Welcome and Introductions

Wednesday, January 12, 2022

Belinda Hawks
Division Director, Quality Management and Planning
Behavioral Health and Developmental Disabilities Administration

Today's topics and guests (90 min. program)

Supplemental 4 COVID Vaccination Grant

- Sharon Milberger, MI-DDI
- Mark McWilliams, Disability Rights Michigan (DRM)
- Jill Matson, Autism Alliance of Michigan (AAoM)

Isolation & Quarantine Updates for Healthcare Personnel

- Chelsea Ludington, Team Lead, Infection Prevention Resource & Assessment Team

COVID-19 Testing Update

- Natasha Radke, COVID Testing and Collection Coordination

Understanding the Omicron Variant

- Dr. Marty Soehnlen, Infectious Disease Division, Bureau of Laboratories

COVID-19 Therapeutics

- Wendy Snyder, Bureau of EMS Trauma and Preparedness

MDHHS Supplemental 4 COVID Vaccine Grants

AFC/HFA COVID webinar

January 12, 2022

Jill Matson, MSN, RN, CPNP (AAoM)
Mark McWilliams, Attorney (DRM)
Sharon Milberger, ScD (MI-DDI)

MI DDI
Michigan Developmental Disabilities Institute

Community Service
Education
Research
Dissemination

WAYNE STATE UNIVERSITY

Agenda

- Brief Overview of MI-DDI, DRM, & AAoM
- Overview of COVID Vaccine Grant
- COVID Vaccine Grant Objectives/Activities
- Next Steps

MI-DDI

MI-DDI is a University Center of Excellence on Developmental Disabilities (UCEDD)

National network of 67 UCEDDs:

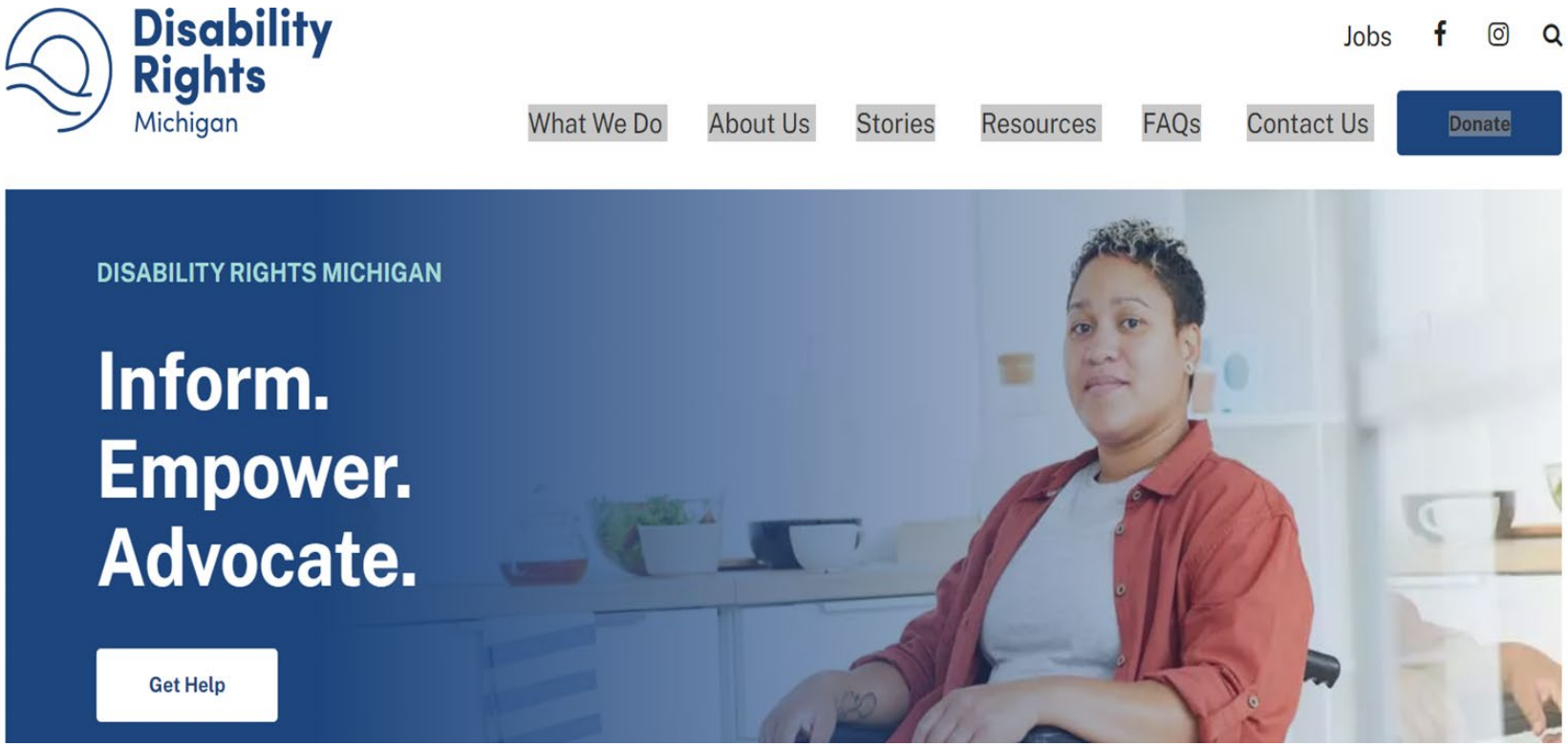
- Federally mandated by the DD Act of 2000
- Administered by the Administration on Community Living (US DHHS)
- Have the same 4 Core Functions:
  - **Training**
  - **Community Supports & Services**
  - **Research**
  - **Information Dissemination**

