Home Care Alliance of Massachusetts
Vikor Scientific - Korgene
Respira-ID & COVID-19

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HOME CARE ALLIANCE of MASSACHUSETTS

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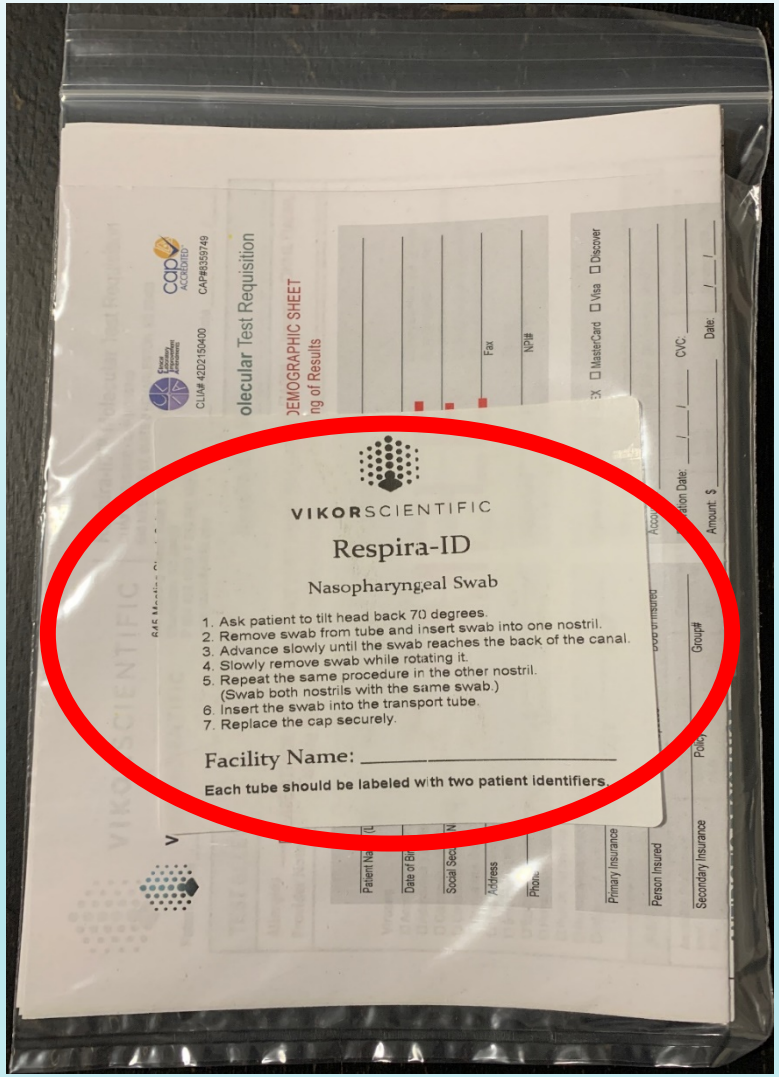
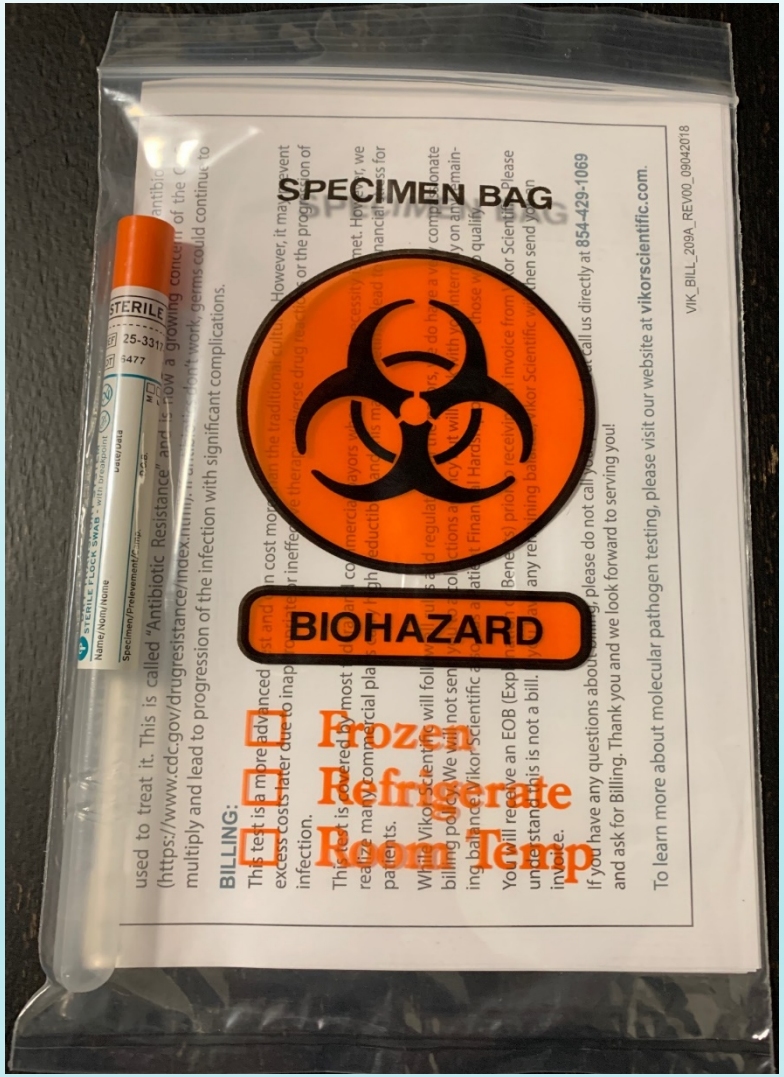
Overview of Vikor Scientific- Korgene

- Vikor Scientific is a market leader in providing targeted, molecular diagnostics and is focused on developing solutions to improve clinical and economic outcomes.
- We were given clearance on March 23rd to add COVID-19 to our full respiratory panel of 40 pathogens and viruses; Respira-ID.
- In effort to protect our most vulnerable population, Vikor Scientific has prioritized offering Respira-ID with COVID-19 Testing to Long Term Care Facilities and Traveling Provider Groups
- Our Respira-ID Test report provides quantitative pathogen results within 24-48 hours from sample arriving at the lab.
- Results are delivered via fax and web portal.
- Our sample testing are all swab based and are not limited by time, temperature, or by any medications the patient is currently taking.

Respira-ID Testing Kits:



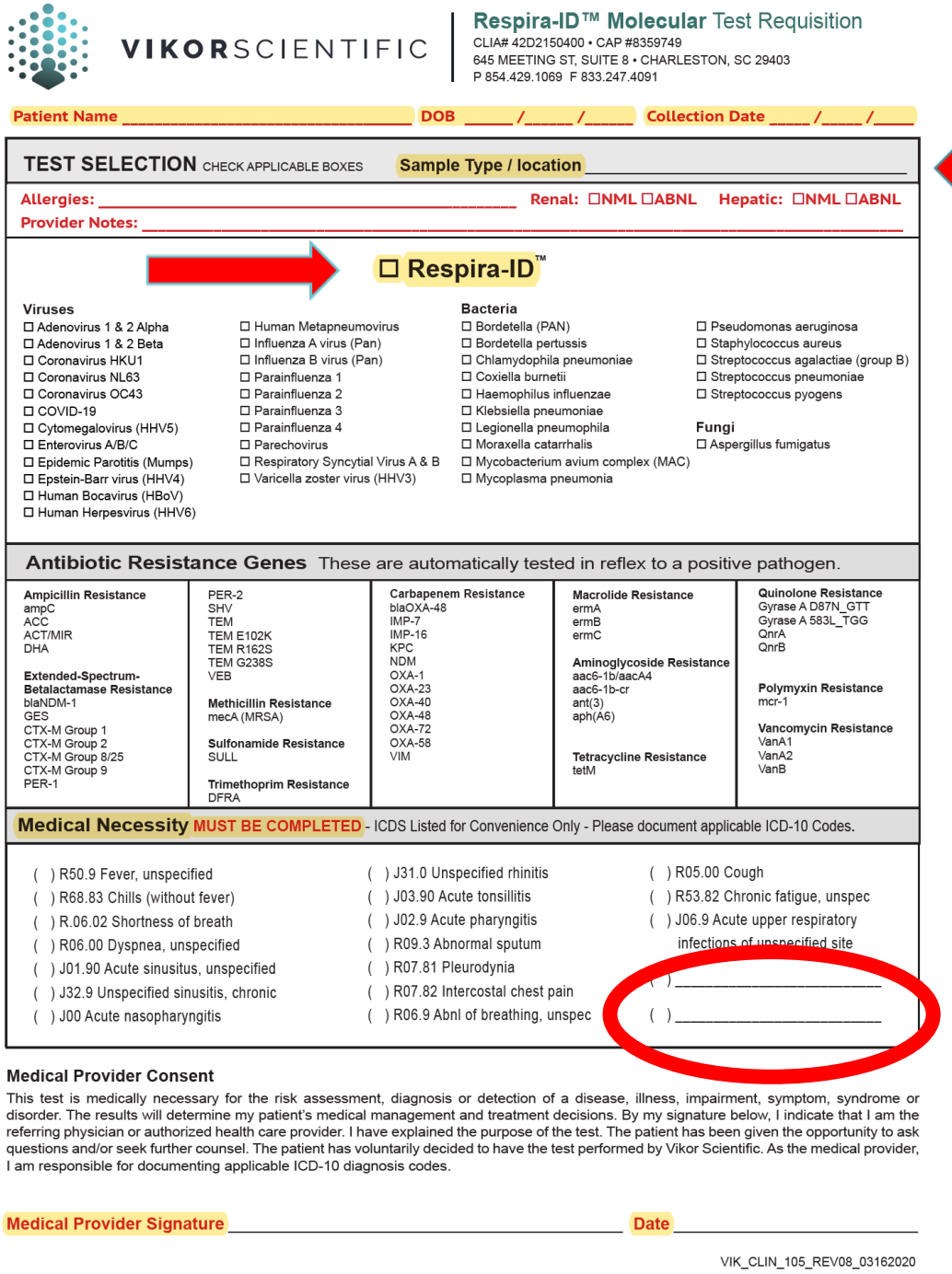


1. FILL OUT THE PATIENT'S NAME, DOB AND COLLECTION DATE

3. CHECK THE RESPIRA-ID BOX

4. CHECK OFF AN ICD-10 CODE OR WRITE ONE IN THE BLANK SPACES.

5. PROVIDER SIGNATURE AND DATE NEEDS TO BE ON THE FORM.



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Respira-ID™ Molecular Test Requisition

