimens collected using the Rheonix Urine Specimen Collection Kit are loaded directly onto the Rheonix Encompass MDx Workstation to which the various disposable consumables contained within the Rheonix STI TriPlex Assay have also been loaded by the user. The user interface of the Rheonix Encompass MDx Workstation guides users regarding the proper placement of the various disposable assay consumables and patient specimens. The workstation automates sample preparation, including target organism lysis, DNA extraction and concentration, reagent rehydration and amplification of target DNA using PCR. Detection of the various targets and controls is achieved by end point hybridization of the resulting amplicons with DNA probes located on microarray filters contained within the disposable microfluidic CARD cartridges. The Rheonix Encompass MDx Workstation performs results interpretation automatically. All assay steps are automatically performed within the microfluidic CARD cartridges and include cell lysis, extraction and purification of DNA, multiplex PCR and finally hybridization of the resulting target and control amplicons with their corresponding probes located on the integrated DNA array.

The control and target amplicons are each generated using biotinylated primer sets and the hybridization spots are detected by the sequential addition of streptavidin conjugated horseradish peroxidase and its substrate, 3, 3', 5, 5' tetramethylbenzidine (TMB). The resulting blue colored

hybridization spots are detected by the Workstation's CMOS camera and the instrument's imaging software interprets the location and intensity of the various hybridization spots. The results are reported as POS (positive), NEG (negative) or IND (indeterminate), based on how the intensity of the hybridization spots corresponds to the threshold intensities established to differentiate a POS from a NEG result. Specimens that yield signal intensities between the POS and NEG thresholds are reported as IND and should be repeated using the same specimen.

**C Instrument Description Information:**

1. Instrument Name:

Rheonix Encompass MDx Workstation

2. Specimen Identification:

The instrument scans barcodes on each specimen tube for identification. The instrument also automatically tracks the sample identity to the final result report.

3. Specimen Sampling and Handling:

Specimens are collected using the Rheonix Urine Specimen Collection Kit. Urine specimens are transferred from the original collection cup to the Rheonix transport tube and loaded directly into the Rheonix Encompass MDx Workstation.

4. Calibration:

The Rheonix Encompass MDx Workstation requires calibration upon installation and then on an annual basis.

5. Quality Control:

Internal process control is extracted and amplified together with each specimen.
External controls are available from ZeptoMetrix Corporation.

## V Substantial Equivalence Information:

**A Predicate Device Name(s):**

BD MAX CTGCTV2, BD MAX System

**B Predicate 510(k) Number(s):**

K182692

## C Comparison with Predicate(s):

| Device & Predicate Device(s): | K193081 | K182692 |
|---|---|---|
| Device Trade Name | Rheonix STI TriPlex Assay, Rheonix Encompass MDx Workstation | BD MAX CTGCTV2, BD MAX System |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | The Rheonix STI TriPlex Assay, as performed on the Rheonix Encompass MDx Workstation, is an automated DNA extraction and multiplex PCR amplification test system intended for the direct, qualitative detection of DNA from *Chlamydia trachomatis* (CT), and/or *Neisseria gonorrhoeae* (NG), and/or *Trichomonas vaginalis* (TV) in male urine specimens collected with the Rheonix Urine Specimen Collection Kit. The test is indicated to aid in the diagnosis of chlamydial urogenital disease, gonococcal urogenital disease and trichomoniasis in asymptomatic or symptomatic male individuals. | The BD MAX CTGCTV2 assay, performed on the BD MAX System, incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from:<br>• *Chlamydia trachomatis* (CT)<br>• *Neisseria gonorrhoeae* (GC)<br>• *Trichomonas vaginalis* (TV)<br>The assay may be used for detection of CT, GC and/or TV DNA in patient- or clinician-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens. The assay may also be used for the detection of CT and GC DNA in endocervical swab and Liquid-Based Cytology (LBC) specimens in PreservCyt® Solution using an aliquot that is removed prior to processing for the ThinPrep Pap test.<br>The assay is indicated for use with asymptomatic and |

| | | |
|---|---|---|
| | | symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease, gonococcal urogenital disease and/or trichomoniasis. |
| Technology/Detection | An automated multiplex polymerase chain reaction | An automated multiplex real-time polymerase chain reaction |
| Type of Test | Qualitative | Qualitative |
| Target Patient Population | Asymptomatic and symptomatic male patients | Asymptomatic and symptomatic female and male patients |
| Specimen Type | Male urine | • Vaginal swab<br>• Male and female urine<br>• Endocervical swab<br>• Liquid-Based Cytology (LBC) specimens |
| Analytical Target | • *Chlamydia trachomatis* (CT)<br>• *Neisseria gonorrhoeae* (GC)<br>• *Trichomonas vaginalis* (TV) | • *Chlamydia trachomatis* (CT)<br>• *Neisseria gonorrhoeae* (GC)<br>• *Trichomonas vaginalis* (TV) |
| Sample Collection Kit | Urine Collection Kit | • Urine Collection Kit<br>• Swab Collection Kit<br>• LBC Sample Buffer Tube |
| Sample Extraction | Cell lysis followed by capture and purification of nucleic acids. | Cell lysis followed by capture and purification of nucleic acids. |
| **General Device Characteristic Differences** | | |
| Detection | Colorimetric | Fluorescent reporter dye |

## VI Standards/Guidance Documents Referenced:

1. Establishing the Performance Characteristics of In Vitro Diagnostic Devices for *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*: Screening and Diagnostic Testing - Draft Guidance for Industry and FDA Staff, May 11, 2011.

2. Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the detection of *Trichomonas vaginalis* – Guideline for Industry and FDA Staff, August 4, 2015.
3. EP7-A2, 2005 – Interference Testing in Clinical Chemistry, CLSI Approved Guideline.
4. EP12-A2, 2008 – User Protocol for Evaluation of Qualitative Test Performance; CLSI Approved Guideline.
5. EP17-A2, 2012 – Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition; CLSI Approved Guideline.

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:

a. Within-laboratory Precision

Within-laboratory precision of the Rheonix STI TriPlex assay was evaluated at one internal site. Testing was performed by three operators over a 12-day period. Each operator performed two different runs each day for three non-consecutive days with duplicates per run. Each run contained an external negative control and external positive control, in addition to the internal process controls. Each blinded panel member contained pooled negative male urine matrix individually spiked with CT, NG or TV at the following concentrations:

- Moderate Positive (MP): 5 x LoD
- Low Positive (LP): 2 x LoD
- High Negative (HN): 0.25 x LoD
- True Negative (TN): No targets present

Composition of Precision Test Panel (PTP) is shown below:

**Precision Test Panel**

| Panel Member | Target Level | | |
|---|---|---|---|
| | CT | NG | TV |
| 1 | MP | TN | TN |
| 2 | LP | TN | TN |
| 3 | HN | TN | TN |
| 4 | TN | MP | TN |
| 5 | TN | LP | TN |
| 6 | TN | HN | TN |
| 7 | TN | TN | MP |
| 8 | TN | TN | LP |
| 9 | TN | TN | HN |
| 10 | TN | TN | TN |

The percent agreement with expected result when detecting each of the three targets in male urine is reported below.

**Within-laboratory Precision-Percent Agreement**

| Panel Member | Percent Agreement with Expected Result for Male Urine | | |
|---|---|---|---|
| | CT | NG | TV |
| | (n/N)<br>95% CI | (n/N)<br>95% CI | (n/N)<br>95% CI |
| [a]TN | 97.2%<br>(35/36)<br>85.8%-99.5% | 100%<br>(36/36)<br>90.4%-100% | 100%<br>(36/36)<br>90.4%-100% |
| [b]HN | 33.3%<br>(12/36)<br>20.2%-49.7% | 85.3%<br>(29/34)<br>69.9%-93.6% | 72.2%<br>(26/36)<br>56.0%-84.2% |
| LP | 91.7%<br>(33/36)<br>78.2%-97.1% | 100%<br>(36/36)<br>90.4%-100% | 100%<br>(36/36)<br>90.4%-100% |
| MP | 97.2%<br>(35/36)<br>85.8%-99.5% | 97.2%<br>(35/36)<br>85.8%-99.5% | 100%<br>(36/36)<br>90.4%-100% |

a. For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
b. For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

b. Site-to-Site Reproducibility

For Site-to-Site reproducibility, three sites (two external, one internal) were provided with the same blinded panels described for the Precision Study. At each site, testing was performed by two operators for five non-consecutive days. Each operator performed two different runs each day with duplicates per run. Each run contained an external negative control and external positive control, in addition to the internal process controls. The overall percent agreement with expected result when detecting each of the three targets in male urine is reported below.

**Overall Percent Agreement-All Sites Combined**

| Panel Member | Overall Percent Agreement with Expected Result for Male Urine (All Sites) | | |
|---|---|---|---|
| | CT | NG | TV |
| | (n/N)<br>95% CI | (n/N)<br>95% CI | (n/N)<br>95% CI |
| [a]TN | 100%<br>(120/120)<br>96.9%-100% | 100%<br>(120/120)<br>96.9%-100% | 100%<br>(120/120)<br>96.9%-100% |
| [b]HN | 44.1%<br>(52/118)<br>35.4%-53.1% | 79.2%<br>(95/120)<br>71.1%-85.5% | 78.8%<br>(93/118)<br>70.6%-85.2% |
| LP | 100%<br>(120/120)<br>96.9%-100% | 100%<br>(120/120)<br>96.9%-100% | 100%<br>(120/120)<br>96.9%-100% |

| | | | |
|---|---|---|---|
| MP | 100%<br>(120/120)<br>96.9%-100% | 100%<br>(120/120)<br>96.9%-100% | 100%<br>(120/120)<br>96.9%-100% |

[a.] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b.] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

The percent agreement with expected result by each individual site when detecting each of the three targets in male urine is reported below.

**Percent Agreement for CT Detection-Site by Site**

| Panel Member | CT-Percent Agreement with Expected Result for Male Urine | | |
|---|---|---|---|
| | (n/N)<br>95% CI | | |
| | Site 1 | Site 2 | Site 3 |
| [a]TN | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% |
| [b]HN | 45.0%<br>(18/40)<br>30.7%-60.2% | 50%<br>(20/40)<br>35.2%-64.8% | 36.8%<br>(14/38)<br>23.4%-52.7% |
| LP | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% |
| MP | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% |

[a.] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b.] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

**Percent Agreement for NG Detection-Site by Site**

| Panel Member | NG-Percent Agreement with Expected Result for Male Urine | | |
|---|---|---|---|
| | (n/N)<br>95% CI | | |
| | Site 1 | Site 2 | Site 3 |
| [a]TN | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% |
| [b]HN | 85.0%<br>(34/40)<br>70.9%-92.9% | 77.5%<br>(31/40)<br>62.5%-87.7% | 75.0%<br>(30/40)<br>59.8%- 85.8% |
| LP | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% |

| | | | |
|---|---|---|---|
| MP | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% |

[a.] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b.] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