MI-DDI Mission: to promote community inclusion and quality of life for people with disabilities and their families

MI DDI
Michigan Developmental Disabilities Institute

Wayne State University

Disability Rights Michigan



DRM Mission: to advocate and protect the legal rights of people with disabilities.

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Autism Alliance of Michigan: Covid-19 Grant

The Autism Alliance of Michigan, founded in 2009, is a non-profit organization that leads collaborative efforts across the state to raise expectations and expand opportunities for people touched by autism throughout the lifespan.

This project is aimed toward individuals with autism and other developmental disabilities and focuses on vaccine awareness and improved access across the State of Michigan

Support vaccination sites and staff to provide accommodations for individuals with disabilities seeking vaccination.

Collect and disseminate information on how to prepare individuals with autism and other developmental disabilities for vaccine

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COVID Vaccine Grant

- **COVID-19 Vaccination Supplement 4:** Funding Equity and prioritizing populations disproportionately affected by COVID-19
- Funding provided to MDHHS through the National Center for Immunization and Respiratory Diseases **(NCIRD)**
- Supported through the Coronavirus Response and Relief Supplemental Appropriations Act of 2021, P.L. 116-260 and the American Rescue Plan Act of 2021, P.L. 117-2 (TOTAL FUNDING $90M)
- Multiple grantees in Michigan including:
  - MI-DDI
  - Disability Rights Michigan (DRM)
  - Autism Alliance of Michigan (AAoM)
  - Brain Injury Association of Michigan (BIAMI)
  - Other

COVID Vaccine Grant

Objective	Primary Org
1. Improve understanding of barriers to vaccination access and uptake	Disability Rights Michigan
2. Develop, cultivate, and strengthen community-based partnerships to reach disproportionately affected populations	TBD
3. Improve access to COVID-19 vaccines (expand and diversify opportunities for getting vaccinated)	MI-DDI
4. Improve and expand messaging/education around vaccination	Autism Alliance of Michigan

