

Metronidazole resistance for *Trichomonas vaginalis*

All positive *Trichomonas vaginalis* PCR results reflex at NO additional cost

- | | | |
|-------------------------------------|-------------------------------------|-------------------------------------|
| <i>Chlamydia trachomatis</i> | <i>Trichomonas vaginalis</i> | <i>Mycoplasma genitalium</i> |
| • Azithromycin | • Metronidazole | • Azithromycin |
| | | • Fluoroquinolone resistance |

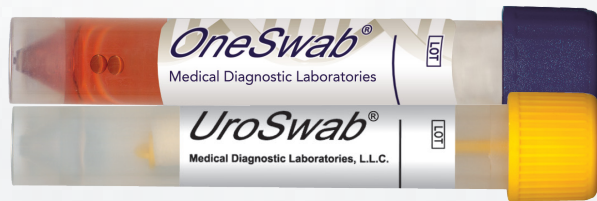
Neisseria gonorrhoeae

- Ceftriaxone/cefixime
- Treatment failures and isolates with reduced susceptibilities and resistance to extended-spectrum cephalosporin (ESC) ceftriaxone have been reported
- Advanced Sanger sequencing assay examines 28 combinations of genetic markers to determine ceftriaxone and cefixime resistance.

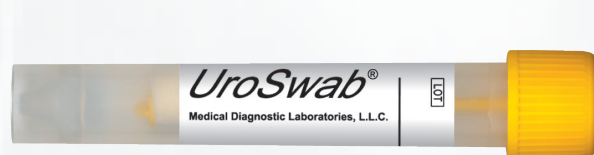
Advantages:

- Detection by Real-Time PCR and sequencing
- Antimicrobial resistance profile in “Real-Time” by SNP analysis
- **Antimicrobial resistance at no additional cost.**

For Women:
Cervical Collection
Urine Collection

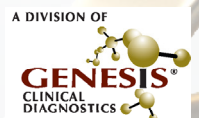


For Men:
Non-invasive Urine Collection



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PATIENT MDL # **13364148**

DOE, JANE **FINAL**
 555 MAIN ROAD
 ANYTOWN, NJ 12345-6789
DOB: 11/30/1998 (Age 25)
Gender: Female
Ethnicity: Not provided
Patient ID: 82100
Home #: 123-456-7890

SPECIMEN

Type	Source	Collected	Received	Reported
Swab	Vag/Anal	04/15/2024	04/16/2024	04/19/2024

CLIENT NPI: 0987654321
DOE FAMILY PRACTICE Tel: (555) 555-1234
JOHN DOE, MD Fax: 555-555-1235
 1234 FIRST AVENUE
 ANYTOWN, NJ 12345-6789

Pathogens Detected

111 *Trichomonas vaginalis* (Reflex to metronidazole resistance) * **POSITIVE**
 Presence of Tvnr6 K80STOP mutation detected. >90% likelihood of metronidazole resistance.

*This test was developed and its performance characteristics determined by the laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

‡ Performing Lab: Medical Diagnostic Laboratories, 2439 Kuser Road, Hamilton, NJ 08690 Lab Director: Jing Jing Yang M.D.

Swab-1;111 : Trichomonas vaginalis by Real-Time PCR (Reflex to metronidazole resistance)

The Tvnr6 K80STOP mutation predicts metronidazole resistance with 40% sensitivity and 96% specificity. The presence of the mutation has a positive predictive value (PPV) for metronidazole resistance of 91%. A negative result is inconclusive and does not indicate susceptibility or resistance to metronidazole. This assay was developed by testing 100 well-characterized metronidazole-sensitive and resistant isolates provided by the Centers for Disease Control and Prevention (CDC).

A positive result is provided for bacteria, virus, parasites, and/or fungal species when PCR amplification (real-time PCR), sequence information (Pyrosequencing), and/or sequencing analysis occurs above cut-off levels established by the laboratory. Pertinent reference intervals for the tests reported above are available from the laboratory upon request.

Medical Director, Jing-Jing Yang, M.D.

MDL#: **13364148** 05/20/2024