



Vaginal-ID Case Review

• Patient History:

35-year-old female has been struggling with discharge and mild itching off and on for about 6 years. Patient has been treated numerous times with the following: Metronidazole (pill and intravaginally), Clindamycin, and Tindamax. Symptoms will clear up for a short time, but always return.

• Disease State:

Does present with odor, which is what bothers patient the most. Patient is married with only one sexual partner.

• Why This Test was Ordered:

Vaginal-ID report showed nine pathogens detected. There were numerous pathogens tied to BV. The pharmacy guidance laid out several recommendations clearly and concisely. The patient struggles with a sensitive stomach, so the provider did the intravaginally paired with oral treatment recommendation. This combination has never been prescribed before.

The provider treated with first line recommendation from Pharmacy Guidance. Amoxicillin/clavulanate 875/125mg bid x 7days and vaginally with Metronidazole 0.75% vaginal Gel: 1 applicator full once daily x 5 days.

• Outcome:

The patient REACHED out to the office. She is ecstatic! For the first time in six years, she has NO symptoms. She completed the treatment and was going on three months of no recurring symptoms.

The oral/vaginal combination was a success. Vaginal-ID added an extra layer of patient care while the PharmD guidance provided much needed assistance in clearing patient infections.

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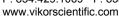




Molecular Pathogen Report

512 E. Township Line Rd; Ste #135 (Tower 4) Blue Bell, PA 19422

P: 854.429.1069 • F: 833.247.4091







Patient Name







Facility Information

PATHOGENS DETECTED

1 x 10⁶ Cells/mL

1 x 10⁶ Cells/mL

1 x 10⁶ Cells/mL

1 x 10⁵ Cells/mL

1 x 10⁴ Cells/mL

1 x 10⁴ Cells/mL

1 x 10⁴ Cells/mL

1 x 10⁴ Cells/mL

1 x 10² Cells/mL

Ordering Provider: Test Provider

Facility: Research Facility Phone:

Facility Fax:

Streptococcus agalactiae (group B)

Specimen Information

ACC: #

Collection Date: 03-09-2021 Report Date: 03-11-2021 Received Date: 03-10-2021 Sample Type: Vaginal Swab

Notes:

RESISTANCE GENES DETECTED & POTENTIAL MED CLASS AFFECTED

ermB Macrolides



tetM Tetracycline



ABXAssist[™]

Atopobium vaginae

Gardnerella vaginalis

Mycoplasma hominis

Enterococcus faecalis

Lactobacillus iners

Escherichia coli

Prevotella bivia

Uncultured Megasphera 1

Pharmacy Guidance

31.846%

31.846%

31.846%

3.185%

0.318%

0.318%

0.318%

0.318%

0.003%

Electronically approved on 03-11-2021 by: Peni Duncan • Email: pharmconsult@vikorscientific.com • Phone: 1.888.964.2141

Report Date: 03-11-2021 Printed: 03-11-2021 05:38

Page: 1 of 4



Vaginal-ID™ Jecular Pathogen Report

Molecular Pathogen Report

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Patient Name



Date of Birth



Sender



Race

Drug Allergies:	NONE

Notes from Ordering Physician:

Notes from Pharmacist:

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 amoxicillin, Augmentin, and levofloxacin. (cephalosporins do not work in enterococcus).

In recurrent Aerobic vaginitis, that does not respond to antibiotics, consider Lactobacillus overgrowth. Lactobacillus is normal flora but at higher loads (10^5 and up) can be considered pathogenic if discharge or ulcers are present along with a severe inflammatory response. This is an inflammatory condition due to ph imbalance of vagina with PH between 3.5 and 4.5, and no leukocytes present.

Use Lotrisone for inflammation and baking soda sitz baths to help with ph balance. Cipro or levofloxacin are only helpful when L iners are elevated and ulcers are present.

If no candida, no Gardnerella, no trich with ulcers is considered cytolytic vaginosis.

In pregnancy, first trimester lactobacillus iners is higher then decreases in second and third trimester.

