

# When an internal exam just isn't an option...

**NEW  
Tests**

## UroSwab®

### Non-invasive STD testing for adolescent females

Of the estimated 15.3 million new cases of sexually transmitted disease in the United States each year, 3 million occur in people between the ages of 13 and 19.

- |                 |                                                                                                                                                        |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Test 105</b> | <b><i>Chlamydia trachomatis</i> by Real-Time PCR</b><br>(*Reflex to antibiotic resistance by Molecular Analysis)                                       |
| <b>Test 121</b> | <b>Leukorrhea Panel by Real-Time PCR</b><br>( <i>N. gonorrhoeae</i> *, <i>C. trachomatis</i> *, <i>T. vaginalis</i> *, <i>Mycoplasma genitalium</i> *) |
| <b>Test 129</b> | <b><i>Mycoplasma genitalium</i></b><br>(*Reflex to antibiotic resistance by Molecular Analysis)                                                        |
| <b>Test 167</b> | <b><i>Neisseria gonorrhoeae</i> by Real-Time PCR</b><br>(*Reflex to antibiotic resistance by Molecular Analysis)                                       |
| <b>Test 109</b> | <b><i>N. gonorrhoeae</i>* &amp; <i>C. trachomatis</i>* by Real-Time PCR</b>                                                                            |
| <b>Test 111</b> | <b><i>Trichomonas vaginalis</i> by Real-Time PCR</b><br>(*Reflex to Metronidazole Resistance)                                                          |

### Simple, non-invasive urine collection



**Step 1.** Urine collection should be at least one hour between voids.

**Step 2.** The patient may void directly on the sponge or collect a urine sample in a urine container. Dip the sponge into the urine container.

**Step 3.** Place the sponge into the vial. Tightly cap the vial and label with patient information.



Step 1.



Step 2.



Step 3.

Applicable for adolescent females who are not candidates for internal exams.



A MEMBER OF GENESIS BIOTECHNOLOGY GROUP

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A DIVISION OF



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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****JOHN DOE, MD**

1234 FIRST AVENUE

ANYTOWN, NJ 12345-6789

**Tel:** (555) 555-1234**Fax:** 555-555-1235**Pathogens Detected****167** *Neisseria gonorrhoeae* (Reflex to Antibiotic Resistance by Molecular Analysis) \***POSITIVE**

\*\*\*\*Genetic mutations not detected.

Suggestive of Ceftriaxone/cefixime susceptibility.

**111** *Trichomonas vaginalis* (Reflex to metronidazole resistance) \***POSITIVE**

Tvntr6 K80STOP mutation not detected. Cannot determine metronidazole susceptibility or resistance.

**Pathogens Not Detected****Leukorrhea****105** *Chlamydia trachomatis* (\*Reflex to antibiotic resistance by Molecular Analysis) \***129** *Mycoplasma genitalium* (\*Reflex to antibiotic resistance by Molecular Analysis) \*

\*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.

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

The Tvntr6 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).

**Swab-1;167 : Neisseria gonorrhoeae by Real-Time PCR (Reflex to Antibiotic Resistance by Molecular Analysis)**

\*\*\*\*The specimen was tested for antibiotic resistance to Ceftriaxone and Cefixime. The PenA gene of *Neisseria gonorrhoeae* is analyzed for mosaicism and the following amino acid substitutions: 201->H, 202->A, 203->G, 204->E, Q230->K, A311->V, I312->M, V316->T/P, and A323->S.

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