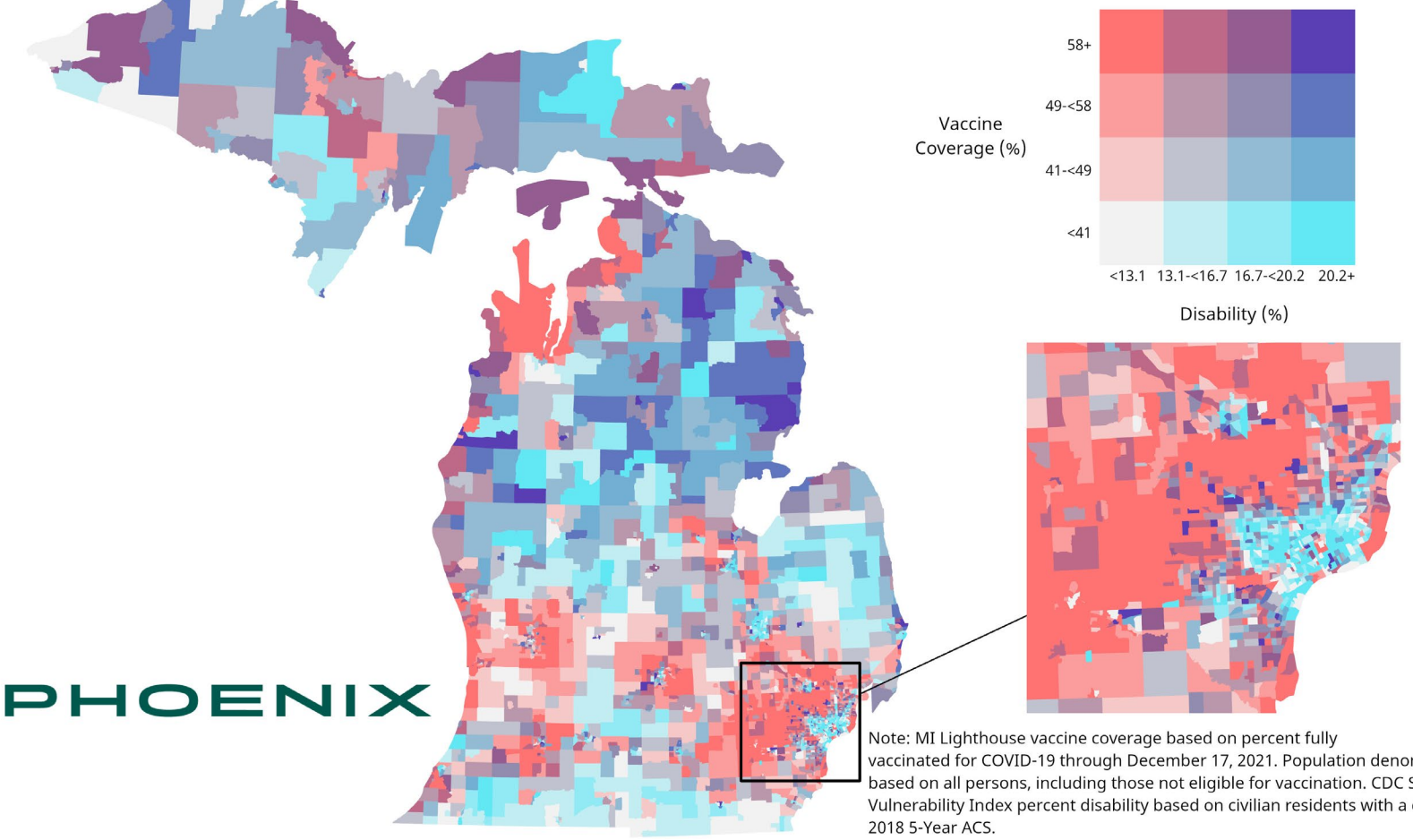
Objective	Activities	Outcomes	Measurement
1. Improve understanding of barriers to vaccination access and uptake	Develop data tools to assess and monitor vaccination	Increased understanding of barriers to access & uptake	• Barriers to access/update identified • High need areas identified • Disability status included on state dashboard (BRFSS questions)

2. Develop, cultivate, and strengthen community-based partnerships to reach disproportionately affected populations	Create and convene an interdisciplinary team of community-based partners	Trusted messengers representing affected communities identified & trained to promote vaccine programs	• # mini-grant applications
			• Demographics of mini-grant applicants and grantees: population served (disability, age, gender identity, zip codes served)
			• # of community partners for each mini-grant activity: 1) Host a Vaccination Event, 2) Trusted Community Communicator, 3) Vaccination Education Session, 4) inclusion of individuals with I/DD in planning
			• Reporting of activities by mini-grantees:
			  • # reached: disability, age, gender identity, zip codes served, disability perspective/role
			  • Activities completed: date(s) of vax event(s) &/or education sessions
			  • # of materials distributed (paper, digital/social media)
			• # Individuals reached with uptake of vaccines [develop tracking methodology]