**Percent Agreement for TV Detection-Site by Site**

| **Panel Member** | **TV-Percent Agreement with Expected Result for Male Urine** | | |
|---|---|---|---|
| | **(n/N)<br>95% CI** | | |
| | **Site 1** | **Site 2** | **Site 3** |
| [a]TN | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% |
| [b]HN | 80.0%<br>(32/40)<br>65.2% -89.5% | 85.0%<br>(34/40)<br>70.9%- 92.9% | 67.5%<br>(27/40)<br>52.0%-79.9% |
| LP | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% |
| MP | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% | 100%<br>(40/40)<br>91.2%- 100% |

[a.] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b.] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

c. Lot-to-Lot Reproducibility

For the Lot-to-Lot reproducibility studies, a single operator completed two separate runs per day with duplicates in each run on a single instrument for each of three separate lots of Rheonix STI TriPlex Assay kits, for three non-consecutive days. The test panel used was the same as described for the Precision study. The percent agreement with expected results across all three lots is reported below.

**Lot-to-Lot Reproducibility-Percent Agreement**

| **Panel Member** | **Overall Percent Agreement with Expected Result for Male Urine (Lot-to-Lot)** | | |
|---|---|---|---|
| | **CT** | **NG** | **TV** |
| | **(n/N)<br>95% CI** | **(n/N)<br>95% CI** | **(n/N)<br>95% CI** |
| [a]TN | 100%<br>(36/36)<br>90.4%-100% | 100%<br>(36/36)<br>90.4%-100% | 100%<br>(36/36)<br>90.4%-100% |

| | | | |
|---|---|---|---|
| [b]HN | 38.9%<br>(14/36)<br>24.8%-55.1% | 20.0%<br>(7/35)<br>10.0%-35.9% | 27.8%<br>(10/36)<br>15.9%-44.0% |
| LP | 100%<br>(36/36)<br>90.4%-100% | 100%<br>(36/36)<br>90.4%-100% | 100%<br>(36/36)<br>90.4%-100% |
| MP | 97.2%<br>(35/36)<br>85.8%-99.5% | 100%<br>(36/36)<br>90.4%-100% | 100%<br>(36/36)<br>90.4%-100% |

[a.] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b.] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

a. Cross-reactivity

The cross-reactivity of the Rheonix STI TriPlex Assay was evaluated in triplicates by testing 156 microorganisms (shown below) likely to be found in the urogenital samples. Quantified stocks of whole microorganisms were spiked into pooled negative male urine matrix and added in sample buffer tube. Each bacterial non-target organism was tested at concentration of $10^6$ CFU/ml while each viral non-target organism was tested at concentration of $10^5$ PFU/ml.

| **Microorganisms Tested for Cross-reactivity** | |
|---|---|
| *Achromobacter xerosis* | *Chlamydophila (Chlamydia) psittaci* |
| *Acinetobacter calcoaceticus* | *Chlamydophila (Chlamydia) psittaci* |
| *Acinetobacter lwoffii* | *Chromobacterium violaceum* |
| *Actinomyces israelii* | *Citrobacter freundii* |
| *Actinomyces pyogenes (Trueperella pyogenes)* | *Clostridium difficile* |
| *Aerococcus viridans* | *Clostridium perfringens* |
| *Aeromonas hydrophila* | *Corynebacterium genitalium* |
| *Alcaligenes faecalis* | *Corynebacterium xerosis* |
| *Atopobium vaginae* | *Cryptococcus neoformans* |
| *Bacillus subtilis* | *Cytomegalovirus (CMV)* |
| *Bacteroides fragilis* | *Deinococcus radiodurans* |
| *Bergeriella (Neisseria) denitrificans* | *Derxia gummosa* |
| *Bifidobacterium adolescentis* | *Eikenella corrodens* |
| *Bifidobacterium breve* | *Elizabethkingia meningoseptica (Flavobacterium melingosepticum)* |
| *Blautia producta (Peptostreptococcus productus)* | *Enterobacter aerogenes* |
| *Brevibacterium linens* | *Enterobacter cloacae* |
| *Campylobacter jejuni* | *Enterococcus avium* |
| *Campylobacter ureolyticus (Bacteroides ureolyticus)* | *Enterococcus faecalis* |
| *Candida albicans* | *Enterococcus faecium* |

