OneSwab®

One Vial... Multiple Pathogens

Simple & Convenient Multipurpose Specimen Collection

A MEMBER OF GENESIS BIOTECHNOLOGY GROUP

Medical Diagnostic Laboratories
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A DIVISION OF GENESIS CLINICAL DIAGNOSTICS

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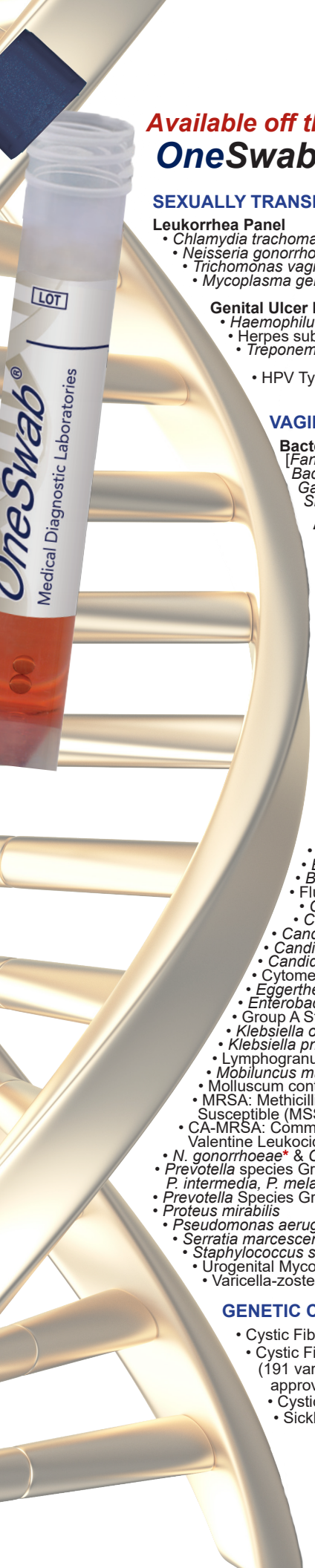
Upd.: 4.2025



Available off the
OneSwab®

OneSwab®
MULTIPLE PATHOGENS

SEXUALLY TRANSMITTED INFECTIONS

Leukorrhea Panel
- *Chlamydia trachomatis* (*Reflex to antibiotic resistance by Molecular Analysis)
- *Neisseria gonorrhoeae* (*Reflex to antibiotic resistance by Molecular Analysis)
- *Trichomonas vaginalis* (Reflex to metronidazole resistance)
- *Mycoplasma genitalium* (*Reflex to antibiotic resistance by Molecular Analysis)

Genital Ulcer Disease Panel
- *Haemophilus ducreyi*
- Herpes subtype (HSV-1 & HSV-2)
- *Treponema pallidum* (syphilis)

- HPV Type-Detect® 4.0 by Multiplex Real-Time PCR

VAGINITIS & VAGINOSIS

Bacterial Vaginosis (BV) Panel with Lactobacillus Profiling by qPCR
[*Fannyhessea vaginae* (*Atopobium vaginae*), BVAB1, BVAB2, BVAB3, *Bacteroides fragilis*, *Bifidobacterium breve*, Megasphaera Type 1 & 2, *Gardnerella vaginalis*, *Mobiluncus curtisii*, *M. mulieris*, *Prevotella bivia*, *Sneathia sanguinegens*, *Streptococcus anginosus*]

Aerobic Vaginitis (AV) Panel
- *Enterococcus faecalis*
- *Escherichia coli*
- Group B Streptococcus (GBS)
- *Staphylococcus aureus*

Candida Vaginitis Panel
- *Candida albicans*
- *Candida parapsilosis*
- *Candida glabrata*
- *Candida tropicalis*
- *Candida krusei*

- **Urogenital Mycoplasma & Ureaplasma Panel**
- *Mycoplasma genitalium* (*Reflex to antibiotic resistance by Molecular Analysis)
- *Mycoplasma hominis*
- *Ureaplasma urealyticum* (*Reflex to antibiotic resistance by Molecular Analysis)