3. Improve access to COVID-19 vaccines (expand and diversify opportunities for getting vaccinated)	Provide direct and indirect assistance to receive vaccines, all types and boosters	Increased vaccination (all types)	• Health professionals trained on working with individuals with I/DD (#, change in knowledge) • Health professionals trained on motivation interview (#, change in knowledge) • Accommodation needs on registration forms • Individuals reached with uptake of vaccines [develop tracking methodology] • Vaccination distributed by date, type of vaccine • Track barriers to vaccination process: transportation, scheduling • Mobile Health outreach: Location, dates, miles driven, # vaccinated at each event • # materials distributed (paper, digital/social media)
4. Improve and expand messaging/education around vaccination	Develop & distribute materials that are accessible & in plain language to increase awareness of vaccination programs	Increased awareness of vaccination protocols and availability for target population	• # vaccine awareness materials developed • # materials offered in other languages • # materials distributed (paper, digital) • # Individuals reached (zip code, social media data)

COVID Vaccine Grant

COVID-19 Vaccine Coverage & Disability



Note: MI Lighthouse vaccine coverage based on percent fully vaccinated for COVID-19 through December 17, 2021. Population denominator based on all persons, including those not eligible for vaccination. CDC Social Vulnerability Index percent disability based on civilian residents with a disability; 2018 5-Year ACS.

PHOENIX

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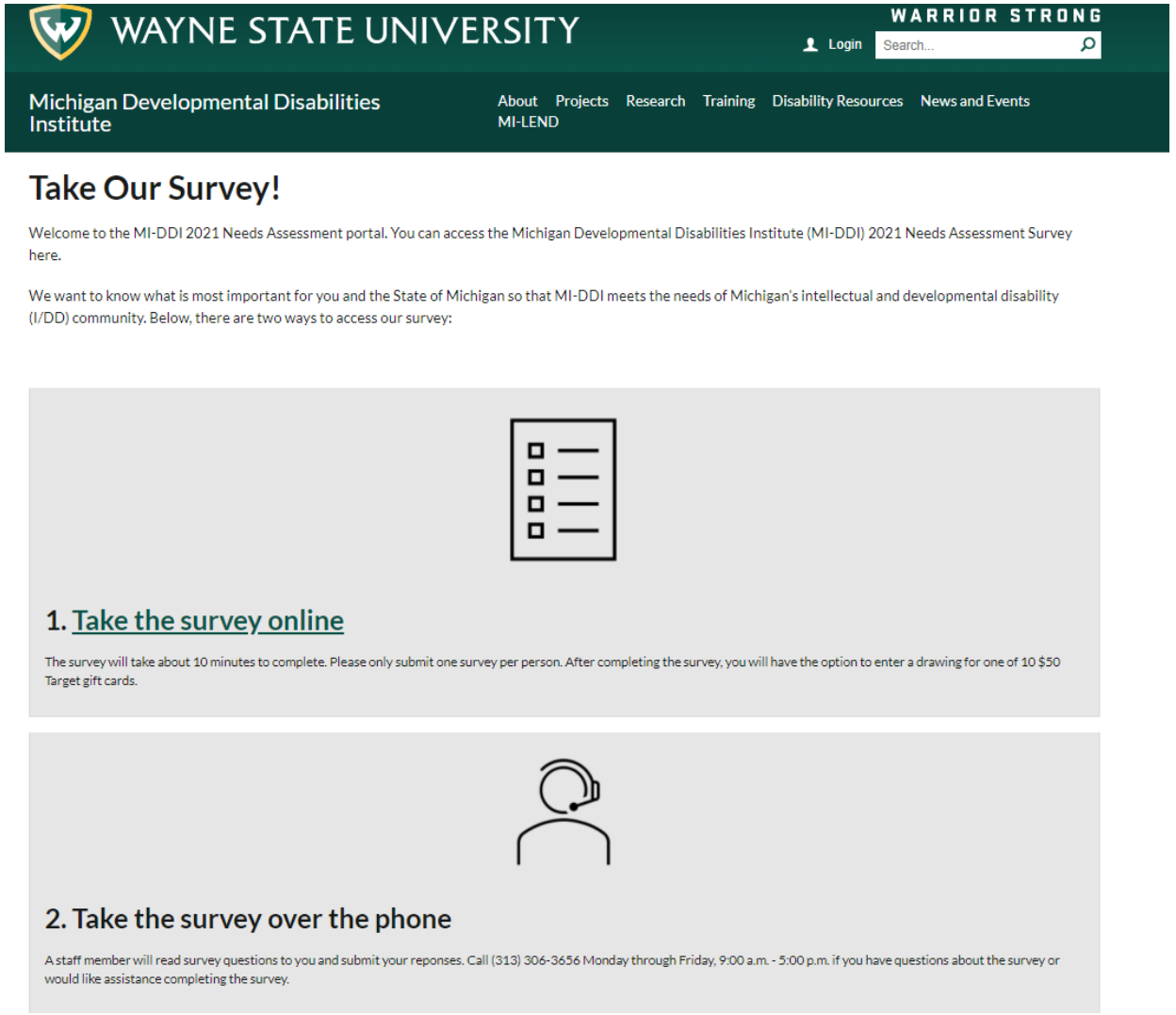
Next Steps

