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

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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. Ask patient to tilt head back 30 degrees.
2. Remove swab from tube and insert swab into one nostril.
3. Advance swab until the swab reaches the back of the nasal.
4. Slowly remove swab while rotating it.
5. Repeat the same procedure of the other nostril.
6. Insert the swab into the transport tube.
7. Replace the cap securely.

Each tube should be labeled with two patient identifiers.

SPECIMEN BAG

BIOHAZARD

Frozen
Refrigerate
Room Temp
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.

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
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.
FACT SHEET FOR PATIENTS
TagPath™ 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 TagPath™ 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 the 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 identified 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 TagPath™ 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 symptoms and signs and your travel history (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 samples will help find out if you 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, you are likely to have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a false positive result (false alarm). 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 their recent illness.

However, if 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 Services (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 (staying emergency of HHS, unless it is terminated or revoked by FDA) (after which the test may no longer be used).

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.

Vikor Scientific
www.vikorscientific.com
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
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.*****
Fedex Tracking Log:

<table>
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<tr>
<th>Date:</th>
<th>Tracking #:</th>
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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
Sample Respira-ID Report:

Vikor Only Reports What Is Clinically Significant And Provides Quantitative Results

We Have Pharmd’s Available To Discuss Results With Your Providers
Sample COVID-19 Reports:
Resources For Providers:

Meet the
Chief Scientific Officer

ABOUT Dr. Massey

Dr. Bill Massey is a neuropharmacologist, pharmacogenetist, 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, Ut莫斯 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, M.D. 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.

Bill Massey, Ph.D
Chief Scientific Officer

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 1-23-2020. 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 fixed and loaded onto our portal for easy access.

In effort to protect our most vulnerable populations, 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 46 pathogens known to cause respiratory illness (46 pathogens listed on second page). If positive for an infection and further assistance be needed, our infectious disease trained Pharmacists 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: masssey@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: Molecular Test Requisition

Patient Name ____________________  DOB ______/_____/______  Collection Date ______/_____/______

TEST SELECTION  CHECK APPLICABLE BOXES  Sample Type / location __________

Allergies: ________________________  Provider Notes: ________________________

- Urine-ID™

Bacteria
- Enterococcus faecalis
- Enterococcus faecium
- Esherichia coli
- Gardnerella vaginalis
- Klebsiella pneumoniae
- Haemophilus ducreyi
- Klebsiella oxytoca
- Lactobacillus gasseri
- Mobiluncus curtisi
- Mobiluncus mulleri
- Morganella morgani
- Mycoplasma genitalium
- Mycoplasma hominis

Fungi
- Candida albicans
- Candida glabrata
- Candida krusei
- Candida parapsilosis
- Candida tropicalis

Parasites
- Trichomonas vaginalis

Virus
- 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
- AcoD
- ACTIMIR
- DNA
- Extended-Spectrum- Beta-Lactamase Resistance
- SHV
- TEM
- TEM-1 20K
- TEM-182
- TEM-22
- VEB
- Methicillin Resistance: mecA
- Sulfonamide Resistance: sulfA
- Trimethoprim Resistance: tfra

Carbapenem Resistance
- IMP-7
- IMP-10
- KPC
- NDM
- OXA-1
- OXA-23
- OXA-48
- OXA-48
- OXA-72
- VIM

Menzolactone Resistance
- ermA
- ermB
- ermC

Aminoglycoside Resistance
- aac(6)-Ib-cr
- aac(6)-Ib-cr
- aph(3’)-Ia

Quinolone Resistance
- GYrase A
- GYrase B
- TIG

Polymyxin Resistance
- mcr-1

Vancomycin Resistance
- VanA
- VanB

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

- IRS 3 Fever unspecified
- N59.0, UTI, site not specified
- Z11.51 Encounter for screening of
Urine-ID:

Pathogens Detected:
- Enterococcus faecalis: 1 x 10^6 Cells/mL, 0.9%, MEDIUM
- Lactobacillus gasseri: 1 x 10^3 Cells/mL, 0.1%, LOW

Resistance Genes Detected & Potential MED Class Affected:
- tetracycline

ABXAssist™ Pharmacy Guidance:
- Electronically approved on 11/20/2019 by: R.Prince - Email: pharmacust@vikorscientific.com - Phone: 1.888.364.2141

Drug Allergies: NKDA

Notes from Ordering Physician:

Notes from Pharmacist:
- Therapy below for Enterococcus faecalis, Bacteri and Cephalosporins are not effective in emerococcus.

Medication Review:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Route</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin</td>
<td>oral</td>
<td>875mg Bid - Tid x 10 - 14 days</td>
</tr>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amoxicillin / Clavulanate</td>
<td>oral</td>
<td>875/125mg BID x 10-14 days</td>
</tr>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>oral</td>
<td>macrobid 100mg BID x 10 days</td>
</tr>
</tbody>
</table>

Considerations: not in prostatitis. Not effective in Pyelonephritis. Use caution and adjust dose CrCl < 60mL/min. contraindicated CrCl < 30mL/min. Avoid GFP.