PREGNANCY

- Group B Streptococcus (GBS)
- Group B Streptococcus (GBS) Antibiotic Resistance
- *Gleimia europaea* (*Actinomyces europaeus*)
- *Actinomyces israelii*
- *Actinomyces turicensis*
- *Bacteroides fragilis*
- *Bacteroides ureolyticus*
- Fluconazole resistance by X-Plate Technology®:
  - *Candida albicans*
  - *Candida parapsilosis*
  - *Candida glabrata*
  - *Candida tropicalis*
- *Candida dubliniensis*
- *Candida kefyr*
- *Candida lusitaniae*
- Cytomegalovirus (CMV)
- *Eggerthella* species
- *Enterobacter cloacae*
- Group A Streptococcus
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- Lymphogranuloma venereum (LGV)
- *Mobiluncus mulieris* & *Mobiluncus curtisii*
- Molluscum contagiosum virus
- MRSA: Methicillin Resistant and Methicillin Susceptible (MSSA) *Staphylococcus aureus*
- CA-MRSA: Community-Associated MRSA. Panton-Valentine Leukocidin (PVL) DNA
- *N. gonorrhoeae** & *C. trachomatis**
- *Prevotella* species Group 1 (*P. bivia, P disiens, P. intermedia, P. melaninogenica*)
- *Prevotella* Species Group 2 (*P. corporis, P. albensis*)
- *Proteus mirabilis*
- *Pseudomonas aeruginosa*
- *Serratia marcescens*
- *Staphylococcus saprophyticus*
- Urogenital Mycoplasma Panel (*M. genitalium** & *M. hominis*)
- Varicella-zoster virus (VZV)

GENETIC CARRIER SCREENING

- Cystic Fibrosis Core Test by Next Generation Sequencing (23 major CFTR mutations approved by ACOG/ACMG)
- Cystic Fibrosis Comprehensive Test by Next Generation Sequencing (191 variants of the CFTR gene, including the 23 major mutations approved by ACOG/ACMG)
- Cystic Fibrosis Site Specific Analysis by DNA Sequencing
- Sickle Cell Anemia by SNP Genotyping with Pyrosequencing

The introduction of molecular techniques, such as the Polymerase Chain Reaction (PCR) method, offers a superior route of pathogen detection with a high diagnostic specificity and sensitivity. MDL offers a number of assays for the detection of multiple pathogens associated with sexually transmitted diseases and gynecologic infections. The unrivaled sensitivity and specificity of the Real-Time PCR method in detecting infectious agents provides the clinician with an accurate and rapid means of diagnosis. This valuable diagnostic tool will assist the clinician with diagnosis, early detection, patient stratification, drug prescription, and prognosis. Tests currently available utilizing the ***OneSwab*®** specimen collection platform are listed to the side.

- **One vial, multiple pathogens**
- **DNA amplification via PCR technology**
- **Microbial drug resistance profiling**
- **High precision robotic accuracy**
- **High diagnostic sensitivity & specificity**
- **Specimen viability up to 5 days after collection**
- **Test additions available up to 30 days after collection**
- **No refrigeration required before or after collection**
- **Blood and excess mucus will not affect results**

* Reflex to antibiotic resistance by Molecular Analysis

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Available Exclusively From

Expanded Bacterial Vaginosis (BV) Testing

MDL has expanded the Bacterial Vaginosis (BV) Panel with Lactobacillus Profiling by qPCR test to allow for a more sensitive and specific determination of BV status, especially when considering the variation among patient vaginal microbial composition and the complex interactions that occur leading to dysbiosis. As BV can be a polymicrobial infectious process involving species that differ among patients with overlapping symptoms with other vaginal disorders, it is critical for an accurate diagnosis to include a comprehensive selection of "pathogenic" bacteria when testing for BV. It also is important to include the detection of Lactobacilli that support vaginal health, whether naturally occurring or introduced by probiotic use, as well as any bacteria that more accurately indicate the transition between a healthy, stable vaginal flora and BV flora.