Treatment: Solution can be prepared by mixing 1-2 tablespoons of baking soda with 4 cups of warm water. For Sitz baths use 5 tablespoons. In bathtub use ½ cup to 1 cup in water to cover vaginal area but not over the thighs.

IDSA recommends antibiotic treatment for pathogens beginning at moderate levels.

FIRST LINE

Medication	Route	Dose
amoxicillin / davulanate	oral	875/125 mg bid x 7 days

Considerations: GBS, Ecoli, Enterococcus - Adjust dose renal impairment, caution B-lactam allergy. Pregnancy category B.

AND

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Vaginal-ID™

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#39D2166771

Patient Name

Date of Birth



Jender



Race

metronidazole

oral

500 mg PO BID x 7 days OR Metronidazole vaginal gel: 1 applicatorful intravaginally once daily x 5 days

Considerations: BV - Avoid alcohol use during and 24hrs after treatment, 2 g x 1 dose has been found to be less efficacious than the 7 day regimen. No dose adjustments needed in renal/hepatic

dysfunction. Pregnancy category B.

ALTERNATIVE

levofloxacin

oral

250-500 mg qd x 5-7 days

Considerations: GBS, Ecoli, Enterococcus - Fluoroquinolones have been associated with serious and possible irreversible reactions; tendonitis/tendon rupture, peripheral neuropathy, CNS effects. These may occur all together or months after tx. Increased risk in patients over 60 and pt on corticosteroids. Avoid in Myasthenia Gravis. Reserve for pts with no alternative tx options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, or uncomplicated UTI. Adjust dose for CrCl <50 mL/min.

OR

tinidazole

oral

2g qd x 2 days

Considerations: BV - Contraindicated during 1st trimester of pregnancy, nausea, candida overgrowth, transient peripheral neuropathy, disulfiram reaction (avoid alcohol during and 3 days after tx).

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OR

secnidazole

oral

single dose packet

Considerations: BV - Sprinkle on applesauce, pudding; do not chew granules, savings card online.

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.

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.

Disclaime

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.

This test was developed and its performance characteristics determined by KorGene M. 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.

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).

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#8779637







NEGATIVE PATHOGENS	NEGATIVE RESISTANCE GENES	
BVAB2	aac6-1b/aacA4, ant(3), aph(A6), aac6-1b-cr	
Bacteroides fragilis	ampC, ACC, DHA, ACT/MIR	
Candida albicans	SULL, DFRA	
Candida dubliniensis	CTX-M, PER-1, PER-2, VEB, blaNDM-1, OXA-	
Candida glabrata	GES, BlaSHV	
andida krusei	OXA-23, OXA-40, OXA-58, OXA-72, IMP-16, N blaOXA-48, OXA-48, KPC, VIM, IMP-7	
andida lusitaniae	ermC, ermA	
Candida parapsilosis	*mecA	
andida tropicalis	mcr-1	
hlamydia trachomatis SV1	qnrS_Pa04646145_s1, Gyrase A D87N_GTT, Gyrase A S83L_TGG, QnrA	
SV2	VanB, VanA1, VanA2	
aemophilus ducreyi		
actobacillus crispatus		
actobacillus gasseri		
actobacillus jensenii		
Nobiluncus curtisii		
lobiluncus mulieris		
lycoplasma genitalium		
leisseria gonorrhoeae		

	ANTIBIOTIC CLASS
	Aminoglycosides
	Ampicillin
	Bactrim
A-1,	Beta-lactams
, NDM,	Carbapenems
	Macrolides
	Methicillin
	Polymyxins
Γ,	Quinolones
	V/

Staphylococcus aureus

Trichomonas vaginalis Uncultured Megasphera 2 Ureaplasma urealyticum

Treponema pallidum (Syphilis)

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

Pharmacist:

Electronically signed and dated on 03-11-2021 05:38 Peni Duncan

Report Reviewer:

Electronically signed and dated on 03-11-2021 06:36 Dan Stroud