OR
- Fosfomycin | oral | 3g po q72 hours x 3 doses |

Considerations: do not use pyelonephritis, may require PA
Wound-ID:

**Wound-ID™ Molecular Test Requisition**

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

**TEST SELECTION**

**Allergies:** ___________________________ **Sample Type / location:** ___________________________

**Bacteria**
- Acinetobacter baumannii
- Anaerobic bacteria
- Bacteroides fragilis
- Bartonella henselae
- Campylobacter coli, jejuni
- Citrobacter freundii
- Clostridium botulinum
- Clostridium difficile toxin A/B
- Clostridium perfringens
- Corynebacterium jeikeium, striatum
- Enteroaggregative E. coli
- Enteropathogenic E. coli
- Enterotoxigenic E. coli
- Escherichia coli
- Enterobacter aerogenes, cloacae
- Enterococcus faecalis, faecium
- Fusobacterium nucleatum
- Haemophilus influenzae
- HPV 16
- HPV 18
- K. pneumoniae, oxytoca
- Listeria monocytogenes
- Morganella morgani
- Mycobacterium marinum
- Mycobacterium ulcerans
- Mycobacterium tuberculosis
- Mycobacterium abscessus
- Mycobacterium fortuitum, chelonae
- Mycobacterium kansasii
- Mycoplasma genitalium, hominis
- Pasteurella multocida
- Peptostreptococcus harei, troas
- Peptostreptococcus spp.
- Prevotella spp.
- Proteus mirabilis
- Pseudomonas aeruginosa
- Salmonella enteritica
- Serratia marcescens
- Staphylococcus aureus, enterotoxins A/B
- Staphylococcus haemolyticus, lugdunensis
- Stenotrophomonas maltophilia
- Vibrio cholerae, parahaemolyticus, vulnificus
- Yersinia enterocolitica

**Viruses**
- Varicella zoster virus (VZV)

**Fungi**
- Aspergillus spp.
- Candida spp.
- Candida auris
- Trichophyton rubrum
- Trichophyton soudanense, violaceum
- Trichophyton tonsurans, interdigitale

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

- AmpC
- AOC
- ACC
- ACT/ER/AR
- DHA
- Quinolone Resistance
- Gyrase A (cfrD76)
- GyrB (cfrD76)

- Macrolide Resistance
- ermA
- ermB
- ermC

- Aminoglycoside Resistance
- aac6-12/apha6-4
- aac6-12/apha4

- Polyoxins Resistance
# Wound-ID: Molecular Pathogen Report

**Patient Information**
- **Name:** [REMOVED]
- **Date of Birth:** [REMOVED]
- **Gender:** [REMOVED]
- **Race:** [REMOVED]

**Facility Information**
- **Provider:** [REMOVED]
- **Facility:** [REMOVED]
- **Phone:** [REMOVED]
- **Fax:** [REMOVED]

**Specimen Information**
- **ACC:**
- **Collection Date:** 11/15/2019
- **Received Date:** 11/16/2019
- **Report Date:** 11/20/2019
- **Sample Type:** Wound Swab
- **Notes:**

### Pathogens Detected

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Resistant to (MICs)</th>
<th>Susceptibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>1 x 10⁴ CFU/mL</td>
<td>Sensitive</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>1 x 10⁴ CFU/mL</td>
<td>Sensitive</td>
</tr>
<tr>
<td>Staphylococcus epidermidis</td>
<td>1 x 10⁴ CFU/mL</td>
<td>Sensitive</td>
</tr>
</tbody>
</table>

### Antibiotic Resistance Genes Detected
- **mecA:** Methicillin
- **ermA:** Macrolides
- **tetM:** Tetracycline
- **TEM:** Extended-Spectrum β-Lactamases

**ABXAssist™ Pharmacy Guidance**

**Drug Allergies:**
- [REMOVED]

**Medication Review**
- **LT PLANT/AR**
- **Notes from Ordering Physician:**
- **Notes from Pharmacist:** Potential MRSA detected. Potential Resistance to clindamycin and doxycycline noted also. Treat aggressively and monitor closely. There is no cross resistance to Daptomycin.

**FIRST LINE**

<table>
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<tr>
<th>Medication</th>
<th>Route</th>
<th>Dose</th>
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<tr>
<td>Sulfamethoxazole / Trimethoprim</td>
<td>oral</td>
<td>1-2 DS Bid x 10-14 days</td>
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<tr>
<td>considerations: 50% dose adjustment for CrCl &lt; 30ml/min. Contraindicated CrCl &lt; 15ml/min. Avoid use in Asthma pts and pregnancy. Avoid use with Warfarin. Avoid in pts with folate deficiency. Avoid pts with sulfa allergies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qor linezolid</td>
<td>oral</td>
<td>600mg po/IV/IO x 10 days</td>
</tr>
<tr>
<td>considerations: monitor for SSRI syndrome. No hepatic or renal adjustment necessary</td>
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</tr>
</tbody>
</table>

**Received Date:** 11/16/2019

**Report Date:** 11/20/2019

[vikorscientific.com](www.vikorscientific.com)
Contact Information

Account Manager: Adam Holden
Cell: 813-317-3192 (Call or Text)
Email: aholden@vikorscientific.com

Account Manager: Gina McBride
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

PharmD Consult: 888-964-2141