| Microorganisms Tested for Cross-reactivity | |
|---|---|
| *Candida glabrata* | *Erysipelothrix rhusiopathiae* |
| *Candida parapsilosis* | *Escherichia coli* |
| *Candida tropicalis* | *Fusobacterium nucleatum* |
| *Chlamydophila pneumoniae* | *Gardnerella vaginalis* |
| *Gemella haemolysans* | *Neisseria cinerea* |
| *Haemophilus ducreyi* | *Neisseria cinerea* |
| *Haemophilus influenzae* | *Neisseria elongata* |
| *Herpes Simplex Virus, type I (HSV1)* | *Neisseria elongata* |
| *Herpes Simplex Virus, type II (HSV2)* | *Neisseria elongata* |
| *HIV type 1* | *Neisseria flavescens* |
| *HPV 16* | *Neisseria flavescens* |
| *Weissella paramesenteroides (Leuconostoc paramensenteroides)* | *Neisseria lactamica* |
| *Human Papilloma Virus 6* | *Neisseria lactamica* |
| *Kingella denitrificans* | *Neisseria lactamica* |
| *Kingella kingae* | *Neisseria lactamica* |
| *Klebsielia oxytoca* | *Neisseria lactamica* |
| *Klebsiella pneumoniae* | *Neisseria lactamica* |
| *Lactobacillus acidophilus* | *Neisseria lactamica* |
| *Lactobacillus brevis* | *Neisseria lactamica* |
| *Lactobacillus crispatus* | *Neisseria lactamica* |
| *Lactobacillus jensenii* | *Neisseria meningitidis serogroup A* |
| *Lactobacillus debrueckii (lactis)* | *Neisseria meningitidis serogroup B* |
| *Lactobacillus vaginalis* | *Neisseria meningitidis serogroup C* |
| *Legionella pneumophila* | *Neisseria meningitidis serogroup C* |
| *Legionella pneumophila* | *Neisseria meningitidis serogroup C* |
| *Listeria monocytogenes* | *Neisseria meningitidis serogroup C* |
| *Micrococcus luteus* | *Neisseria meningitidis serogroup D** |
| *Mobiluncus curtisii* | *Rhodospirillum rubrum* |
| *Moraxella (Branhamella) catarrhalis* | *Saccharomyces cerevisiae* |
| *Moraxella lacunata* | *Yersinia enterocolitica* |
| *Moraxella osloensis* | *Neisseria meningitidis serogroup W135* |
| *Morganella morganii* | *Neisseria meningitidis serogroup Y* |
| *Mycobacterium smegmatis* | *Neisseria mucosa* |
| *Mycoplasma genitalium* | *Neisseria mucosa* |
| *Mycoplasma hominis* | *Neisseria mucosa* |
| *Neisseria cinerea* | *Neisseria polysaccharea* |
| *Neisseria cinerea* | *Neisseria sicca* |
| *Neisseria sicca* | *Pseudomonas aeruginosa* |
| *Neisseria sicca* | *Pseudomonas fluorescens* |
| *Neisseria subflava biovar flava* | *Pseudomonas putida* |
| *Neisseria subflava biovar flava* | *Rahnella aquatilis* |
| *Neisseria subflava biovar perflava* | *Rhizobium (Agrobacterium) radiobacter* |
| *Neisseria subflava biovar perflava* | *Salmonella enterica minnesota* |
| *Neisseria subflava biovar perflava* | *Salmonella typhimurium* |
| *Neisseria subflava biovar perflava* | *Serratia marcescens* |
| *Neisseria subflava biovar perflava* | *Staphylococcus aureus* |
| *Neisseria subflava biovar perflava* | *Staphylococcus epidermidis* |
| *Neisseria subflava biovar subflava* | *Staphylococcus saprophyticus* |
| *Pantoea agglomerans (Erwinia herbicola)* | *Streptococcus agalactiae* |
| *Paracoccus denitrificans* | *Streptococcus bovis* |
| *Pentatrichomonas hominis* | *Streptococcus mitis* |
| *Peptostreptococcus anaerobius* | *Streptococcus mutans* |
| *Peptostreptococcus magnus (Finegoldia magna)* | *Streptococcus pneumoniae* |

| Microorganisms Tested for Cross-reactivity | |
|---|---|
| *Plesiomonas shigelloides* | *Streptococcus pyogenes* |
| *Prevotella bivia* | *Streptococcus salivarius* |
| *Propionibacterium acnes* | *Streptococcus sanguinis* |
| *Proteus mirabilis* | *Trichomonas tenax* |
| *Proteus vulgaris* | *Ureaplasma urealyticum* |
| *Providencia stuartii* | *Vibrio parahaemolyticus* |

All microbes tested, with the exception of Herpes Simplex Virus, type 1 (HSV1) and *Neisseria meningitides* serogroup D, returned negative results for all three replicates. When initially tested in triplicate, the HSV1 sample (tested at $10^5$ PFU/ml) returned one positive result for TV while the *N. meningitides* (tested at $10^6$ CFU/ml) returned one positive result for NG. Upon retest in triplicate, all three replicates for each of these two microbes were negative for all three target microbes.

b. Competitive Interference

Competitive Interference study was conducted to determine whether any of the target organisms, when present at high concentrations (CT at $10^6$ IFU/ml, NG at $10^6$ CFU/ml, and TV at $10^5$ Trophozoites/ml) could potentially interfere with the detection of the other organism present at low concentrations (~1.5x LoD). The test samples were prepared by spiking quantified stocks of CT, NG and TV into pooled negative male urine matrix in different combinations of concentrations (see below). Each panel member was tested in 24 replicates.

**Panel Member Tested for Competitive Interference**

| Panel Member | Concentration of Spiked Target | | |
|---|---|---|---|
| | CT | NG | TV |
| 1 | Low | High | High |
| 2 | High | Low | High |
| 3 | High | High | Low |

Results of the above studies demonstrated positivity rate above 95% for target spiked at the low concentration for all panel members tested, suggesting that targets present at high concentrations do not interfere with the detection of the other target.

c. Interfering Substances

A total of 26 potentially interfering substances that could be present in urogenital tract specimens were evaluated for their impact on the assay results. Each potentially interfering substance was evaluated in pooled negative male urine matrix in the presence or absence of a mixture of all three targets at level of 1.5xLoD or 3xLoD (substances that showed potential interference at 1.5xLoD were retested using samples spiked with targets at 3xLoD). Testing was performed in duplicate. None of the substances tested yielded interference at the concentrations noted in the following table.