Test 759 Bacterial Vaginosis (BV) Panel with Lactobacillus Profiling by qPCR Includes

- *Fannyhessea vaginae (Atopobium vaginae)*
- Bacterial Vaginosis Associated Bacteria 1 (BVAB1)
- Bacterial Vaginosis Associated Bacteria 2 (BVAB2)
- Bacterial Vaginosis Associated Bacteria 3 (BVAB3)
- *Bacteroides fragilis*
- *Bifidobacterium breve*
- *Gardnerella vaginalis*
- Megasphaera type 1
- Megasphaera type 2
- *Mobiluncus curtisii*
- *Mobiluncus mulieris*
- *Prevotella bivia*
- *Sneathia sanguinegens*
- *Streptococcus anginosus*
- *Lactobacillus crispatus*
- *Lactobacillus gasseri*
- *Lactobacillus jensenii*
- *Lactobacillus iners*
- *Lactobacillus acidophilus*

Advantages:

- **Includes 14 BV-associated organisms with Lactobacillus Profiling**
- Improved sensitivity and specificity to better correlate symptom presentations with BV status
- Improved resolution and definition of transitional BV.
- MDL's BV Panel accounts for more than 99% of BV infections.
- *F. vaginae (A. vaginae)* is frequently co-existent with Gardnerella, and both can be resistant to metronidazole.
- *F. vaginae (A. vaginae)*, Megasphaera and BVAB2 cannot be detected under the microscope.
- Accurate vaginal microbiome assessment with Lactobacillus profiling at no additional charge.
- Lactobacillus profiling indicates the concentration of pathogenic bacteria relative to lactobacillus, enabling tailored treatment decisions based on the pathogen and infection severity.
- Includes *Lactobacillus acidophilus*, a common probiotic bacteria used to treat BV and establish a healthy vaginal microenvironment.

References:

1. **Diagnosis of Vaginitis** 2022, October 31. "Diagnosis of Vaginitis". https://www.aetna.com/cpb/medical/data/600_699/0643.html
2. **Workowski KA, Bachmann LH, Chan PA, et al.** 2021, July 23. "Sexually Transmitted Infections Treatment Guidelines, 2021". https://www.cdc.gov/mmwr/volumes/70/rr/rr7004a1.htm

Now Available

Genetic Carrier Screening

Available from whole blood.

ACOG Recommends Offering Carrier Screening to All Women, Regardless of Ethnicity or Family History…

1274 Genetic Carrier Screening Panel (2 genes) includes:

- Cystic Fibrosis Core Test (23 major CFTR variants approved by ACOG/ACMG)
- Spinal Muscular Atrophy

1. American College of Obstetricians and Gynecologists Committee on Genetics. ACOG Committee Opinion No. 691: Carrier Screening for Genetic Conditions. *Obstet Gynecol* 2017 Mar;129(3):e41-e55.

IH0012 Upd: 9_2023

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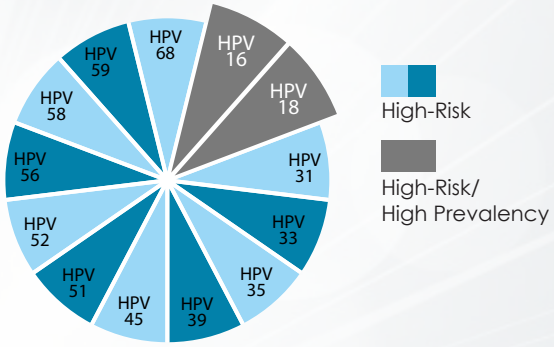
An Even Better Choice....