- Coordination across Supplement 4 Grantees
- Identification of areas in high need
- Training of mobile health unit personnel on working with individuals with I/DD and older adults
- Review/revise mobile health unit electronic health record (EHR)
- Schedule mobile health unit events
- Collect and analyze evaluation data
- Disseminate accurate/up-to-date information
- MI-DDI statewide Needs Assessment

https://ddi.wayne.edu/2021needsassess



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Isolation & Quarantine Updates for Healthcare Personnel

Chelsea Ludington, MPH, CIC

IPRAT

Infection Prevention Resource and Assessment Team

Updated Healthcare Personnel Isolation & Quarantine Guidelines

- MDHHS has aligned with the CDC guidance updated December 23, 2021.
  - An updated version of the Return to Work & Health Monitoring for Healthcare Employees will be coming soon.

- MDHHS has adopted the updated CDC guidance on isolation and quarantine for healthcare workers.

- MDHHS applies these guidelines to Residential Care Settings, including AFCs and HFAs.

Healthcare Personnel

- **Healthcare personnel (HCP)**: All paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air.

THIS INCLUDES:

- EMS personnel
- Nurses
- Nursing assistants
- Physicians
- Technicians
- Therapists
- Phlebotomists
- Pharmacists
- Students & trainees
- Contractual staff not employed by the health care facility

- Persons not directly involved in patient care but potentially exposed to infectious agents that can be transmitted among HCP and patients:
  - **Clerical**
  - **Dietary**
  - **Environmental services**
  - **Laundry**
  - **Security**
  - **Maintenance**
  - **Engineering & facilities management**
  - **Administrative**
  - **Billing**
  - **Volunteer personnel**

Direct Care Workers

- Director Care Workers: Include only those staff who are employees of the facility and provide direct hands-on personal care services or direct hands on supervised personal care to residents.

- Direct Care Workers **are included** in the application of the guidance we are discussing today.

Direct Care Workers Continued...

- Personal care: Personal assistance provided by a licensee or employee of a licensee to a resident who requires assistance with dressing, personal hygiene, grooming, maintenance of a medication schedule (administration of medication) as directed and supervised by the resident's physician, or the development of those personal and social skills required to live in the least restrictive environment.
- Supervised personal care: Guidance (cuing, prompting, reminding) or assistance with eating, toileting, bathing, grooming, dressing, transferring, mobility, medication management, reminding resident of important activities to be carried out, assisting a resident to keep appointments. This does not mean supervising other staff performing hands on assistance.

Evaluating Healthcare Personnel with Symptoms of SARS-CoV-2 Infection

- Prioritize HCP for viral testing with nucleic acid or antigen detection assays.
  - This applies to HCP with even mild symptoms of COVID-19.

- For HCP who were initially suspected of having COVID-19 but following evaluation another diagnosis is suspected or confirmed, return to work decisions should be based on their other suspected or confirmed diagnoses.

Return to Work Criteria

Return to Work Criteria for HCP with SARS-CoV-2 Infection: Conventional Strategies

- **Conventional staffing strategy**: No anticipated or current staffing shortage.