| Substances Tested in Urine Matrix | |
|---|---|
| **Interfering Substance** | **Concentration** |
| Whole Blood | 2% (v/v) |
| Semen | 5% (v/v) |
| Hormones | 0.48 ng/mL 17-α-Ethinylestradiol |
| Anti-Protozoal (Metronidazole) | 48 µg/mL |
| Glucose | 0.48 mg/mL |
| Acetylsalicylic Acid | 260.8 µg/mL |
| Azithromycin | 4.8 µg/mL |
| Phenazopyridine Hydrochloride | 80 µg/mL |
| Norithindrone | 8 ng/mL |
| 4-Acetaminophenol | 80 µg/mL |
| Naproxen | 200 µg/mL |
| Ibuprofen | 200 µg/mL |
| Amoxicillin Trihydrate | 30.08 µg/mL |
| Tetracycline Hydrochloride | 6 µg/mL |
| Ceftriaxone | 324.4 µg/mL |
| Sulfamethoxazole | 160 µg/mL |
| Trimethoprim | 16 µg/mL |
| Erythromycin | 24 µg/mL |
| Human Serum Albumin | 0.4 mg/mL |
| Leukocytes | $10^6$ cells/mL |
| Feminine Deodorant Spray | 0.68% v/v |
| Talcum Powder[a] | 0.6% w/v |
| Bilirubin | 0.08 mg/mL |
| Biotin | 3500 ng/mL |
| Urine (high pH) | pH 9 |
| Urine (low pH 4) | pH 4 |

[a]May interfere with the Rheonix STI TriPlex assay when at concentrations higher than shown.

4. Assay Reportable Range:

Not applicable

5. Sample Stability:

To determine the maximum amount of time that clinical specimens collected from male subjects can be stored at two temperature ranges (2°C to 8°C and 30°C) prior to evaluation with the Rheonix STI TriPlex Assay, pooled negative male urine matrix spiked with all three target microorganisms at 1.5 x LoD was tested in ten replicates over seven time points spanning a period of 132 days. The results demonstrated that male urine transferred immediately to transport medium after collection remains stable for 120 days if stored at 2–8°C, or 75 days if stored at 30°C.

6. Detection Limit:

a. Limit of Detection (LoD)

Two strains (or serovars) of each target organism were tested to determine the LoD. Each organism was individually spiked into pooled negative male urine matrix. The LoD was first

estimated by probit analysis by testing six concentrations of each organism in 26 replicates using three different lots of assay reagents. The calculated LoD for each strain was verified by testing 44 replicates at the estimated concentration and demonstrating that at least 95% of the replicates (42 out of 44) were positive. If the criteria of at least 42 out of 44 positive replicates were not met, the results were added to the data set and re-analyzed to obtain a new estimated LoD value. Additional replicates were tested at the revised estimate and the process was repeated until at least 95% of all replicates gave a positive test result. The final LoD concentrations confirmed in this study for each target are summarized in the table below.

**Limit of Detection in Urine Matrix**

| Target | Serovar/Strain | Limit of Detection |
|---|---|---|
| CT | Serovar D | 19 IFU/ml |
| | Serovar H | 26 IFU/ml |
| NG | ATCC 49226 | 180 CFU/ml |
| | ATCC 19424 | 110 CFU/ml |
| TV | ATCC 30236 (Metronidazole sensitive) | 4 Trophozoites/ml |
| | ATCC 50143 (Metronidazole resistant) | 5 Trophozoites/ml |

b. Inclusivity

An additional 13 serovars of CT, 30 strains of NG and 6 strains of TV were tested in 20 replicates at the most challenging LoD noted above for each target in pooled negative male urine matrix. If the initial concentration tested yielded lower than 95% positive results for a particular strain, then additional replicates were tested at a higher target concentration. Of all 13 CT serovars tested, 11 were detected at $\leq$3xLoD, and L1 as well as Ba were detected at higher concentrations with $\geq$95% positivity. All NG and TV strains were detected at 1xLoD with $\geq$95% positivity. The results of the inclusivity study are shown below.

**Results for Additional Serovars of CT**

| CT Serovar | IFU/mL | xLoD | %Pos |
|---|---|---|---|
| A | 11 | 0.6 | 100 |
| B | 11 | 0.6 | 100 |
| C | 33 | 1.7 | 100 |
| E, nvCT | 22 | 1.2 | 100 |
| F | 11 | 0.6 | 100 |
| I | 22 | 1.2 | 100 |
| J | 55 | 2.9 | 100 |
| K | 33 | 1.7 | 95 |
| G | 33 | 1.7 | 100 |
| L1 | 154 | 8.1 | 100 |
| L2 | 11 | 0.6 | 100 |
| L3 | 55 | 2.9 | 100 |
| Ba | 110 | 5.8 | 95 |

**Results for Additional Strains of NG**

| NG Strain | CFU/ml | x LoD | %Pos | NG Strain | CFU/ml | xLoD | %Pos |
|---|---|---|---|---|---|---|---|
| Z423 | 110 | 1 | 100 | Z438 | 110 | 1 | 100 |
| Z424 | 110 | 1 | 100 | Z439 | 110 | 1 | 100 |
| Z425 | 110 | 1 | 100 | Z440 | 110 | 1 | 100 |
| Z426 | 110 | 1 | 100 | Z441 | 110 | 1 | 100 |
| Z427 | 110 | 1 | 100 | Z442 | 110 | 1 | 100 |
| Z428 | 110 | 1 | 95 | Z443 | 110 | 1 | 100 |
| Z429 | 110 | 1 | 100 | Z444 | 110 | 1 | 100 |
| Z430 | 110 | 1 | 100 | Z445 | 110 | 1 | 100 |
| Z431 | 110 | 1 | 100 | Z446 | 110 | 1 | 100 |
| Z432 | 110 | 1 | 100 | Z448 | 110 | 1 | 100 |
| Z433 | 110 | 1 | 100 | Z449 | 110 | 1 | 100 |
| Z434 | 110 | 1 | 100 | Z450 | 110 | 1 | 100 |
| Z435 | 110 | 1 | 100 | Z451 | 110 | 1 | 100 |
| Z436 | 110 | 1 | 100 | Z452 | 110 | 1 | 100 |
| Z437 | 110 | 1 | 100 | Z466 | 110 | 1 | 100 |