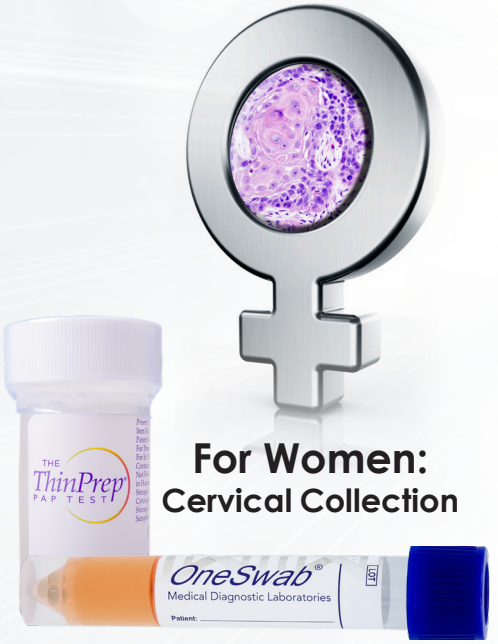
HPV Type-Detect 4.0® by Multiple Real-Time PCR

Simple & Convenient Specimen Collection

- Differentiates between 13 HR HPVs
- Determines patient's specific HPV type(s)
- Detects newly acquired HPV infections
- Detects multiple infections
- No cross-reaction with other HPV types
- Not affected by blood & excess mucus

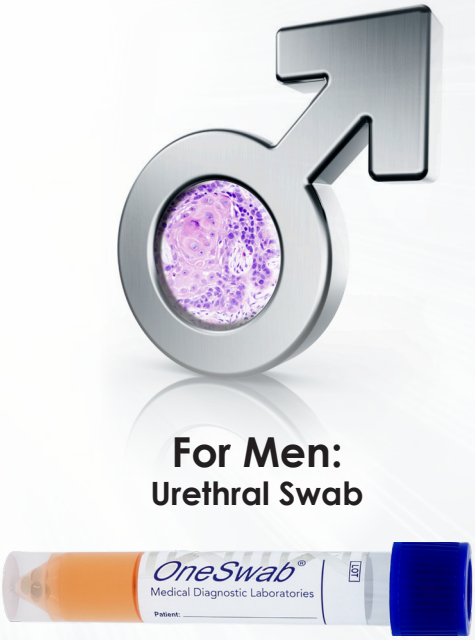
Classification of HPV Types





For Women:
Cervical Collection

The only test that offers type specific detection of 13 HPV types in a single vial



For Men:
Urethral Swab

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IH0034 upd: 6.2024

The ABC's of Vaginal Health...

A 182 Aerobic Vaginitis (AV)

- Group B Streptococcus (GBS)
- *Staphylococcus aureus*
- *Escherichia coli*
- *Enterococcus faecalis*

B 759 Bacterial Vaginosis (BV) with Lactobacillus Profiling by PCR

- *Fannyhessea vaginae (Atopobium vaginae)*
- Bacterial Vaginosis Associated Bacteria 1
- Bacterial Vaginosis Associated Bacteria 2
- Bacterial Vaginosis Associated Bacteria 3
- *Bacteroides fragilis*
- *Bifidobacterium breve*
- *Gardnerella vaginalis*
- Megasphaera type 1
- Megasphaera type 2
- *Mobiluncus curtisii*
- *Mobiluncus mulieris*
- *Prevotella bivia*
- *Sneathia sanguinegens*
- *Streptococcus anginosus*

Considered Medically Necessary by the CDC and Aetna for the Management of Vaginitis and the Diagnosis of Bacterial Vaginosis in Symptomatic Women[1, 2]

C 560 Candida Vaginitis (CV)

- *Candida albicans*
- *Candida glabrata*
- *Candida krusei*
- *Candida parapsilosis*
- *Candida tropicalis*

Fluconazole Resistance Testing Available

Diagnostic Advantages...

- One vial, multiple pathogens
- DNA amplification via PCR technology
- Microbial drug resistance profiling
- High precision robotic accuracy
- High diagnostic sensitivity & specificity
- Specimen viability up to 5 days after collection
- Test additions available up to 30 days after collection
- No refrigeration required before or after collection
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2. **Workowski KA, Bachmann LH, Chan PA, et al.** 2021, July 23. "Sexually Transmitted Infections Treatment Guidelines, 2021 ". https://www.cdc.gov/mmwr/volumes/70/rr/rr7004a1.htm

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IH0068 upd: 4.2025

Founded in 1998, Medical Diagnostic Laboratories (MDL) serves mainly as a reference laboratory for molecular diagnostic based testing to laboratories, hospitals and physicians worldwide. The success of MDL is attributed directly to client retention through our ability to customize our unique services to specifically address the individual needs of our clients. Enhanced turn-around time, cost effectiveness, and the capability to tailor services to best suit the needs and budgets of our clients gives MDL a distinct advantage over its competitors.