CLIA# 42D2150400 • CAP #8359749
645 MEETING ST, SUITE 8 • CHARLESTON, SC 29403
P 854.429.1069 F 833.247.4091

Patient Name _____ **DOB** ____/____/____ **Collection Date** ____/____/____

TEST SELECTION CHECK APPLICABLE BOXES **Sample Type / location** _____

Allergies: _____ **Renal:** ☐NML ☐ABNL **Hepatic:** ☐NML ☐ABNL

Provider Notes: _____

☐ **Respira-ID™**

Viruses
- ☐ Adenovirus 1 & 2 Alpha
- ☐ Adenovirus 1 & 2 Beta
- ☐ Coronavirus HKU1
- ☐ Coronavirus NL63
- ☐ Coronavirus OC43
- ☐ COVID-19
- ☐ Cytomegalovirus (HHV5)
- ☐ Enterovirus A/B/C
- ☐ Epidemic Parotitis (Mumps)
- ☐ Epstein-Barr virus (HHV4)
- ☐ Human Bocavirus (HBoV)
- ☐ Human Herpesvirus (HHV6)
- ☐ Human Metapneumovirus
- ☐ Influenza A virus (Pan)
- ☐ Influenza B virus (Pan)
- ☐ Parainfluenza 1
- ☐ Parainfluenza 2
- ☐ Parainfluenza 3
- ☐ Parainfluenza 4
- ☐ Parechovirus
- ☐ Respiratory Syncytial Virus A & B
- ☐ Varicella zoster virus (HHV3)

Bacteria
- ☐ Bordetella (PAN)
- ☐ Bordetella pertussis
- ☐ Chlamydophila pneumoniae
- ☐ Coxiella burnetii
- ☐ Haemophilus influenzae
- ☐ Klebsiella pneumoniae
- ☐ Legionella pneumophila
- ☐ Moraxella catarrhalis
- ☐ Mycobacterium avium complex (MAC)
- ☐ Mycoplasma pneumonia
- ☐ Pseudomonas aeruginosa
- ☐ Staphylococcus aureus
- ☐ Streptococcus agalactiae (group B)
- ☐ Streptococcus pneumoniae
- ☐ Streptococcus pyogens

Fungi
- ☐ Aspergillus fumigatus

Antibiotic Resistance Genes These are automatically tested in reflex to a positive pathogen.

Ampicillin Resistance
ampC
ACC
ACT/MIR
DHA

Extended-Spectrum-Betalactamase Resistance
blaNDM-1
GES
CTX-M Group 1
CTX-M Group 2
CTX-M Group 8/25
CTX-M Group 9
PER-1
PER-2
SHV
TEM
TEM E102K
TEM R162S
TEM G238S
VEB

Methicillin Resistance
mecA (MRSA)

Sulfonamide Resistance
SULL

Trimethoprim Resistance
DFRA

Carbapenem Resistance
blaOXA-48
IMP-7
IMP-16
KPC
NDM
OXA-1
OXA-23
OXA-40
OXA-48
OXA-72
OXA-58
VIM

Macrolide Resistance
ermA
ermB
ermC

Aminoglycoside Resistance
aac6-1b/aacA4
aac6-1b-cr
ant(3)
aph(A6)

Tetracycline Resistance
tetM

Quinolone Resistance
Gyrase A D87N_GTT
Gyrase A 583L_TGG
QnrA
QnrB

Polymyxin Resistance
mcr-1

Vancomycin Resistance
VanA1
VanA2
VanB

Medical Necessity MUST BE COMPLETED - ICDS Listed for Convenience Only - Please document applicable ICD-10 Codes.

- ( ) R50.9 Fever, unspecified
- ( ) R68.83 Chills (without fever)
- ( ) R.06.02 Shortness of breath
- ( ) R06.00 Dyspnea, unspecified
- ( ) J01.90 Acute sinusitus, unspecified
- ( ) J32.9 Unspecified sinusitis, chronic
- ( ) J00 Acute nasopharyngitis
- ( ) J31.0 Unspecified rhinitis
- ( ) J03.90 Acute tonsillitis
- ( ) J02.9 Acute pharyngitis
- ( ) R09.3 Abnormal sputum
- ( ) R07.81 Pleurodynia
- ( ) R07.82 Intercostal chest pain
- ( ) R06.9 Abnl of breathing, unspec
- ( ) R05.00 Cough
- ( ) R53.82 Chronic fatigue, unspec
- ( ) J06.9 Acute upper respiratory infections of unspecified site
- ( ) _____
- ( ) _____

Medical Provider Consent

This test is medically necessary for the risk assessment, diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder. The results will determine my patient's medical management and treatment decisions. By my signature below, I indicate that I am the referring physician or authorized health care provider. I have explained the purpose of the test. The patient has been given the opportunity to ask questions and/or seek further counsel. The patient has voluntarily decided to have the test performed by Vikor Scientific. As the medical provider, I am responsible for documenting applicable ICD-10 diagnosis codes.

Medical Provider Signature _____ **Date** _____

VIK_CLIN_105_REV08_03162020

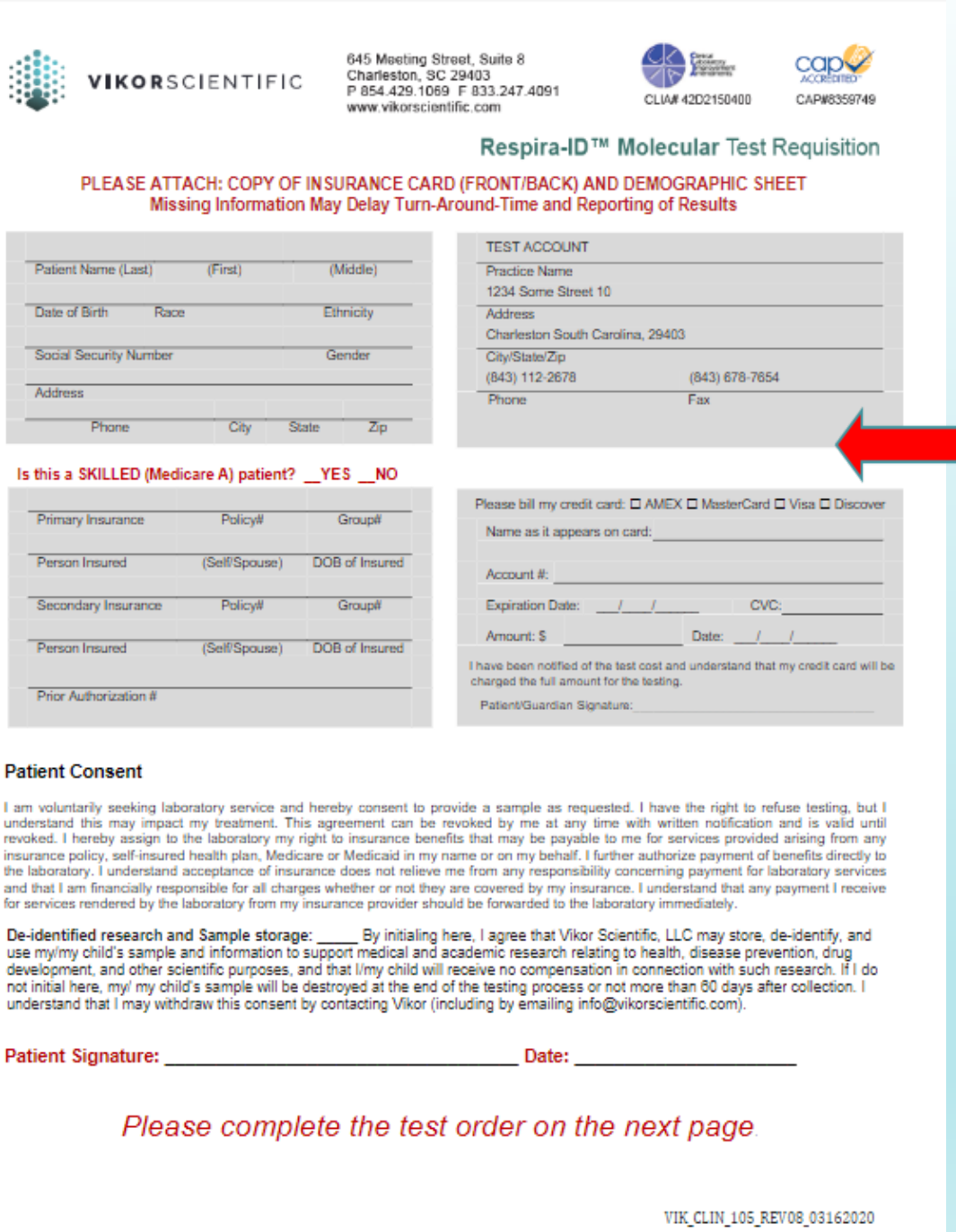
2. FOR SAMPLE TYPE/LOCATION WRITE NASAL SWAB

YOUR RCD OR ED WILL HAVE ICD-10 CODES FOR YOU IF YOU NEED THEM.

1. PLEASE ATTACH COPY OF INSURANCE CARD (FRONT/BACK) AND DEMOGRAPHICS SHEET OR FILL OUT PROVIDED BOXES

2. PLEASE MAKE SURE TO CHECK BOX OF WHICH ORDERING PROVIDER OR WRITE IN NAME AND NPI NUMBER OF PROVIDER

3. PATIENT SIGNATURE IS OPTIONAL UNLESS THEY HAVE TRICARE



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Charleston, SC 29403
P 854.429.1069 F 833.247.4091
www.vikorscientific.com

CLIA# 42D2150400 CAP#8359749

Respira-ID™ Molecular Test Requisition

PLEASE ATTACH: COPY OF INSURANCE CARD (FRONT/BACK) AND DEMOGRAPHIC SHEET
Missing Information May Delay Turn-Around-Time and Reporting of Results

Patient Name (Last) (First) (Middle)
Date of Birth Race Ethnicity
Social Security Number Gender
Address
Phone City State Zip

TEST ACCOUNT
Practice Name
1234 Some Street 10
Address
Charleston South Carolina, 29403
City/State/Zip
(843) 112-2678 (843) 678-7654
Phone Fax

Is this a SKILLED (Medicare A) patient? __YES __NO

Primary Insurance Policy# Group#
Person Insured (Self/Spouse) DOB of Insured
Secondary Insurance Policy# Group#
Person Insured (Self/Spouse) DOB of Insured
Prior Authorization #

Please bill my credit card: ☐ AMEX ☐ MasterCard ☐ Visa ☐ Discover
Name as it appears on card:
Account #:
Expiration Date: ___/___/_____ CVC:
Amount: $ Date: ___/___/_____
I have been notified of the test cost and understand that my credit card will be charged the full amount for the testing.
Patient/Guardian Signature:

Patient Consent

I am voluntarily seeking laboratory service and hereby consent to provide a sample as requested. I have the right to refuse testing, but I understand this may impact my treatment. This agreement can be revoked by me at any time with written notification and is valid until revoked. I hereby assign to the laboratory my right to insurance benefits that may be payable to me for services provided arising from any insurance policy, self-insured health plan, Medicare or Medicaid in my name or on my behalf. I further authorize payment of benefits directly to the laboratory. I understand acceptance of insurance does not relieve me from any responsibility concerning payment for laboratory services and that I am financially responsible for all charges whether or not they are covered by my insurance. I understand that any payment I receive for services rendered by the laboratory from my insurance provider should be forwarded to the laboratory immediately.