Return to Work Criteria for HCP with SARS-CoV-2 Infection: Conventional Strategies

- **HCP with mild to moderate illness who are *not* moderately to severely immunocompromised:**
  - At least 7 days, if a negative antigen or NAAT is obtained within 48 hours prior to returning to work (or 10 days if testing is not performed or if a positive test at day 5-7) have passed *since symptoms first appeared,* **and**
  - At least 24 hours have passed *since last fever* without the use of fever-reducing medications, **and**
  - Symptoms (e.g., cough, shortness of breath) have improved.

Return to Work Criteria for HCP with SARS-CoV-2 Infection: Conventional Strategies

- **HCP who were asymptomatic throughout their infection and are *not* moderately to severely immunocompromised:**
  - At least 7 days if a negative antigen or NAAT is obtained within 48 hours prior to returning to work (or 10 days if testing is not performed or a positive test at day 5-7) have passed since the date of their first positive viral test.

Return to Work Criteria for HCP with SARS-CoV-2 Infection: Conventional Strategies

- **HCP with severe to critical illness and are *not* moderately to severely immunocompromised:**
  - In general, when 20 days have passed *since symptoms first appeared,* **and**
  - At least 24 hours have passed *since last fever* without the use of fever-reducing medications, **and**
  - Symptoms (e.g., cough, shortness of breath) have improved.

Return to Work Criteria for HCP with SARS-CoV-2 Infection: Conventional Strategies

- **HCP who are moderately to severely immunocompromised** may produce replication-competent virus beyond 20 days after symptom onset or, for those who were asymptomatic throughout their infection, the date of their first positive viral test.
  - Use of a test-based strategy and consultation with an infectious disease specialist or other expert and an occupational health specialist is recommended to determine when these HCP may return to work.

Mitigation Strategies for Staffing Shortages

- Maintaining appropriate staffing in healthcare facilities is essential to providing a safe work environment for healthcare personnel and safe patient care.
  - Protecting the health and safety of healthcare personnel remains critical and includes ensuring the recommended personal protective equipment (PPE) is available and that healthcare personnel are trained to use it properly.
- Mitigation strategies need to be implemented sequentially.

Work Restrictions for HCP with SARS-CoV-2 Infection

Work Restrictions for HCP With SARS-CoV-2 Infection and Exposures

HCP are considered "boosted" if they have received all COVID-19 vaccine doses, including a booster dose, as recommended by CDC. HCP are considered "vaccinated" or "unvaccinated" if they have NOT received all COVID-19 vaccine doses, including a booster dose, as recommended by CDC.

For more details, including recommendations for healthcare personnel who are immunocompromised, refer to Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2 (conventional standards) and Strategies to Mitigate Healthcare Personnel Staffing Shortages (contingency and crisis standards).

Work Restrictions for HCP With SARS-CoV-2 Infection

Vaccination Status	Conventional	Contingency	Crisis
Boosted, Vaccinated, or Unvaccinated	10 days OR 7 days with negative test†, if asymptomatic or mildly symptomatic (with improving symptoms)	5 days with/without negative test, if asymptomatic or mildly symptomatic (with improving symptoms)	No work restriction, with prioritization considerations (e.g., asymptomatic or mildly symptomatic)

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Contingency Staffing

- **Contingency staffing strategy**:
  - When staffing shortages are anticipated, healthcare facilities and employers should use contingency capacity strategies to plan and prepare for mitigating this problem.
  - This can include:
    - Adjusting staff schedules and work with staffing agencies
    - Hiring additional healthcare personnel
    - Rotating personnel to positions that support patient care activities
    - Modifications in practices for work restrictions of healthcare personnel who have had higher-risk exposures to SARS-CoV-2 or who have been infected with SARS-CoV-2

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Crisis Staffing

- **Crisis staffing strategy**:
  - Before implementing, work with your healthcare coalition and local health department to explore staffing options.
  - When contingency strategy is unable to meet criteria for safe patient care. Implement crisis capacity as **a last resort**.
  - Crisis capacity strategies should only be implemented after considering and implementing conventional and contingency capacity strategies.