**Results for Additional Strains of TV**

| TV Strain | Trophozoites/ml | xLoD | %Pos |
|---|---|---|---|
| Z070 | 4 | 1 | 100 |
| [a]CDC252 | 4 | 1 | 100 |
| Z158 | 4 | 1 | 100 |
| Z159 | 4 | 1 | 100 |
| ATCC 30238 | 4 | 1 | 100 |
| ATCC 30001 | 4 | 1 | 100 |

[a.] Metronidazole resistant

7. Assay Cut-Off:

Results for the Rheonix STI TriPlex assay are generated in the form of blue colored spots for which the saturation of color is converted to intensity unit values, ranging from 0 to 200 units, and evaluated by the instrument's software to establish the test result. The cut-off values were established by testing ~100 blank samples and ~500 samples contrived at low target level for each of the three targets. The cut-off values for the targets are demonstrated in the table below. The cut-off for each target was validated in the clinical study.

| Target | Spot Intensity | |
|---|---|---|
| | [a]Lower Threshold | [b]Upper Threshold |
| *Chlamydia trachomatis* | 14 | 28 |
| *Neisseria gonorrhoeae* | 64 | 79 |
| *Trichomonas vaginalis* | 18 | 32 |

[a, b.] Samples with intensity readings equal to or less than the lower threshold are scored as Negative (NEG) while samples with intensity readings equal to or greater than the upper threshold are scored as Positive (POS). Any sample that yields intensity readings between the lower threshold and upper threshold is scored as "indeterminate" (IND) and must be reanalyzed.

8. Carry-Over:

Carry-over study was conducted to investigate within-run carryover and between-run carryover while processing samples with high microbial loads of target organisms by the Rheonix STI TriPlex Assay. Two different panel members were tested. One panel member consisted of all three targets at high concentration (CT at $10^6$ IFU/ml, NG at $10^6$ CFU/ml and TV at $10^5$ Trophozoites/mL) and a second panel member consisted of only the negative matrix without any spiked targets. The high positive samples were run in a CARD cartridge lane immediately adjacent to a lane that contained the negative sample. A total of 144 alternating samples were run across five days on a single Rheonix Encompass MDx Workstation. All high positive samples yielded positive results for all three targets while the negative samples yielded negative results for all three targets. Therefore, no carry over was observed.

## B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable.

2. Matrix Comparison:

Not applicable.

## C Clinical Studies:

1627 male subjects, aged 14 years and older, were enrolled through eight geographically distinct clinical collection sites in US. The study enrolled both symptomatic and asymptomatic subjects. One first-catch urine specimen was collected from each subject. The collected specimen from each subject was subsequently aliquoted and transferred into a total of four different manufacturers' transport tubes (one from Rheonix Urine Specimen Collection kit and three others for reference methods). All processed urine specimens were shipped via overnight courier to a central laboratory for Patient Infection Status (PIS) testing and then distributed to one of three separate testing laboratories for test by Rheonix STI TriPlex assay.

Subjects were excluded from the data analysis for reasons including ineligibility issues (n=1), patient withdrawal (n=3), and sample mishandling/shipping issues (n=10). Urine specimens from the remaining 1613 subjects were tested by both Rheonix STI TriPlex Assay and the reference assays. 1606 subjects were evaluated for performance with CT and NG (7 subjects were excluded from performance analysis due to protocol deviations or unevaluable PIS testing results), while 1585 subjects were evaluated for performance with TV (27 subjects were excluded from performance analysis due to protocol deviations or unevaluable PIS testing results. One additional subject was excluded due to invalid test result for Rheonix STI TriPlex Assay). Therefore, the final data analysis of clinical performance of the Rheonix STI TriPlex Assay was based on:

- A total of 1606 male urine specimens for CT and NG, respectively.
- A total of 1585 male urine specimens for TV.

Using the FDA-cleared comparator tests, male subjects were classified as Infected or Not Infected according to the following PIS determination algorithm. Each urine specimen was analyzed by up to three different FDA-cleared nucleic acid amplification tests (NAATs) for the presence of CT, NG or TV. Only two tests were utilized if their results were concordant. When discordant results were obtained, a third "tie-breaker" NAAT was performed. A Positive Infection Status was established when at least two comparator NAATs yielded positive results. A Negative Infection Status was established when at least two comparator NAATs yielded negative results. All other assay result combinations were reported as indeterminate.

1. Clinical Sensitivity and Specificity

The following three tables summarize the clinical performance of the Rheonix STI TriPlex Assay for CT, NG and TV, established by comparing to PIS:

**Clinical Performance for CT Detection**

| Symptom | Rheonix STI TriPlex Assay vs. PIS for CT Detection | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | N | TP | FP | TN | FN | Prevalence% | Sensitivity (95% CI) | Specificity (95% CI) |
| Asymptomatic | 1202 | 96 | 0 | 1104 | 2 | 8.2% | 98.0% (92.9% - 99.4%) | 100% (99.7% - 100%) |
| Symptomatic | 404 | 62 | 0 | 339 | 3 | 16.1% | 95.4% (87.3% - 98.4%) | 100% (98.9% - 100%) |
| ALL | 1606 | 158 | 0 | 1443 | 5 | 10.1% | 96.9% (93.0% - 98.7% | 100% (99.7% - 100.0%) |