De-identified research and Sample storage: _____ By initialing here, I agree that Vikor Scientific, LLC may store, de-identify, and use my/my child's sample and information to support medical and academic research relating to health, disease prevention, drug development, and other scientific purposes, and that I/my child will receive no compensation in connection with such research. If I do not initial here, my/ my child's sample will be destroyed at the end of the testing process or not more than 60 days after collection. I understand that I may withdraw this consent by contacting Vikor (including by emailing info@vikorscientific.com).

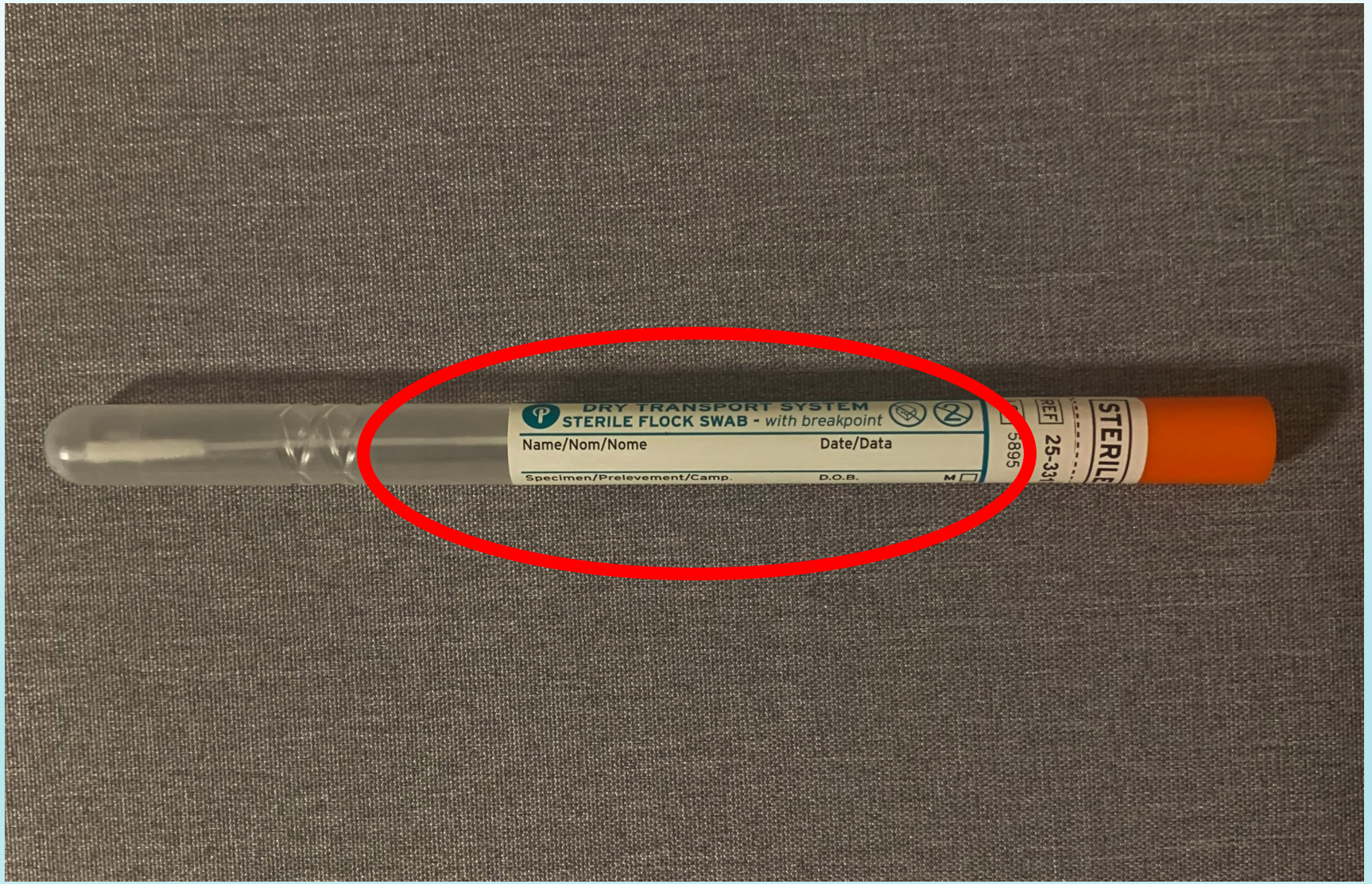
Patient Signature: _____ **Date:** _____

Please complete the test order on the next page

VIK_CLIN_105_REV08_03162020

LABEL THE TRANSPORT TUBE WITH 2 PATIENT IDENTIFIERS

1. PATIENT NAME
2. DATE OF BIRTH



INSTRUCTIONS

Respira-ID™ Swab Collection

Package Contents:

- Biohazard Bag
- Sterile swab with transport tube
- Paper Test Requisition
- Patient Education Handout

STEP #1:
Ask the patient to tilt head back 70 degrees. Remove the swab from the tube and insert the swab into one nostril. Advance the swab slowly until the swab reaches the back of the nasal canal.

STEP #2:
Slowly remove the swab from the nasal canal while rotating it. Repeat the same procedure in the other nostril. Swab both nostrils with the same swab.

STEP #3:
Insert the swab into the transport tube and replace the cap securely.

STEP #5:
Label the transport tube with two patient identifiers.
*Patient Name
*Date of Birth

STEP #6:
Give the patient the educational handout that explains the testing and billing policy.

Please Give Patient Test Information And COVID-19 Fact Sheet To Resident Or Patient.

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Patient Test Information | MOLECULAR DIAGNOSTIC TESTING

ACCURACY:
Your provider has ordered a molecular test to help diagnose your infection. This test is more rapid and accurate than the traditional culture technique you have had in the past.

TIME MATTERS:
Your results will return within 24 hours of the sample arriving at our lab. In contrast, traditional culture could take 3-7 days to return and may not be able to accurately identify the culprit pathogen causing your infection. Today's pathogens are more robust and not as responsive to older techniques.

ANTIBIOTIC RESISTANCE:
This test will also help your provider determine if your infection may be resistant to the antibiotics used to treat it. This is called "Antibiotic Resistance" and is now a growing concern of the CDC (https://www.cdc.gov/drugresistance/index.html). If antibiotics don't work, germs could continue to multiply and lead to progression of the infection with significant complications.

BILLING:
This test is a more advanced test and can cost more than the traditional culture. However, it may prevent excess costs later due to inappropriate or ineffective therapy, adverse drug reactions or the progression of infection.

This test is covered by most federal and commercial payors when medical necessity is met. However, we realize many commercial plans carry high deductibles and this may sometimes lead to financial stress for patients.

While Vikor Scientific will follow all rules and regulations of the payors, we do have a very compassionate billing policy. We will not send you to a collections agency but will work with you internally on any remaining balance. Vikor Scientific also has a Patient Financial Hardship program for those who qualify.

You will receive an EOB (Explanation of Benefits) prior to receiving an invoice from Vikor Scientific. Please understand this is not a bill. If you have any remaining balance, Vikor Scientific will then send you an invoice.

If you have any questions about billing, please do not call your provider but call us directly at **854-429-1069** and ask for Billing. Thank you and we look forward to serving you!

To learn more about molecular pathogen testing, please visit our website at **vikorscientific.com**.

VIK_BILL_209A_REV00_09042018

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FACT SHEET FOR PATIENTS

TaqPath™ COVID-19 Combo Kit **March 13, 2020** **Coronavirus Disease 2019 (COVID-19)**

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the TaqPath™ COVID-19 Combo Kit.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**
- **https://www.cdc.gov/COVID19**

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first idenitifed in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19 but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, sneezing, difficulty breathing, etc.).

What is the TaqPath™ COVID-19 Combo Kit?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to

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- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.

FACT SHEET FOR PATIENTS

TaqPath™ COVID-19 Combo Kit March 13, 2020 Coronavirus Disease 2019 (COVID-19)

others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, and your symptoms, possible exposures, and geographic location of places you have recently traveled.

What does it mean if I have a negative test result?
A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, duration of illness, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

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- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.

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Very Important To Write Down Or Take A Picture Of Tracking Number Of Shipment To Our Lab!

Shipping your test kits to our lab

- All Samples are delivered to our lab via FedEx Overnight Express
- Three options for sending out samples
  1) Call Fedex for pickup at 1-800-GOFEDEX
  2) Drop sealed FedEx package in a FedEx drop bin. FedEx cannot accept clinical packs inside a FedEx store due to COVID-19
  3) Contact your account manager to schedule a pickup for your location

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Call: **1-800-GOFEDEX (1-800-463-3339)**

1. Say “Schedule pickup at prompt”

2. If asked if package is under 150 lbs.: say yes

3. **Then PRESS 0 until a rep gets on the phone**

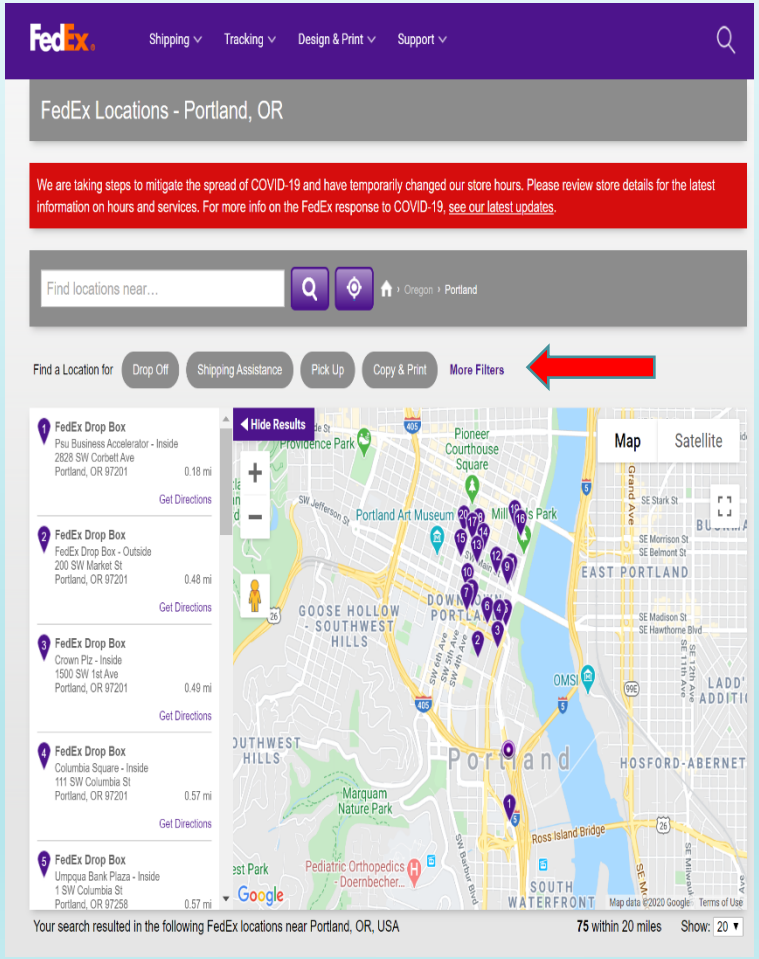
4. Tell customer service rep that you need to schedule an **EXPRESS** pickup **USING A BLACK AND WHITE PREPRINTED LABEL. Also tell them it is one package under 1 lb. and that it will be ready at front desk** (It is very important to tell them this, so they don’t ask for an account #. These labels are billed to our main account.)