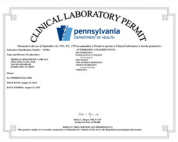
MDL specializes in high complexity, state-of-the-art, automated DNA-based molecular analysis. By utilizing molecular techniques, MDL is able to provide clinicians from many different specialties valuable diagnostic information to assist in the detection, diagnosis, evaluation, and treatment of bacterial, viral and fungal infections as well as genetic based testing and cancer diagnostics. For example, the unique testing MDL offers for the specialties of Urology, Gynecology and Pediatric Medicine enables the detection of multiple pathogens from a single swab by Polymerase Chain Reaction (PCR) testing. MDL's primary focus is in the fields of infectious disease testing for Women's Health and Gynecology, Pediatric Respiratory Infections, Urology, Vector-borne Diseases, Mycology and chronic illnesses.

Laboratory Licenses and Permits

MDL is routinely inspected by both the New Jersey State Department of Health and the College of American Pathologists (CAP). MDL also participates in the proficiency testing programs administered by both CAP as well as the American Proficiency Institute to maintain licensing in multiple states. MDL is accredited by CAP which is an internationally recognized program designed to advance the quality of Laboratory Services. Through the use of rigorous checklists designed to improve the overall quality practice of the management and operation of a clinical laboratory in combination with routine peer-led inspections, a laboratory can gain accreditation by meeting or exceeding CAP standards. CAP standards are recognized to be the highest standards of excellence. MDL has continually maintained exemplary ratings by these agencies.







New Jersey - Clinical Laboratory License - ID #0000875
New York - Clinical Laboratory Permit - PFI #7469
Maryland - Medical Laboratory Permit - ID #1133

Pennsylvania - Clinical Laboratory Permit - ID #26538A
Rhode Island - Clinical Laboratory License - ID #LCO00420
California - Clinical Laboratory License - ID #CDS00800136
CLIA - ID #31D0938156

The testing offered by Medical Diagnostic Laboratories is developed and validated by MDL's Research & Development Department. The R&D Department performs studies on sensitivity, specificity, interference, optimization, accuracy, and precision prior to offering testing for a specific pathogen by PCR. These studies are used to establish the ability of the PCR method to detect specific genetic sequences of a target pathogen within a given clinical specimen.

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PCR Testing *For Best Results*

The proper specimen collection technique is very important in identifying pathogens from DNA. Medical Diagnostic Laboratories provides the ***OneSwab®,*** and ***UroSwab®*** specimen collection platforms for your convenience. For women, the sequence of Pap testing in relation to other cervical or vaginal specimens does not appear to influence Pap test results or their interpretation. Therefore, when other specimens are collected for gynecological testing, the Pap test can be obtained last.

Collecting samples with OneSwab®

Step 1. Firmly, yet gently, sample the endocervical canal with the sterile swab rotating it 360° for 10 to 30 seconds to ensure adequate sampling. When sampling a crusted over lesion, moisten the swab in sterile saline prior to taking the sample.

Step 2. Remove the swab and place into the vial. Break the shaft at scored break point and insert into transport medium.

Step 3. To prevent leakage, be sure the swab fits into the vial prior to capping. Tightly cap the vial and label with a minimum of two patient identifiers such as name and date of birth. For packaging and shipping instructions, please refer to MDL's catalog of services.

Collecting samples for Vaginal Group B Strep (GBS) with OneSwab®

Obtaining specimens for the diagnosis of GBS infection from both the anorectum and the distal vagina increases the sensitivity by a considerable percentage (5% to 25%) over vaginal swabbing alone. Within the genital tract, the highest isolation rates are reported from introitus and the lowest from the cervix. Pregnancy does not influence colonization.

Collecting samples of loose stool specimens with OneSwab®

Step 1. Utilize the swab provided to obtain a sample of loose stool and insert into the vial.