**Clinical Performance for NG Detection**

| Symptom | Rheonix STI TriPlex Assay vs. PIS for NG Detection | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | N | TP | FP | TN | FN | Prevalence% | Sensitivity (95% CI) | Specificity (95% CI) |
| Asymptomatic | 1201 | 14 | 0 | 1187 | 0 | 1.2% | 100% (78.5% - 100%) | 100% (99.7% - 100%) |
| Symptomatic | 405 | 99 | 0 | 305 | 1 | 24.7% | 99.0% (94.6% - 99.8%) | 100% (98.8% - 100%) |
| ALL | 1606 | 113 | 0 | 1492 | 1 | 7.1% | 99.1% (95.2% - 99.8%) | 100% (99.7% - 100%) |

**Clinical Performance for TV Detection**

| Symptom | Rheonix STI TriPlex Assay vs. PIS for TV Detection | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | N | TP | FP | TN | FN | Prevalence% | Sensitivity (95% CI) | Specificity (95% CI) |
| Asymptomatic | 1187 | 22 | 1 | 1163 | 1 | 1.9% | 95.7% (79.0% - 99.2%) | 99.9% (99.5% - 100%) |
| Symptomatic | 398 | 12 | 0 | 386 | 0 | 3.0% | 100% (75.8% - 100%) | 100% (99.0% - 100%) |
| ALL | 1585 | 34 | 1 | 1549 | 1 | 2.2% | 97.1% (85.5% - 99.5%) | 99.9% (99.6% - 100%) |

The following three tables demonstrate the distribution of Rheonix results based on possible PIS outcomes:

## Distribution of Rheonix Assay Results Based on Possible PIS Outcomes for CT

| CT-Male Urine | | | | | | | |
|---|---|---|---|---|---|---|---|
| PIS | PIS Tests | | | Rheonix Result | Symptoms | | |
| | NAAT 1 | NAAT 2 | NAAT 3 | | [a]CT_SX | [b]CT_ASX | CT_Total |
| Not Infected | - | - | NA | - | 333 | 1098 | 1431 |
| | - | + | - | - | 1 | 5 | 6 |
| | + | - | - | - | 2 | 1 | 3 |
| | Invalid | - | - | - | 3 | 0 | 3 |
| | - | - | NA | + | 0 | 0 | 0 |
| | - | + | - | + | 0 | 0 | 0 |
| | + | - | - | + | 0 | 0 | 0 |
| | - | - | NA | Invalid | 0 | 0 | 0 |
| | - | + | - | Invalid | 0 | 0 | 0 |
| | + | - | - | Invalid | 0 | 0 | 0 |
| Total Not Infected | | | | | 339 | 1104 | 1443 |
| Infected | + | + | N/A | + | 60 | 95 | 155 |
| | + | - | + | + | 2 | 0 | 2 |
| | - | + | + | + | 0 | 0 | 0 |
| | + | Invalid | + | + | 0 | 1 | 1 |
| | + | + | N/A | - | 2 | 2 | 4 |
| | + | - | + | - | 0 | 0 | 0 |
| | - | + | + | - | 1 | 0 | 1 |
| | + | + | N/A | Invalid | 0 | 0 | 0 |
| | + | - | + | Invalid | 0 | 0 | 0 |
| | - | + | + | Invalid | 0 | 0 | 0 |
| Total Infected | | | | | 65 | 98 | 163 |

[a]CT_SX (Symptomatic Males)
[b]CT_ASX (Asymptomatic Males)

## Distribution of Rheonix Assay Results Based on Possible PIS Outcomes for NG

| NG-Male Urine | | | | | | | |
|---|---|---|---|---|---|---|---|
| PIS | PIS Tests | | | Rheonix Result | Symptoms | | |
| | NAAT 1 | NAAT 2 | NAAT 3 | | [a]NG_SX | [b]NG_ASX | NG_Total |
| Not Infected | - | - | NA | - | 305 | 1185 | 1490 |
| | - | + | - | - | 0 | 1 | 1 |
| | + | - | - | - | 0 | 1 | 1 |
| | Invalid | - | - | - | 0 | 0 | 0 |
| | - | - | NA | + | 0 | 0 | 0 |
| | - | + | - | + | 0 | 0 | 0 |
| | + | - | - | + | 0 | 0 | 0 |
| | - | - | NA | Invalid | 0 | 0 | 0 |
| | - | + | - | Invalid | 0 | 0 | 0 |
| | + | - | - | Invalid | 0 | 0 | 0 |
| Total Not Infected | | | | | 305 | 1187 | 1492 |
| Infected | + | + | N/A | + | 99 | 14 | 113 |
| | + | - | + | + | 0 | 0 | 0 |
| | - | + | + | + | 0 | 0 | 0 |
| | + | Invalid | + | + | 0 | 0 | 0 |
| | + | + | N/A | - | 1 | 0 | 1 |
| | + | - | + | - | 0 | 0 | 0 |
| | - | + | + | - | 0 | 0 | 0 |
| | + | + | N/A | Invalid | 0 | 0 | 0 |
| | + | - | + | Invalid | 0 | 0 | 0 |
| | - | + | + | Invalid | 0 | 0 | 0 |
| Total Infected | | | | | 100 | 14 | 114 |

[a]NG_SX (Symptomatic Males)
[b]NG_ASX (Asymptomatic Males)