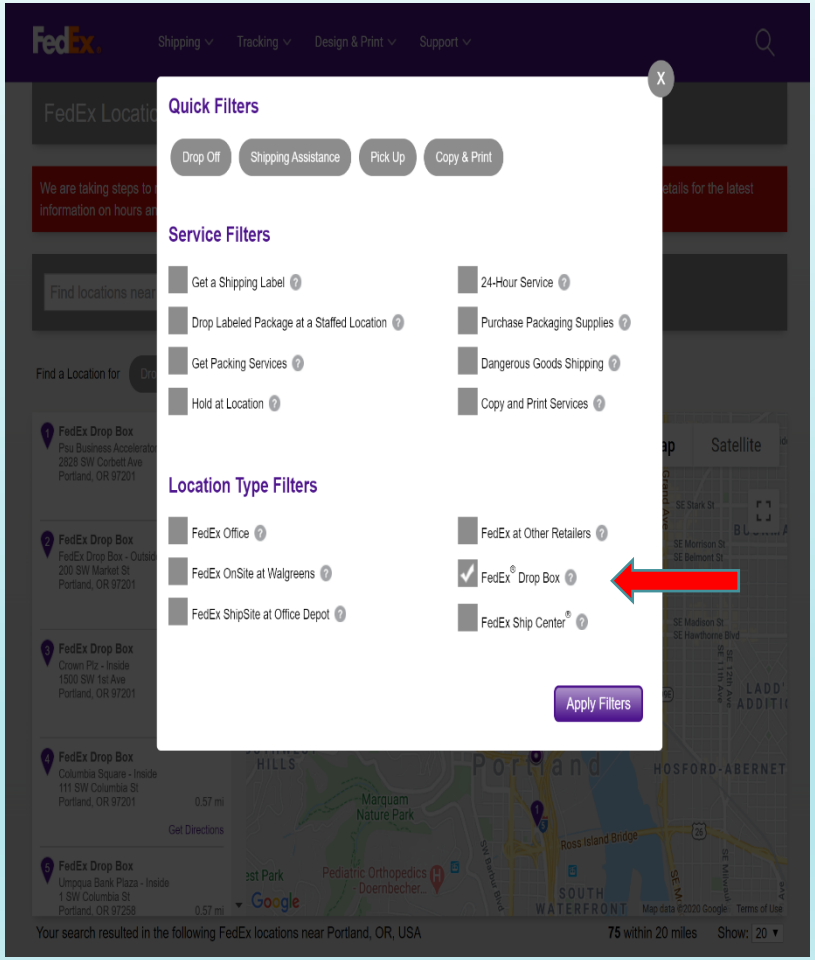
4. Give pickup address.

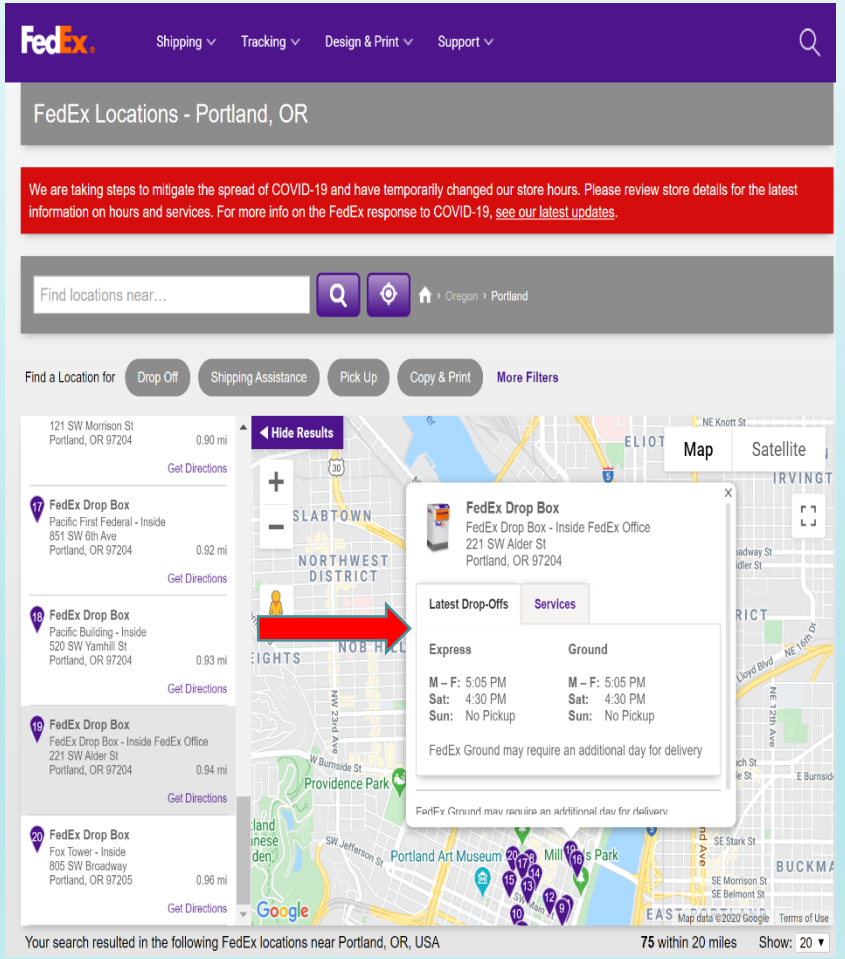
5. Get confirmation #. Please write down tracking #

*****No account # is needed. FedEx will bill our main account.*****

https://www.fedex.com/en-us/shipping/store/all-location-types.html







Fedex Tracking Log:

VIKORSCIENTIFIC

Date:	Tracking #:

Getting Your Reports

- Faxed Results

- Web Portal: A web portal link from Ovation will be emailed to the email address provided.

https://portal.labtests.io

Vikor Scientific - Physician Portal

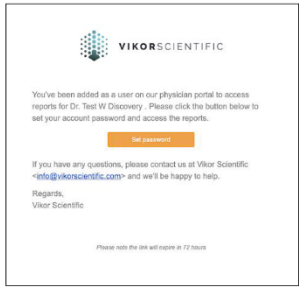
Please follow these step-by-step Instructions to create your user account for viewing orders and downloading reports from the Vikor Scientific Physician Portal

The physician portal is a HIPAA compliant, easy way for physicians and approved staff to access patient orders and reports. The portal works with most web browsers.

Account Setup

Your Vikor administrator will create an account for you. When you are added to the portal, you will receive an email with a link to set your new account password.

Note: this link is only valid for 72 hours

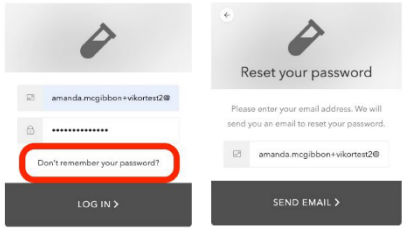


- Follow the link in your email to set your password. You'll be asked to enter your new password twice. Once you have created your password, you will be automatically logged in to the portal.

Login Screen

For easy access to the Vikor Scientific portal please bookmark: https://portal.labtests.io

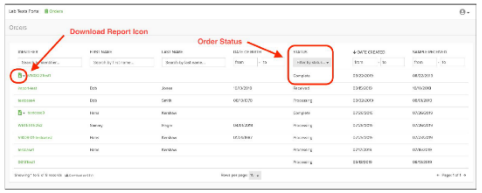
Note: If you forget your password, you can click 'Don't remember your password?' You will be redirected to a page where you can enter your email address. Once you submit, a link will be sent to your email; follow the link to reset your password.



Portal Main Page

- Once on the Portal main page, you can search Orders by Identifier, First Name, Last Name, Date of Birth, Date Created or Sample Received
- You are also able to sort by any of these fields by clicking on the title
- With the dropdown Status filter you can quickly see all orders with a specific status such as Received, Processing, or Complete

- If the status of an order is marked Complete, you will see an icon to the left of the identifier to download the report

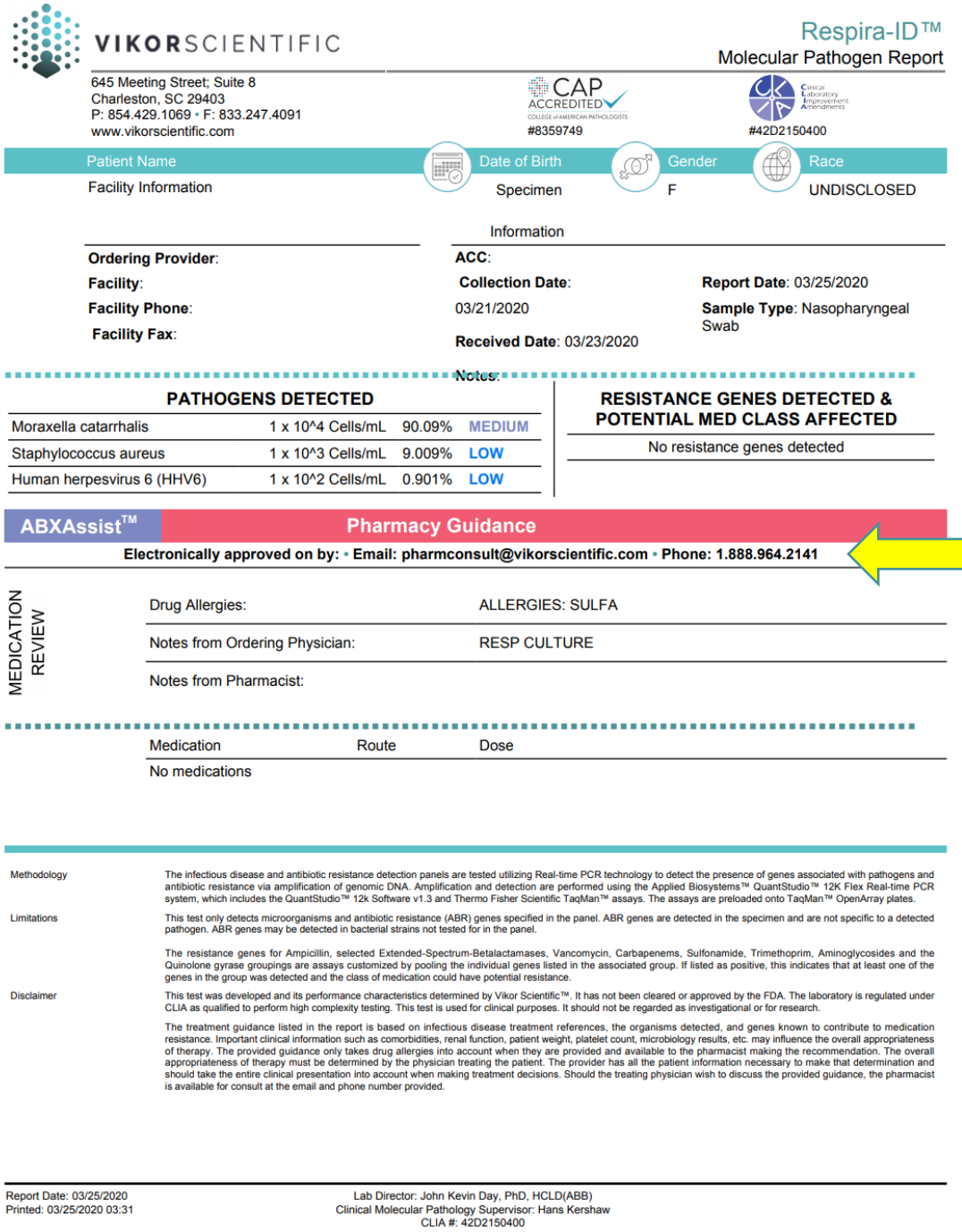


- Click this link, then select the applicable identifier and download your report.

