VIKORSCIENTIFIC

KORPATH

Vaginal-ID Case Review

- **Patient History:**
  Patient self-treated for yeast infection and came to see her doctor after no relief.

- **Disease State:**
  Presented with discharge and severe vaginal itching and burning.

- **Why This Test was Ordered:**
  Clinician was happy to use Vaginal-ID since patient already used Monistat vaginal suppository.

- **Outcome:**
  After weeks and weeks of discomfort, the patient began to feel relief in 3 days and all symptoms resolved within one week! Patient had 3 bacterial infections 10^6 with resistance to 3 antibiotic classes PLUS 4 lactobacilli overgrowth. She didn't tell her doctor that she recently started a diet that included probiotics. Her only option was a quinolone which has some warnings. The benefit was one pill daily for only 5 days. The patient was also asked to stop taking her probiotics since this contributed to the lactobacilli overgrowth.

KORGENE

Vaginal-ID™
Molecular Pathogen Report

512 E. Township Line Rd; Ste #135 (Tower 4)
Blue Bell, PA 19422
P: 854.429.1069 • F: 833.247.4091
www.vikorscientific.com

Clinical Laboratory Improvement Amendments
#39D2166771

Patient Name | Date of Birth | Gender | Race

Facility Information

Ordering Provider:

Facility:

Facility Phone:

Facility Fax:

Specimen Information

ACC:

Collection Date: 07-02-2021

Received Date: 07-03-2021

Report Date: 07-04-2021

Sample Type: Vaginal Swab

Notes:

Laboratory Results

PATHOGENS DETECTED

Enterococcus faecalis	1 x 10^6 copies/uL	32.041%
Streptococcus agalactiae (group B)	1 x 10^6 copies/uL	32.041%
Escherichia coli	1 x 10^6 copies/uL	32.041%
Lactobacillus iners	1 x 10^5 copies/uL	3.204%
Lactobacillus crispatus	1 x 10^4 copies/uL	0.32%
Lactobacillus jensenii	1 x 10^4 copies/uL	0.32%
Lactobacillus gasseri	1 x 10^3 copies/uL	0.032%

RESISTANCE GENES DETECTED & POTENTIAL MED CLASS AFFECTED

ermC, ermB	Macrolides
tetM	Tetracycline
ampC, ACC, DHA, ACT/MIR	Ampicillin

ABXAssist™

Pharmacy Guidance Provided by: Advance Therapeutic Assist

Electronically approved on 07-04-2021 by: Colton Moorman
•Email: pharmconsult@vikorscientific.com • Phone: 1-855-742-7635, 1-855-PharmD5

KORGENE
512 E. Township Line Rd; Ste #135 (Tower 4)
Blue Bell, PA 19422
P: 854.429.1069 • F: 833.247.4091
www.vikorscientific.com

Vaginal-ID™
Molecular Pathogen Report

Clinical Laboratory Improvement Amendments
#39D2166771

Patient Name | Date of Birth | Gender | Race

MEDICATION REVIEW

Drug Allergies:	MILK CONTAINING PRODUCTS
Notes from Ordering Physician:	VAGINAL
Notes from Pharmacist:	1) The treatment guidance listed is based on infectious disease treatment references, the organisms detected, and genes known to contribute to medication resistance. Important clinical information such as comorbidities, renal function, etc. may influence the overall appropriateness of therapy. The provided guidance only takes drug allergies into account when they are provided. The provider should take the entire clinical presentation into account when making treatment decisions. Not all detected microbes will require antimicrobial therapy as some are part of the normal flora or can be non-pathogenic colonizers. 2) Recommendation reflects coverage for E coli, Enterococcus, and GBS. Treatment options are limited due to potential ampC resistance. 3) E.coli, Enterococcus, Staph aureus and Strep B alone or in combination are known as aerobic pathogens that can trigger a localized inflammatory immune response, inflammation of vagina, itching and burning, dyspareunia, and discharge. It can cause complications in pregnancy, like neonatal sepsis. Very common in postmenopausal women. Recommended treatments are levofloxacin.

	Medication	Route	Dose
FIRST LINE	levofloxacin	oral	250-500mg q24h x 5 days

Considerations: E coli, Enterococcus, and GBS.

Black box warning for tendinitis and tendon rupture, peripheral neuropathy, and CNS effects such as anxiety, confusion, depression, and hallucinations. May cause blood glucose disturbances, especially in elderly and renal impaired. Adjust dose for CrCl < 50ml/min. FDA advises that the serious side effect risks of fluoroquinolones outweigh the benefits for use in patients with acute sinusitis, acute bronchitis, and uncomplicated UTI who have other treatment options. Not recommended in children under 18 years old. Not first line agent in children with complicated UTI or pyelonephritis.