**Distribution of Rheonix Assay Results Based on Possible PIS Outcomes for TV**

| TV-Male Urine | | | | | | | |
|---|---|---|---|---|---|---|---|
| **PIS** | **PIS Tests** | | | **Rheonix Result** | **Symptoms** | | |
| | **NAAT 1** | **NAAT 2** | **NAAT 3** | | **[a]TV_SX** | **[b]TV_ASX** | **TV_Total** |
| **Not Infected** | - | - | NA | - | 382 | 1161 | 1543 |
| | - | + | - | - | 1 | 2 | 3 |
| | + | - | - | - | 1 | 0 | 1 |
| | Invalid | - | - | - | 2 | 0 | 2 |
| | - | - | NA | + | 0 | 0 | 0 |
| | - | + | - | + | 0 | 1 | 1 |
| | + | - | - | + | 0 | 0 | 0 |
| | - | - | NA | Invalid | 0 | 1 | 1 |
| | - | + | - | Invalid | 0 | 0 | 0 |
| | + | - | - | Invalid | 0 | 0 | 0 |
| **Total Not Infected** | | | | | 386 | 1165 | 1551 |
| **Infected** | + | + | N/A | + | 12 | 22 | 34 |
| | + | - | + | + | 0 | 0 | 0 |
| | - | + | + | + | 0 | 0 | 0 |
| | + | Invalid | + | + | 0 | 0 | 0 |
| | + | + | N/A | - | 0 | 1 | 1 |
| | + | - | + | - | 0 | 0 | 0 |
| | - | + | + | - | 0 | 0 | 0 |
| | + | + | N/A | Invalid | 0 | 0 | 0 |
| | + | - | + | Invalid | 0 | 0 | 0 |
| | - | + | + | Invalid | 0 | 0 | 0 |
| **Total Infected** | | | | | 12 | 23 | 35 |

[a]TV_SX (Symptomatic Males)
[b]TV_ASX (Asymptomatic Males)

2. The Positive Predictive Value (PPV) and Negative Predictive Value (NPV)

The PPV and NPV were calculated based on the Clinical Sensitivity and Clinical Specificity observed above and hypothetical prevalence rates for the three targets of interest. These values are shown as below.

| **Hypothetical Prevalence** | ***Chlamydia trachomatis*** | | | | ***Neisseria gonorrhoeae*** | | | | ***Trichomonas vaginalis*** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **% Sen** | **% Spec** | **% PPV** | **% NPV** | **% Sen** | **% Spec** | **% PPV** | **% NPV** | **% Sen** | **% Spec** | **% PPV** | **% NPV** |
| 1% | 96.9% | 100% | 100% | 100% | 99.1% | 100% | 100 % | 100% | 97.1% | 99.9% | 90.8% | 100% |
| 2% | | | 100% | 99.9% | | | 100 % | 100% | | | 95.2% | 99.9% |
| 5% | | | 100% | 99.8% | | | 100% | 100% | | | 98.1% | 99.9% |
| 10% | | | 100% | 99.7% | | | 100 % | 99.9% | | | 99.1% | 99.7% |
| 15% | | | 100% | 99.5% | | | 100 % | 99.8% | | | 99.4% | 99.5% |
| 20% | | | 100% | 99.2% | | | 100 % | 99.8% | | | 99.6% | 99.3% |
| 25% | | | 100% | 99.0% | | | 100 % | 99.7% | | | 99.7% | 99.0% |

3. Repeat and Unresolved Rates

The Rheonix Encompass MDx workstation reports results as Positive, Negative or Indeterminate for each of the three target microorganisms. In addition, the workstation also reports error codes (ERR) that require repeat testing. The combined IND and ERR code rates are reported as below. The values reported as "Initial" represent samples that displayed either an IND or ERR code that required a reanalysis. The "Unresolved" values represent samples that, upon repeat, did not yield valid results. Of all male subjects, only one urine specimen yielded an unresolved final result. All other initially failed runs yielded valid, interpretable results upon repeat testing.

**Rates of Initial and Final Unresolved Results for Male Urine by Rheonix STI TriPlex™ Assay**

| Target | Total N | Initial Unresolved Rate | | Final Unresolved Rate | |
|---|---|---|---|---|---|
| | | Percentage | 95% CI | Percentage | 95% CI |
| ***Chlamydia trachomatis*** | 1606 | 1.3% (20/1606) | (0.8% - 1.9%) | 0.0% (0/1606) | (0.0% - 0.2%) |
| ***Neisseria gonorrhoeae*** | 1606 | 1.0% (16/1606) | (0.6% - 1.6%) | 0.0% (0/1606) | (0.0% - 0.2%) |
| ***Trichomonas vaginalis*** | 1586 | 1.5% (24/1586) | (1.0% - 2.2%) | 0.1% (1/1586) | (0.01%-0.04%) |

## D Clinical Cut-Off:

Not applicable.

## E Expected Values/Reference Range:

During the clinical evaluation, the positivity rate for detection of CT, NG, and/or TV in male urine using the Rheonix STI TriPlex Assay, by clinical study site and overall, is shown in the table below.

| Collection Site | Positivity Rate as Determined by Rheonix STI TriPlex Assay by Clinical Site | | |
|---|---|---|---|
| | CT | NG | TV |
| 1 | 19.5% | 17.7% | 7.1% |
| 2 | 4.6% | 7.2% | 0.0% |
| 3 | 9.7% | 4.7% | 1.7% |
| 4 | 13.2% | 5.0% | 1.3% |
| 5 | 10.9% | 2.0% | 2.0% |
| 6 | 8.7% | 10.6% | 5.9% |
| 7 | 1.9% | 4.8% | 0.0% |
| 8 | 23.1% | 23.1% | 0.0% |
| All Sites | 9.8% | 7.0% | 2.2% |

## F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

## VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

## IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.