- You can download your report by clicking Download on the top right hand side of your screen.

Sample Respira-ID Report:

Vikor Only Reports What Is Clinically Significant And Provides Quantitative Results



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Respira-ID™
Molecular Pathogen Report

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www.vikorscientific.com

CAP ACCREDITED #8359749

CLIA #42D2150400

Patient Name	Date of Birth	Gender	Race
Facility Information	Specimen	F	UNDISCLOSED

Information

Ordering Provider:
Facility:
Facility Phone:
Facility Fax:

ACC:
Collection Date: 03/21/2020
Received Date: 03/23/2020

Report Date: 03/25/2020
Sample Type: Nasopharyngeal Swab

Notes:

PATHOGENS DETECTED

Moraxella catarrhalis	1 x 10^4 Cells/mL	90.09%	MEDIUM
Staphylococcus aureus	1 x 10^3 Cells/mL	9.009%	LOW
Human herpesvirus 6 (HHV6)	1 x 10^2 Cells/mL	0.901%	LOW

RESISTANCE GENES DETECTED & POTENTIAL MED CLASS AFFECTED

No resistance genes detected

ABXAssist™ **Pharmacy Guidance**

Electronically approved on by: • Email: pharmconsult@vikorscientific.com • Phone: 1.888.964.2141

MEDICATION REVIEW

Drug Allergies: ALLERGIES: SULFA

Notes from Ordering Physician: RESP CULTURE

Notes from Pharmacist:

Medication	Route	Dose
No medications		

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.

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 Vikor Scientific™. 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.

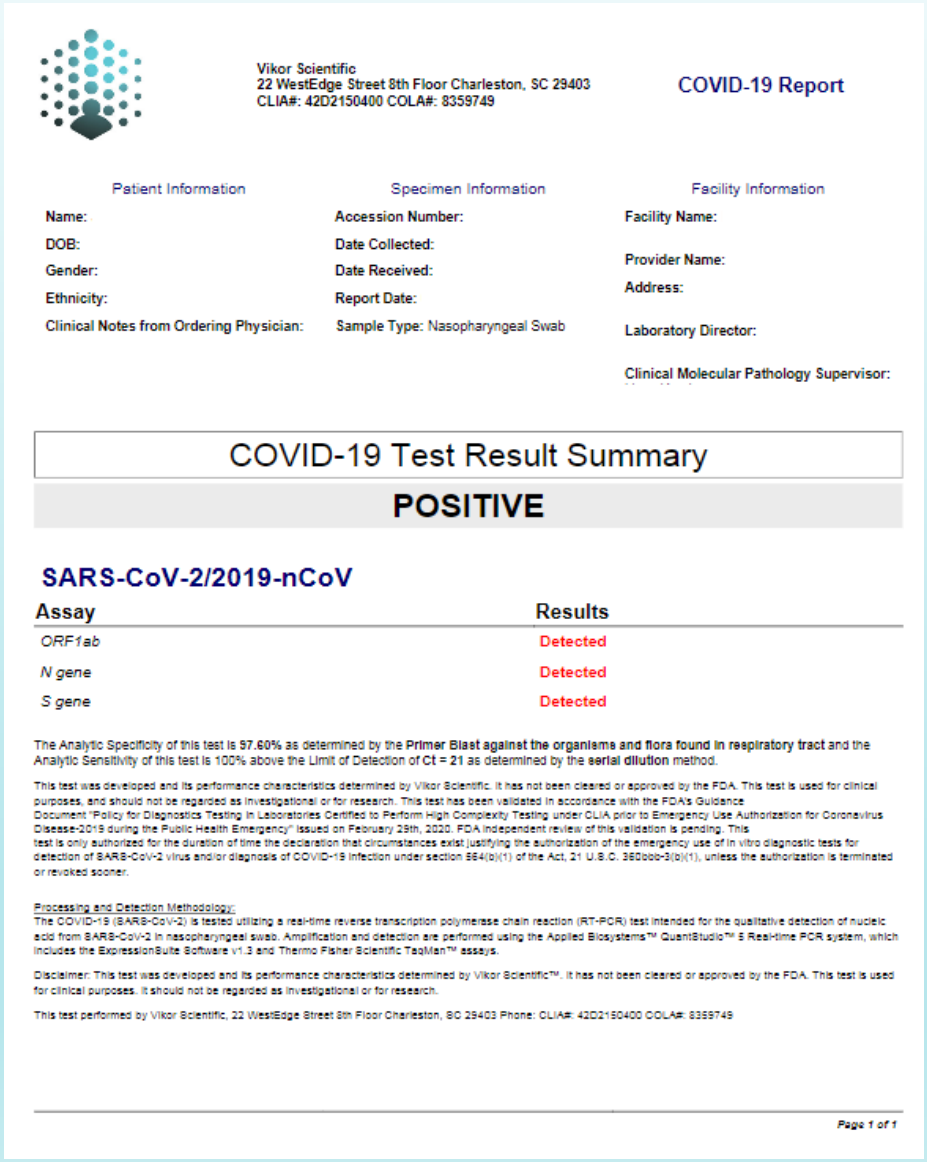
The treatment guidance listed in the report is based on infectious disease treatment references, the organisms detected, and genes known to contribute to medication resistance. Important clinical information such as comorbidities, renal function, patient weight, platelet count, microbiology results, 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.

Report Date: 03/25/2020
Printed: 03/25/2020 03:31

Lab Director: John Kevin Day, PhD, HCLD(ABB)
Clinical Molecular Pathology Supervisor: Hans Kershaw
CLIA #: 42D2150400

We Have Pharmd's Available To Discuss Results With Your Providers

Sample COVID-19 Reports:



Vikor Scientific
22 WestEdge Street 8th Floor Charleston, SC 29403
CLIA#: 42D2150400 COLA#: 8359749

COVID-19 Report

Patient Information	Specimen Information	Facility Information
Name:	Accession Number:	Facility Name:
DOB:	Date Collected:	Provider Name:
Gender:	Date Received:	Address:
Ethnicity:	Report Date:	Laboratory Director:
Clinical Notes from Ordering Physician:	Sample Type: Nasopharyngeal Swab	Clinical Molecular Pathology Supervisor:

COVID-19 Test Result Summary

POSITIVE

SARS-CoV-2/2019-nCoV

Assay	Results
ORF1ab	Detected
N gene	Detected
S gene	Detected

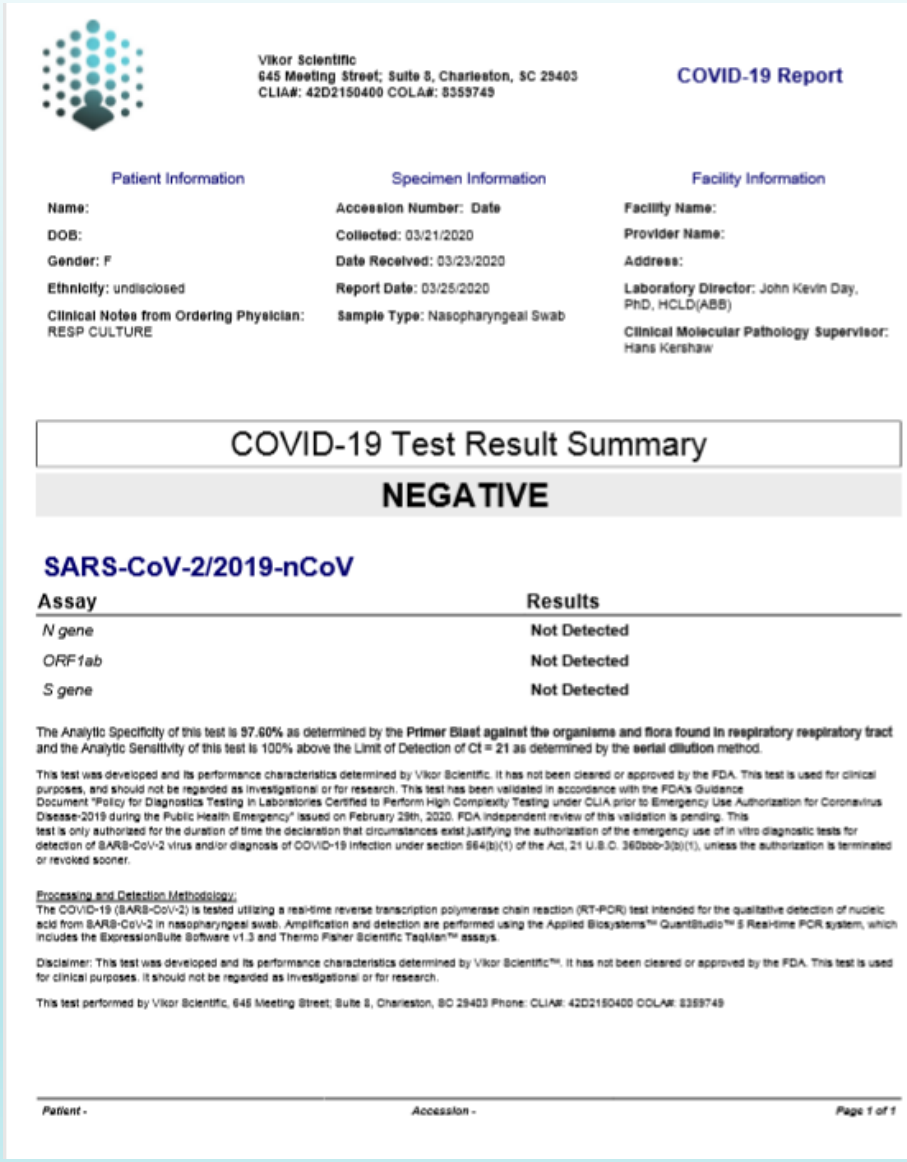
The Analytic Specificity of this test is **97.60%** as determined by the **Primer Blast against the organisms and flora found in respiratory tract** and the Analytic Sensitivity of this test is 100% above the Limit of Detection of **Ct = 21** as determined by the **serial dilution** method.