Step 2. Break the shaft at molded break point and insert into transport medium.

Step 3. To prevent leakage, be sure the swab fits into the vial prior to capping. Tightly cap the vial and label with a minimum of two patient identifiers such as name and date of birth. For packaging and shipping instructions, please refer to MDL's catalog of services.

Collecting samples with UroSwab®

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

Step 2. Have the patient collect a urine sample in a urine container.

Step 3. Dip the sponge into the urine container.

Step 4. Place the sponge into the vial. To prevent leakage, tightly cap the vial. Label with a minimum of two patient identifiers such as name and date of birth. For packaging and shipping instructions, please refer to MDL's catalog of services.

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Urinary Tract Infections

Urinary tract infections are a major cause of morbidity in the United States. They are the second most common infection after respiratory infections, and largely affect women. Approximately 11% of women suffer from a UTI, 60% of women will have at least one UTI during their lifetime, 25% of UTIs will recur within six months of the initial infection. Although UTIs are not sexually transmitted, they frequently occur in young, sexually active women, although they are by no means confined to this population. Medical Diagnostic Laboratories (MDL) has developed sensitive and specific Real-Time PCR tests to detect these pathogens in ***UroSwab***® specimens to assist the physician in the diagnosis of UTI. We offer two urinary tract infection panels:

Urinary Pathogens Antibiotic Resistance

Escherichia coli

E. coli
Enterococcus faecium
Klebsiella pneumoniae

- **amoxicillin-clavulanic acid**
- **cephalothin (cephalexin)**
- **trimethoprim-sulfamethoxazole**
- **nitrofurantoin**
- **ciprofloxacin**
- **fosfomycin**

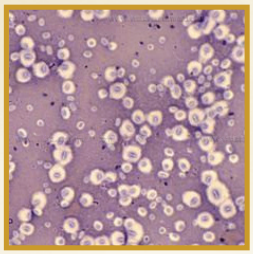
Enterococcus faecalis
Klebsiella oxytoca
Proteus mirabilis

- **ampicillin**
- **nitrofurantoin**
- **ciprofloxacin**
- **fosfomycin**
- **doxycycline**
- **linezolid**

With colony counts at no additional cost

Urinary Tract Infection Tests Available

(male and female specimens)



Klebsiella species

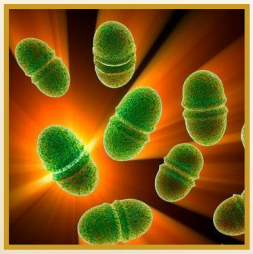
Test No. 6286 Urinary Pathogens Panel

- 153 *Enterococcus faecalis* by Real-Time PCR
- 154 *Enterococcus faecium* by Real-Time PCR
- 141 *Escherichia coli* by Real-Time PCR
- 127 Group B Streptococcus (GBS) by Real-Time PCR
- 137 Group B Streptococcus (GBS) Antibiotic Resistance
- 727 *Klebsiella oxytoca*
- 728 *Klebsiella pneumoniae*
- 146 *Proteus mirabilis* by Real-Time PCR
- 174 *Pseudomonas aeruginosa* by Real-Time PCR
- 151 *Staphylococcus saprophyticus* by Real-Time PCR
- 176 **Urinary Pathogens Antibiotic Resistance Testing** *(E. coli, Enterococcus faecalis, Enterococcus faecium, K. oxytoca, K. pneumoniae, Proteus mirabilis)*

Proteus mirabilis

Test No. 6815 Complex Urinary Tract Infection Panel

- 551 *Candida albicans* by Real-Time PCR
- 576 *Candida dubliniensis* by Real-Time PCR
- 559 *Candida glabrata* by Real-Time PCR
- 578 *Candida kefyr* by Real-Time PCR
- 566 *Candida krusei* by Real-Time PCR
- 577 *Candida lusitaniae* by Real-Time PCR
- 558 *Candida parapsilosis* by Real-Time PCR
- 557 *Candida tropicalis* by Real-Time PCR
- 129 *Mycoplasma genitalium* by Real-Time PCR (Reflex to antibiotic resistance by Molecular Analysis)
- 130 *Mycoplasma hominis* by Real-Time PCR
- 178 *Ureaplasma parvum* by Real-Time PCR (Reflex to antibiotic resistance by Molecular Analysis)
- 320 *Ureaplasma urealyticum* by Real-Time PCR (Reflex to antibiotic resistance by Molecular Analysis)