Methodology

The infectious disease and antibiotic resistance detection panels are tested utilizing Real-time PCR technology to detect the presence of genes associated with pathogens and antibiotic resistance via amplification of genomic DNA. Amplification and detection are performed using the Applied Biosystems™ QuantStudio™ 12K Flex Real-time PCR system, which includes the QuantStudio™ 12k Software v1.3 and Thermo Fisher Scientific TaqMan™ assays. The assays are preloaded onto TaqMan™ OpenArray plates.

512 E. Township Line Rd; Ste #135 (Tower 4)
Blue Bell, PA 19422
P: 854.429.1069 • F: 833.247.4091
www.vikorscientific.com

Clinical Laboratory Improvement Amendments
#39D2166771

Patient Name	Date of Birth	Gender	Race

Limitations

This test only detects microorganisms and antibiotic resistance (ABR) genes specified in the panel. ABR genes are detected in the specimen and are not specific to a detected pathogen. ABR genes may be detected in bacterial strains not tested for in the panel.

The resistance genes for Ampicillin, selected Extended-Spectrum-Betalactamases, Vancomycin, Carbapenems, Sulfonamide, Trimethoprim, Aminoglycosides and the Quinolone gyrase groupings are assays customized by pooling the individual genes listed in the associated group. If listed as positive, this indicates that at least one of the genes in the group was detected and the class of medication could have potential resistance.

Disclaimer

This test was developed and its performance characteristics determined by KorGene™. It has not been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. Pharmacy guidance and recommendations therein are not under the purview of the laboratory or agencies which accredit the laboratory.

The treatment guidance listed in the report is based on infectious disease treatment references, the organisms detected, and genes known to contribute to medication resistance. Important clinical information such as comorbidities, renal function, patient weight, platelet count, microbiology results, etc. may influence the overall appropriateness of therapy. The provided guidance only takes drug allergies into account when they are provided and available to the pharmacist making the recommendation. The overall appropriateness of therapy must be determined by the physician treating the patient. The provider has all the patient information necessary to make that determination and should take the entire clinical presentation into account when making treatment decisions. Should the treating physician wish to discuss the provided guidance, the pharmacist is available for consult at the email and phone number provided. KorGene™ is currently in the Accreditation phase by the College of American Pathologist (CAP).

KORGENE
512 E. Township Line Rd; Ste #135 (Tower 4)
Blue Bell, PA 19422
P: 854.429.1069 • F: 833.247.4091
www.vikorscientific.com

Vaginal-ID™
Molecular Pathogen Report

Clinical Laboratory Improvement Amendments
#39D2166771

Patient Name | Date of Birth | Gender | Race

NEGATIVE PATHOGENS
Atopobium vaginae
BVAB2
Bacteroides fragilis
Candida albicans
Candida dubliniensis
Candida glabrata
Candida krusei
Candida lusitaniae
Candida parapsilosis
Candida tropicalis
Chlamydia trachomatis
Gardnerella vaginalis
HSV1
HSV2
Haemophilus ducreyi
Mobiluncus curtisii
Mobiluncus mulieris
Mycoplasma genitalium
Mycoplasma hominis
Neisseria gonorrhoeae
Prevotella bivia
Staphylococcus aureus
Treponema pallidum (Syphilis)
Trichomonas vaginalis
Uncultured Megasphera 1
Uncultured Megasphera 2
Ureaplasma urealyticum

NEGATIVE RESISTANCE GENES	ANTIBIOTIC CLASS
aac6-1b/aacA4, ant(3), aph(A6), aac6-1b-cr	Aminoglycosides
SULL, DFRA	Bactrim
CTX-M, PER-1, PER-2, VEB, blaNDM-1, OXA-1, GES, BlaSHV	Beta-lactams
OXA-23, OXA-40, OXA-58, OXA-72, IMP-16, NDM, blaOXA-48, OXA-48, KPC, VIM, IMP-7	Carbapenems
ermA	Macrolides
mecA	Methicillin
mcr-1	Polymyxins
qnrS_Pa04646145_s1, Gyrase A D87N_GTT, Gyrase A S83L_TGG, QnrA	Quinolones
VanB, VanA1, VanA2	Vancomycin

This report, associated with order #, has been approved by the following reviewers:

Pharmacist:

Electronically signed and dated on 07-04-2021 01:51
Colton Moorman

Report Reviewer:

Electronically signed and dated on 07-04-2021 06:47
Dan Stroud