This test was developed and its performance characteristics determined by Vikor Scientific. It has not been cleared or approved by the FDA. This test is used for clinical purposes, and should not be regarded as investigational or for research. This test has been validated in accordance with the FDA's Guidance Document "Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency" issued on February 29th, 2020. FDA independent review of this validation is pending. This test is only authorized for the duration of time the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of SARS-CoV-2 virus and/or diagnosis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Processing and Detection Methodology:
The COVID-19 (SARS-CoV-2) is tested utilizing a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab. Amplification and detection are performed using the Applied Biosystems™ QuantStudio™ 5 Real-time PCR system, which includes the ExpressionSuite Software v1.3 and Thermo Fisher Scientific TaqMan™ assays.

Disclaimer: This test was developed and its performance characteristics determined by Vikor Scientific™. It has not been cleared or approved by the FDA. This test is used for clinical purposes. It should not be regarded as investigational or for research.

This test performed by Vikor Scientific, 22 WestEdge Street 8th Floor Charleston, SC 29403 Phone: CLIA#: 42D2150400 COLA#: 8359749



Vikor Scientific
645 Meeting Street; Suite 8, Charleston, SC 29403
CLIA#: 42D2150400 COLA#: 8359749

COVID-19 Report

Patient Information	Specimen Information	Facility Information
Name:	Accession Number: Date	Facility Name:
DOB:	Collected: 03/21/2020	Provider Name:
Gender: F	Date Received: 03/23/2020	Address:
Ethnicity: undisclosed	Report Date: 03/25/2020	Laboratory Director: John Kevin Day, PhD, HCLD(ABB)
Clinical Notes from Ordering Physician: RESP CULTURE	Sample Type: Nasopharyngeal Swab	Clinical Molecular Pathology Supervisor: Hans Kershaw

COVID-19 Test Result Summary

NEGATIVE

SARS-CoV-2/2019-nCoV

Assay	Results
N gene	Not Detected
ORF1ab	Not Detected
S gene	Not Detected

The Analytic Specificity of this test is **97.60%** as determined by the **Primer Blast against the organisms and flora found in respiratory respiratory tract** and the Analytic Sensitivity of this test is 100% above the Limit of Detection of **Ct = 21** as determined by the **serial dilution** method.

This test was developed and its performance characteristics determined by Vikor Scientific. It has not been cleared or approved by the FDA. This test is used for clinical purposes, and should not be regarded as investigational or for research. This test has been validated in accordance with the FDA's Guidance Document "Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency" issued on February 29th, 2020. FDA independent review of this validation is pending. This test is only authorized for the duration of time the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of SARS-CoV-2 virus and/or diagnosis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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This test performed by Vikor Scientific, 645 Meeting Street; Suite 8, Charleston, SC 29403 Phone: CLIA#: 42D2150400 COLA#: 8359749

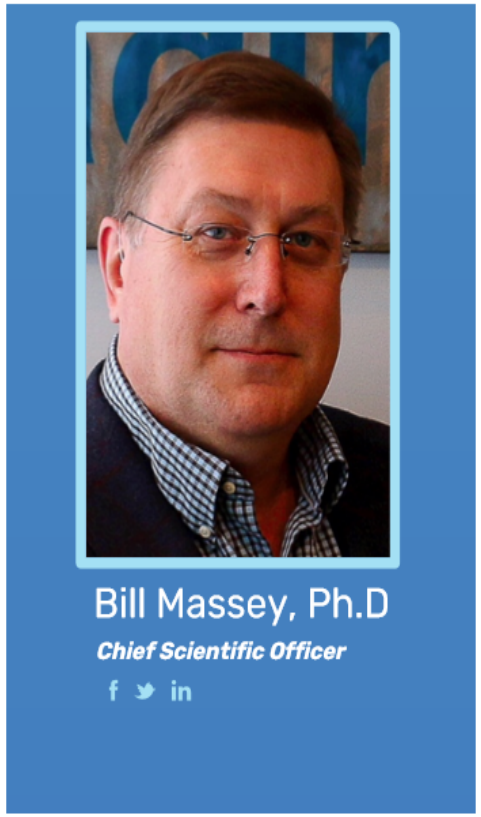
Resources For Providers:

Meet the
Chief Scientific Officer

ABOUT Dr. Massey

Dr. Bill Massey is a neuropharmacologist, pharmacogeneticist, life sciences professional, senior executive, inventor and entrepreneur. Dr. Massey received his Ph.D. in Pharmacology at the University of Arkansas for Medical Sciences. Dr. Massey holds long-standing adjunct faculty appointments at the University of Arkansas for Medical Sciences (Associate Professor, Dept. of Pharmacology and Interdisciplinary Toxicology) and the University of Mississippi Medical Center (Clinical Assistant Professor, Dept. of Psychiatry).

Dr. Massey has held leadership positions at Merck, Astra Merck, Quintiles, Scirex, Astra Zeneca, Scientific Commercialization, Litmus Molecular Design, SureGene, and GeneAlign. He has played a leadership role in placing 28 new drugs into human testing and 8 new drugs onto the market. Dr. Massey formerly held the Jack Martin, MD Research Professorship in Psychopharmacology at Vanderbilt University, where he conducted research into the genetics, biological basis and pharmacological treatment of schizophrenia and serious mental illness in collaboration with Dr. Herbert Meltzer.



VIKORSCIENTIFIC

April 6, 2020

Dear Providers,

Vikor Scientific™ is a high complexity CLIA-certified and CAP-accredited laboratory that has been approved to test for COVID-19 as of 3-23-2020. The testing will be conducted via the QuantStudio™ 12K Flex Open Array from Thermo Fisher, which is an industry-leading instrument for PCR testing and has the capacity for high throughput. This allows Vikor to test a high volume of patients daily to maintain a 24-hour turn-around-time upon sample arrival at the lab. Test results are faxed and loaded onto our portal for easy access.

In effort to protect our most vulnerable population, Vikor Scientific has prioritized this testing for Assisted Living, Memory Care and other Long-Term Care facilities. Vikor's Respira-ID™ molecular panel can accurately detect over 40 pathogens known to cause respiratory illness. (40 pathogens listed on second page) If positive for an infection and further assistance be needed, our infectious disease trained PharmDs are available by phone for provider consultations.

It is vital during this time to remember that while the COVID-19 virus is our most recent and urgent pathogen invading the United States, there are other significant pathogens that cause hospitalization and death daily. The CDC is encouraging clinicians to test for other causes or respiratory illness in addition to COVID-19.

I also urge providers to conduct full panel testing to not only detect or rule out COVID-19, but to also determine what may be causing a patient's symptoms. The causative pathogen could be viral, bacterial, or co-infection and lead to significant illness, hospitalizations, and death. If you have any questions or concerns, please do not hesitate to reach out to us directly.

Sincerely yours,
Bill Massey, Ph.D.
Chief Scientific Officer Vikor Scientific
Email: bmassey@vikorscientific.com

Other Vikor Scientific Tests Available via RT/PCR:

- Urine-ID: Tests for 49 Pathogens that cause UTI/STI's

- Wound-ID: Tests for 54 Pathogens

- Gastro–ID: (Coming Soon)

All tests are swab based, 99.8% accuracy, include 49 Antibiotic Resistance Genes, PharmD Guidance and 24 Hour Turnaround Time from receipt of sample at the lab.

Urine-ID:

VIKORSCIENTIFIC
645 Meeting Street, Suite 8
Charleston, SC 29403
P 854.429.1069 F 833.247.4091
www.vikorscientific.com

CLIA# 42D2150400 CAP#8359749

Urine-ID™ Molecular Test Requisition

Patient Name _____ DOB ____/____/____ Collection Date ____/____/____

TEST SELECTION CHECK APPLICABLE BOXES **Sample Type / location** _____

Allergies: _____ Renal: ☐ NML ☐ ABNL Hepatic: ☐ NML ☐ ABNL
Provider Notes: _____

☐ Urine-ID™

Bacteria

- ☐ Acinetobacter baumannii
- ☐ Actinobaculum schaalii
- ☐ Actinomyces neuii
- ☐ Aerococcus urinae
- ☐ Alloscardovia omnicolens
- ☐ Atopobium vaginae
- ☐ BVAB-2
- ☐ Citrobacter freundii
- ☐ Citrobacter koseri
- ☐ Chlamydia trachomatis
- ☐ Corynebacterium pyruviciproducens
- ☐ Corynebacterium urealyticum
- ☐ Enterobacter aerogenes
- ☐ Enterobacter cloacae
- ☐ Enterococcus faecalis
- ☐ Enterococcus faecium
- ☐ Escherichia coli
- ☐ Gardnerella vaginalis (Female Only)
- ☐ Haemophilus ducreyi
- ☐ Klebsiella oxytoca
- ☐ Klebsiella pneumoniae
- ☐ Lactobacillus gasseri
- ☐ Mobiluncus curtisii
- ☐ Mobiluncus mulieris
- ☐ Morganella morganii
- ☐ Mycoplasma genitalium
- ☐ Mycoplasma hominis
- ☐ Neisseria gonorrhoeae
- ☐ Prevotella bivia
- ☐ Proteus mirabilis
- ☐ Proteus vulgaris
- ☐ Providencia stuartii
- ☐ Pseudomonas aeruginosa
- ☐ Staphylococcus aureus
- ☐ Staphylococcus saprophyticus
- ☐ Streptococcus agalactiae
- ☐ Treponema pallidum
- ☐ Uncultured Megasphera 1
- ☐ Ureaplasma urealyticum

Fungi

- ☐ Candida albicans
- ☐ Candida glabrata
- ☐ Candida krusei
- ☐ Candida parapsilosis
- ☐ Candida tropicalis

Parasites

- ☐ Trichomonas vaginalis

Viruses

- ☐ Herpes simplex virus 1
- ☐ Herpes simplex virus 2
- ☐ Human Papillomavirus 16
- ☐ Human Papillomavirus 18

Antibiotic Resistance Genes These are automatically tested in reflex to a positive pathogen.