Enterococcus species

UroSwab®

MULTIPLE PATHOGENS

The introduction of molecular techniques, such as the Polymerase Chain Reaction (PCR) method, offers a superior route of pathogen detection with a high diagnostic specificity and sensitivity. MDL offers a number of assays for the detection of multiple pathogens associated with urological infections and sexually transmitted infections. The unrivaled sensitivity and specificity of the Real-Time PCR method in detecting infectious agents provides the clinician with an accurate and rapid means of diagnosis. This valuable diagnostic tool will assist the clinician with diagnosis, early detection, patient stratification, drug prescription, and prognosis. Tests currently available utilizing the ***UroSwab®*** specimen collection platform are listed to the side.

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Acinetobacter baumannii
Gleimia europaea (Actinomyces europaeus)
Actinomyces turicensis
Adenovirus
Fannyhessea vaginae (Atopobium vaginae)
Bacteroides ureolyticus
Candida utilis
Cytomegalovirus (CMV)
Epstein-Barr virus (EBV)
Gardnerella vaginalis
Legionella pneumophila
Lymphogranuloma venereum (LGV)
Mycoplasma penetrans
Polyomavirus BK
Polyomavirus JC
Prevotella Species Group 1 *(P. bivia, P. disiens, P. intermedia, P. melaninogenica)*
Prevotella Species Group 2 *(P. corporism, P. albensis)*
Serratia marcescens

URINARY TRACT INFECTIONS

Candida albicans
Candida dubliniensis
Candida glabrata
Candida kefyr
Candida krusei
Candida lusitaniae
Candida parapsilosis
Candida tropicalis
Enterobacter cloacae
Enterococcus faecalis
Enterococcus faecium
Escherichia coli
Group B Streptococcus (GBS)
Group B Streptococcus (GBS) Antibiotic Resistance
Klebsiella oxytoca
Klebsiella pneumoniae
Mycoplasma hominis
Proteus mirabilis
Pseudomonas aeruginosa
Staphylococcus saprophyticus
Urealplasma parvum (*Reflex to antibiotic resistance by Molecular Analysis)
Ureaplasma urealyticum (*Reflex to antibiotic resistance by Molecular Analysis)
Urinary Pathogens Antibiotic Resistance Testing *(E. coli, Enterococcus faecalis, Enterococcus faecium, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis)*
Urogenital Candidiasis Panel (*C. albicans, C. glabrata, C. krusei, C. parapsilosis, C. tropicalis*)
Urogenital Mycoplasma Panel (*M. genitalium**, M. hominis*)
Urogenital Mycoplasma & Ureaplasma Panel (*M. genitalium**, M. hominis, U. urealyticum**)

SEXUALLY TRANSMITTED DISEASE TESTING (male and female specimens)

Chlamydia trachomatis (*Reflex to antibiotic resistance by Molecular Analysis) ‡
Leukorrhea Panel (*N. gonorrhoeae**, C. trachomatis**, T. vaginalis*♦, Mycoplasma genitalium**) ‡
Mycoplasma genitalium (ΨReflex to azithromycin & fluroquinolone resistance by Pyrosequencing)
Neisseria gonorrhoeae (*Reflex to antibiotic resistance by Molecular Analysis) ‡
*N. gonorrhoeae** & C. trachomatis** ‡
Treponema pallidum (syphilis)
Trichomonas vaginalis (♦Reflex to Metronidazole Resistance) ‡

‡ **Applicable for adolescent females who are not candidates for pelvic exams.**

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* Reflex to antibiotic resistance by Molecular Analysis
♦ Reflex to metronidazole resistance

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Simple & Convenient Urine Specimen Collection

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