Ampicillin Resistance
ampC
ACC
ACT/MIR
DHA

Extended-Spectrum-Betalactamase Resistance
blaNDM-1
GES
CTX-M Group 1
CTX-M Group 2
CTX-M Group 8/25
CTX-M Group 9
PER-1
PER-2
SHV
TEM
TEM E102K
TEM R162S
TEM G238S
VEB

Methicillin Resistance
mecA (MRSA)

Sulfonamide Resistance
SULL

Trimethoprim Resistance
DFRA

Carbapenem Resistance
blaOXA-48
IMP-7
IMP-18
KPC
NDM
OXA-1
OXA-23
OXA-40
OXA-48
OXA-72
OXA-58
VIM

Macrolide Resistance
ermA
ermB
ermC

Aminoglycoside Resistance
aac6-1b/aacA4
aac6-1b-cr
ant(3)
aph(A6)

Tetracycline Resistance
tetM

Quinolone Resistance
Gyrase A D87N_GTT
Gyrase A 583L_TGG
QnrA
QnrB

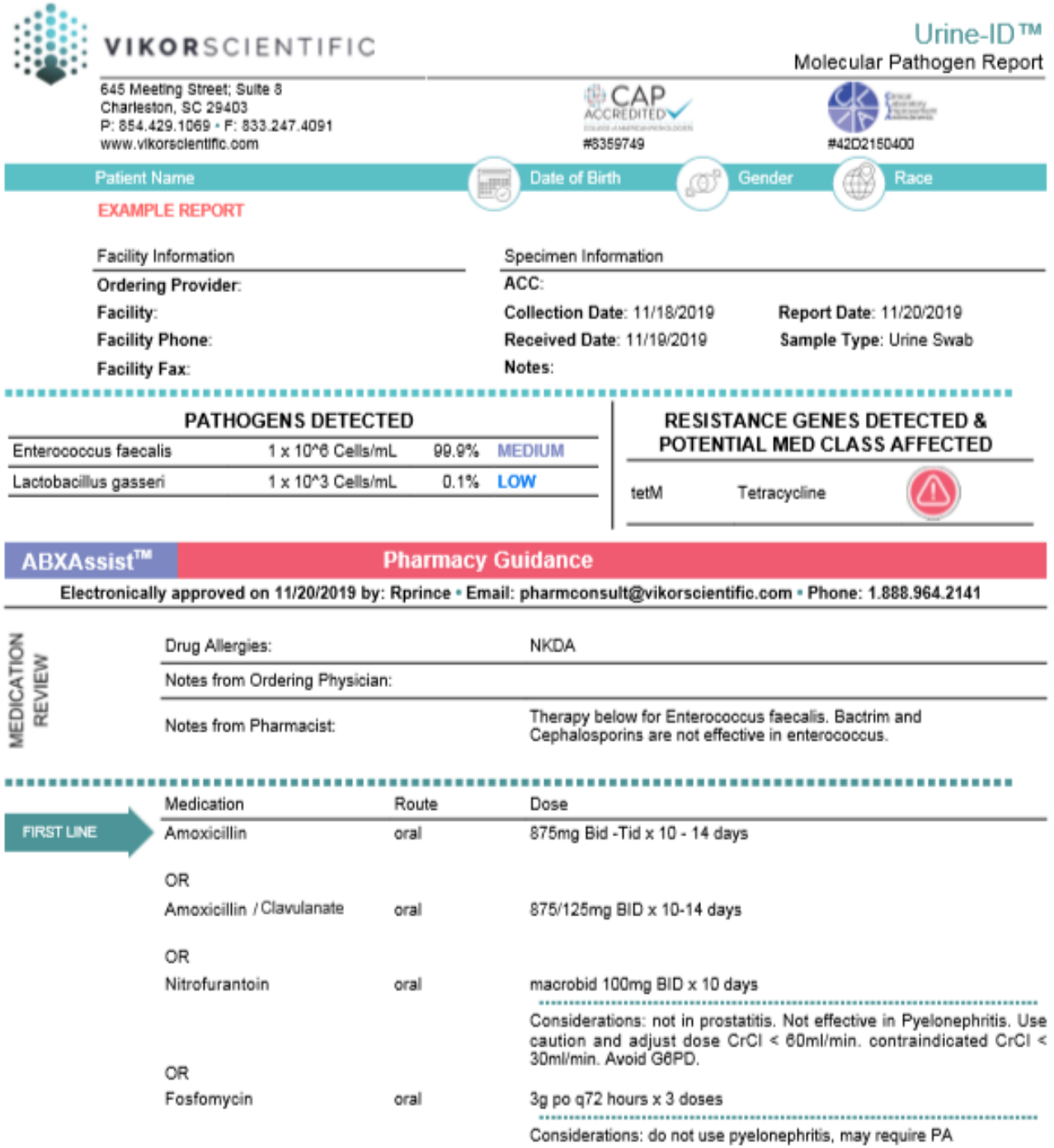
Polymyxin Resistance
mcr-1

Vancomycin Resistance
VanA1
VanA2
VanB

Medical Necessity MUST BE COMPLETED - ICDS Listed for Convenience Only - Please document applicable ICD-10 Codes.

( ) R50.9 Fever, unspecified
( ) N39.0, UTI, site not specified
( ) Z11.51 Encounter for screening of

Urine-ID:



VIKORSCIENTIFIC

Urine-ID™
Molecular Pathogen Report

645 Meeting Street; Suite 8
Charleston, SC 29403
P: 854.429.1069 • F: 833.247.4091
www.vikorscientific.com

CAP ACCREDITED #8359749

#42D2150400

Patient Name | Date of Birth | Gender | Race

EXAMPLE REPORT

Facility Information
Ordering Provider:
Facility:
Facility Phone:
Facility Fax:

Specimen Information
ACC:
Collection Date: 11/18/2019 **Report Date:** 11/20/2019
Received Date: 11/19/2019 **Sample Type:** Urine Swab
Notes:

PATHOGENS DETECTED

Enterococcus faecalis	1 x 10^6 Cells/mL	99.9%	MEDIUM
Lactobacillus gasseri	1 x 10^3 Cells/mL	0.1%	LOW

RESISTANCE GENES DETECTED & POTENTIAL MED CLASS AFFECTED

tetM	Tetracycline

ABXAssist™ Pharmacy Guidance

Electronically approved on 11/20/2019 by: Rprince • Email: pharmconsult@vikorscientific.com • Phone: 1.888.964.2141

MEDICATION REVIEW

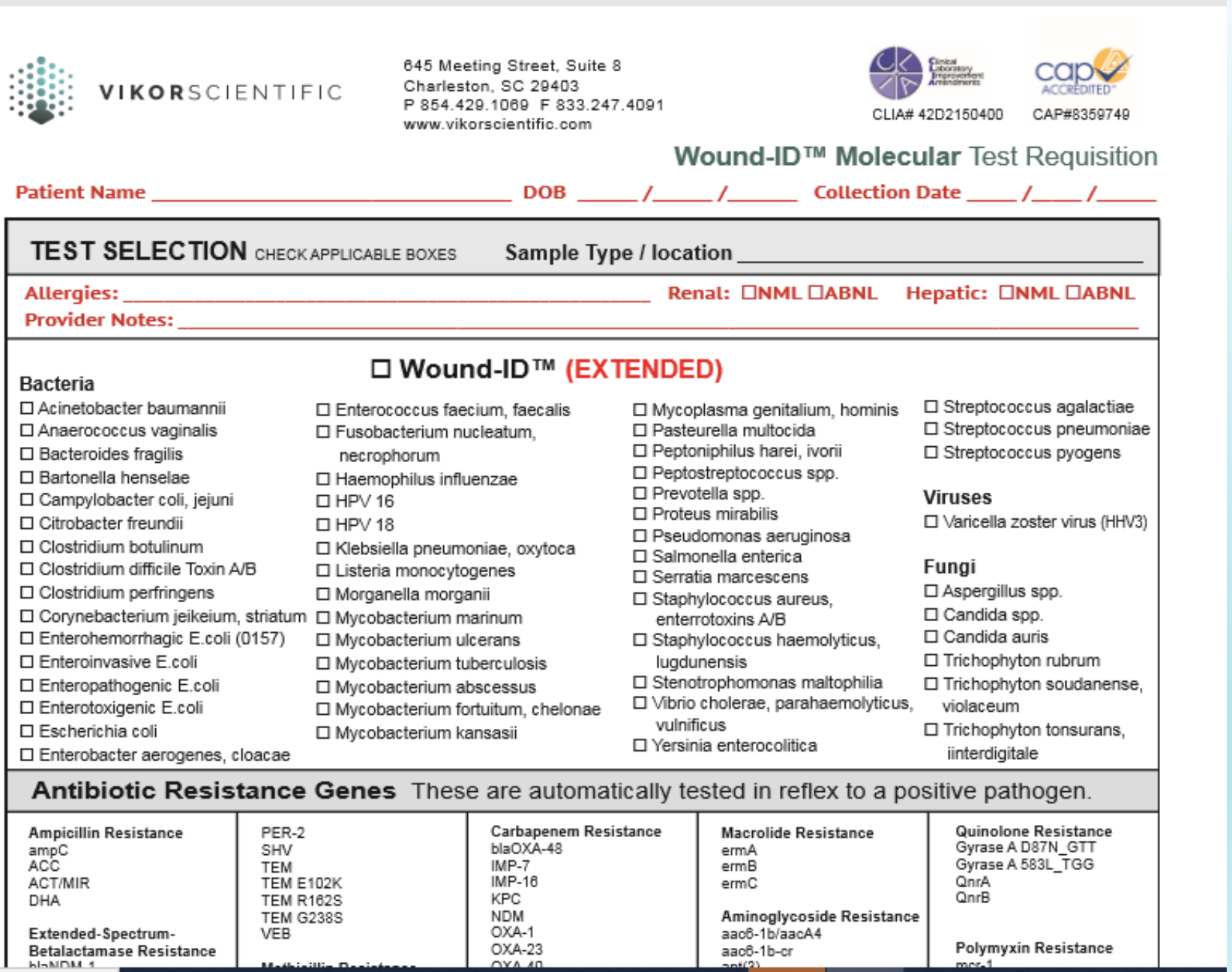
Drug Allergies: NKDA

Notes from Ordering Physician:

Notes from Pharmacist: Therapy below for Enterococcus faecalis. Bactrim and Cephalosporins are not effective in enterococcus.

	Medication	Route	Dose
FIRST LINE	Amoxicillin	oral	875mg Bid -Tid x 10 - 14 days
	OR		
	Amoxicillin / Clavulanate	oral	875/125mg BID x 10-14 days
	OR		
	Nitrofurantoin	oral	macrobid 100mg BID x 10 days
			Considerations: not in prostatitis. Not effective in Pyelonephritis. Use caution and adjust dose CrCl < 60ml/min. contraindicated CrCl < 30ml/min. Avoid G6PD.
	OR		
	Fosfomycin	oral	3g po q72 hours x 3 doses
			Considerations: do not use pyelonephritis, may require PA

Wound-ID:



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Charleston, SC 29403
P 854.429.1069 F 833.247.4091
www.vikorscientific.com

CLIA# 42D2150400 CAP#8359749

Wound-ID™ Molecular Test Requisition

Patient Name _____ **DOB** ____/____/____ **Collection Date** ____/____/____

TEST SELECTION CHECK APPLICABLE BOXES **Sample Type / location** _____

Allergies: _____ **Renal:** ☐NML ☐ABNL **Hepatic:** ☐NML ☐ABNL

Provider Notes: _____

☐ Wound-ID™ (EXTENDED)

Bacteria

- ☐ Acinetobacter baumannii
- ☐ Anaerococcus vaginalis
- ☐ Bacteroides fragilis
- ☐ Bartonella henselae
- ☐ Campylobacter coli, jejuni
- ☐ Citrobacter freundii
- ☐ Clostridium botulinum
- ☐ Clostridium difficile Toxin A/B
- ☐ Clostridium perfringens
- ☐ Corynebacterium jeikeium, striatum
- ☐ Enterohemorrhagic E.coli (0157)
- ☐ Enteroinvasive E.coli
- ☐ Enteropathogenic E.coli
- ☐ Enterotoxigenic E.coli
- ☐ Escherichia coli
- ☐ Enterobacter aerogenes, cloacae
- ☐ Enterococcus faecium, faecalis
- ☐ Fusobacterium nucleatum, necrophorum
- ☐ Haemophilus influenzae
- ☐ HPV 16
- ☐ HPV 18
- ☐ Klebsiella pneumoniae, oxytoca
- ☐ Listeria monocytogenes
- ☐ Morganella morganii
- ☐ Mycobacterium marinum
- ☐ Mycobacterium ulcerans
- ☐ Mycobacterium tuberculosis
- ☐ Mycobacterium abscessus
- ☐ Mycobacterium fortuitum, chelonae
- ☐ Mycobacterium kansasii
- ☐ Mycoplasma genitalium, hominis
- ☐ Pasteurella multocida
- ☐ Peptoniphilus harei, ivorii
- ☐ Peptostreptococcus spp.
- ☐ Prevotella spp.
- ☐ Proteus mirabilis
- ☐ Pseudomonas aeruginosa
- ☐ Salmonella enterica
- ☐ Serratia marcescens
- ☐ Staphylococcus aureus, enterrotoxins A/B
- ☐ Staphylococcus haemolyticus, lugdunensis
- ☐ Stenotrophomonas maltophilia
- ☐ Vibrio cholerae, parahaemolyticus, vulnificus
- ☐ Yersinia enterocolitica
- ☐ Streptococcus agalactiae
- ☐ Streptococcus pneumoniae
- ☐ Streptococcus pyogens

Viruses

- ☐ Varicella zoster virus (HHV3)

Fungi

- ☐ Aspergillus spp.
- ☐ Candida spp.
- ☐ Candida auris
- ☐ Trichophyton rubrum
- ☐ Trichophyton soudanense, violaceum
- ☐ Trichophyton tonsurans, iinterdigitale

Antibiotic Resistance Genes These are automatically tested in reflex to a positive pathogen.

Ampicillin Resistance
ampC
ACC
ACT/MIR
DHA

Extended-Spectrum-Betalactamase Resistance
PER-2
SHV
TEM
TEM E102K
TEM R162S
TEM G238S
VEB

Carbapenem Resistance
blaOXA-48
IMP-7
IMP-16
KPC
NDM
OXA-1
OXA-23

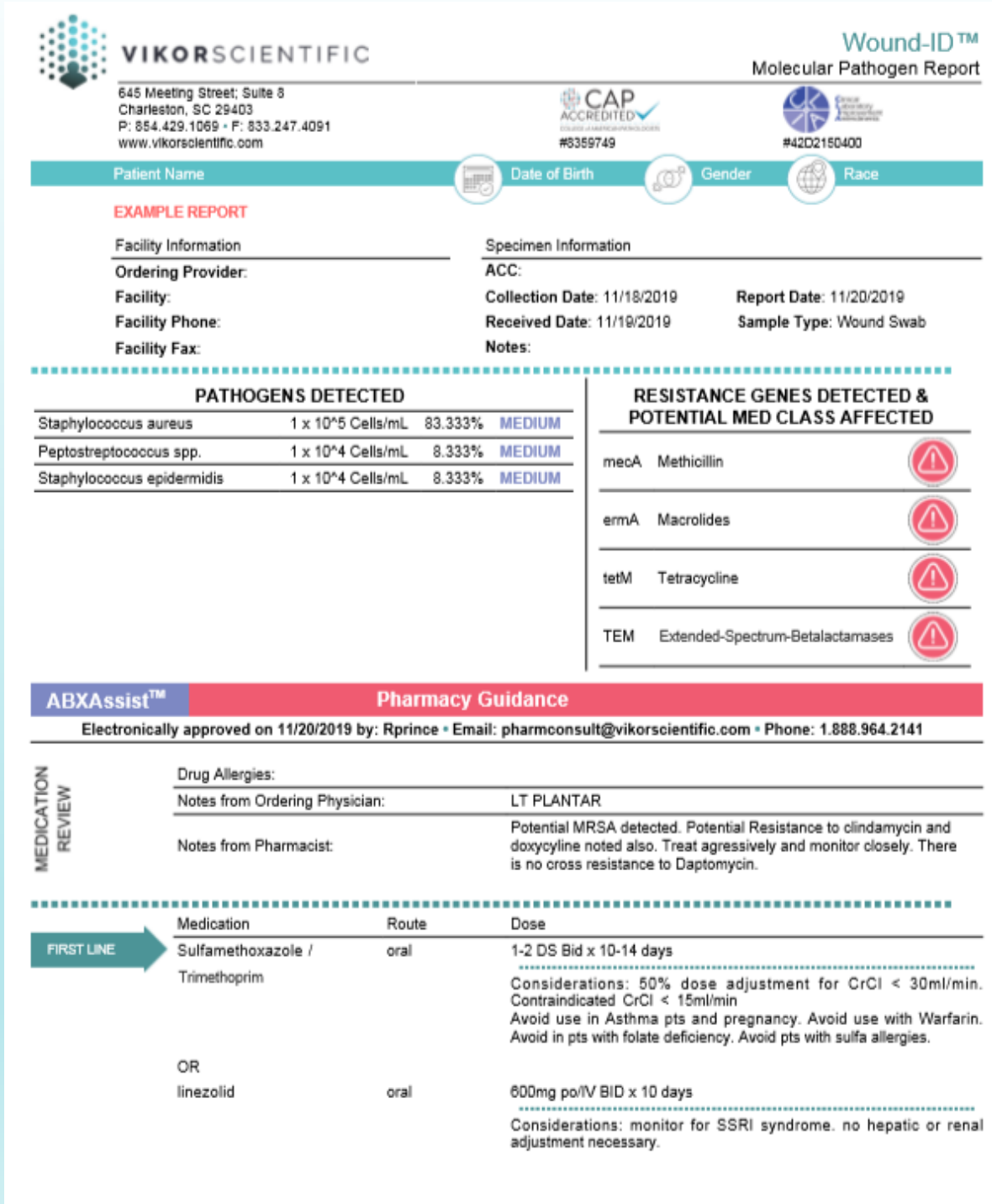
Macrolide Resistance
ermA
ermB
ermC

Aminoglycoside Resistance
aac6-1b/aacA4
aac6-1b-cr

Quinolone Resistance
Gyrase A D87N_GTT
Gyrase A 583L_TGG
QnrA
QnrB

Polymyxin Resistance

Wound-ID:



VIKORSCIENTIFIC

Wound-ID™
Molecular Pathogen Report

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CAP ACCREDITED #8359749

#42D2150400

Patient Name | Date of Birth | Gender | Race

EXAMPLE REPORT

Facility Information	Specimen Information	
Ordering Provider:	**ACC:**	
Facility:	**Collection Date:** 11/18/2019	**Report Date:** 11/20/2019
Facility Phone:	**Received Date:** 11/19/2019	**Sample Type:** Wound Swab
Facility Fax:	**Notes:**	

PATHOGENS DETECTED

Staphylococcus aureus	1 x 10^5 Cells/mL	83.333%	MEDIUM
Peptostreptococcus spp.	1 x 10^4 Cells/mL	8.333%	MEDIUM
Staphylococcus epidermidis	1 x 10^4 Cells/mL	8.333%	MEDIUM

RESISTANCE GENES DETECTED & POTENTIAL MED CLASS AFFECTED

mecA	Methicillin
ermA	Macrolides
tetM	Tetracycline
TEM	Extended-Spectrum-Betalactamases

ABXAssist™ Pharmacy Guidance

Electronically approved on 11/20/2019 by: Rprince • Email: pharmconsult@vikorscientific.com • Phone: 1.888.964.2141

MEDICATION REVIEW

Drug Allergies:	
Notes from Ordering Physician:	LT PLANTAR
Notes from Pharmacist:	Potential MRSA detected. Potential Resistance to clindamycin and doxycyline noted also. Treat agressively and monitor closely. There is no cross resistance to Daptomycin.

	Medication	Route	Dose
FIRST LINE	Sulfamethoxazole / Trimethoprim	oral	1-2 DS Bid x 10-14 days Considerations: 50% dose adjustment for CrCl < 30ml/min. Contraindicated CrCl < 15ml/min Avoid use in Asthma pts and pregnancy. Avoid use with Warfarin. Avoid in pts with folate deficiency. Avoid pts with sulfa allergies.
	OR		
	linezolid	oral	600mg po/IV BID x 10 days Considerations: monitor for SSRI syndrome. no hepatic or renal adjustment necessary.


VIKORSCIENTIFIC
BETTER DIAGNOSTICS FOR A BETTER FUTURE
Urine-ID™ Molecular Test Requisition
KIT/BACK) AND DEMOGRAPHIC SHEET
VIKORSCIENTIFIC
BETTER DIAGNOSTICS FOR A BETTER FUTURE


KORGENE
VIKORSCIENTIFIC

VIKORSCIENTIFIC KORGENE

Contact Information

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Cell: 541-954-2204 (Call or Text)

Email: gmcbride@vikorscientific.com

Area Vice President: Jamie Ryan

Cell: 919-600-8983 (Call or Text)

Email: jryan@vikorscientific.com

Laboratory Direct: 854-429-1069

**** If looking for results and calling outside of 8:00 AM – 6:00 PM EST, please have patient name, DOB & best contact info available and someone from our staff will get back to you. ****

Held Status or Rejected Samples:
Laura Lesburg
Fax: 833-247-4091
Email: llesburg@vikorscientific.com

Missing Info :
missinginfo@vikorscientific.com
Fax: 833-247-4091

Laboratory Fax: 833-247-4091

PharmD Consult: 888-964-2141

THANK YOU.

VIKORSCIENTIFIC

645 Meeting Street; Suite 8
Charleston, SC 29403
Phone: 854.429.1069

info@vikorscientific.com

www.vikorscientific.com

KORGENE