Crisis Staffing

- If HCP are requested to work before meeting all criteria, they should be restricted from contact with moderately to severely immunocompromised patients (e.g., transplant, hematology-oncology) and facilities should consider prioritizing their duties in the following order:
  1. If not already done, allow HCP with suspected or confirmed SARS-CoV-2 infection to perform job duties where they do not interact with others (e.g., patients or other HCP), such as in telemedicine services.
  2. Allow HCP with confirmed SARS-CoV-2 infection to provide direct care only for patients with confirmed SARS-CoV-2 infection, preferably in a cohort setting.
  3. Allow HCP with confirmed SARS-CoV-2 infection to provide direct care only for patients with suspected SARS-CoV-2 infection.
  4. As a last resort, allow HCP with confirmed SARS-CoV-2 infection to provide direct care for patients *without* suspected or confirmed SARS-CoV-2 infection.
     - If this is being considered, this should be used only as a bridge to longer term strategies that do not involve care of uninfected patients by potentially infectious HCP. Strict adherence to all other recommended infection prevention and control measures (e.g., use of respirator or well-fitting facemask for source control) is essential.

Healthcare Personnel Exposures

HCP Exposure

High Risk Exposure: HCP who had prolonged close contact with a patient, visitor, or HCP with confirmed SARS-CoV-2 infection.

PPE Used:

- HCP not wearing a respirator (or if wearing a facemask, the person with SARS-CoV-2 infection was not wearing a cloth mask or facemask)
- HCP not wearing eye protection if the person with SARS-CoV-2 infection was not wearing a cloth mask or facemask
- HCP not wearing all recommended PPE (i.e., gown, gloves, eye protection, respirator) while performing an aerosol-generating procedure

Work Restrictions for Asymptomatic HCP with Exposures

Work Restrictions for Asymptomatic HCP with Exposures

Vaccination Status	Conventional	Contingency	Crisis
Boosted	No work restrictions, with negative test on days 2‡ and 5–7	No work restrictions	No work restrictions
Vaccinated or Unvaccinated, even if within 90 days of prior infection	10 days OR 7 days with negative test	No work restriction with negative tests on days 1‡, 2, 3, & 5–7	No work restrictions (test if possible)

†Negative test result within 48 hours before returning to work

‡For calculating day of test: 1) for those with infection consider day of symptom onset (or first positive test if asymptomatic) as day 0; 2) for those with exposure consider day of exposure as day 0

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Resident Isolation

- Isolation duration for specific residents should be followed:
  - Asymptomatic resident: 10 days after the first positive test result.
  - Immunocompetent resident: 10 days after symptom onset, resolution of fever for at least 24 hours, without the use of fever reducing medications, and with improvement of other symptoms.
  - Severely ill or severely immunocompromised: Up to 20 days in consultation with an infectious disease expert. A test-based strategy can be used for these individuals.
- Please refer to Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes | CDC for more information.

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IPRAT

Infection Prevention Resource and Assessment Team

COVID-19 Testing Collection and Coordination Team Update

NATASHA RADKE, MPH

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

JANUARY 12, 2022

MDHHS COVID-19 Testing Recommendations

- Due to rising cases throughout the state, the Michigan Department of Health and Human Services (MDHHS) strongly encourages you to use testing supplies to test not only residents and staff, but ALL INDIVIDUALS entering the facility, including visitors, maintenance workers, and contractors.

- MDHHS recommends that all non-employees entering your facility, regardless of vaccination status, are tested for COVID-19 before entry in the facility each day they visit the facility.

- Testing provides an additional layer of protection for everyone, especially our most vulnerable and high-risk residents.

MDHHS COVID-19 Test Availability

Who qualifies to receive tests through MDHHS?

- All HFA, AFC, SNF, ALF, and Hospice facilities may request tests from MDHHS.

Who qualifies to receive testing and support through MDHHS?

- Licensed 13+ facilities may request testing and vendor support.

Current supply: Due to increase demand, there are current testing supply constraints. MDHHS asks that orders be placed for no more than a 1-month supply at a time.

Ordering Guidelines

Test orders must be placed by using the **Testing and Support Ordering Form.**

Orders should be placed for no more than a 1-month supply at a time.

Expiration dates: Please use the lot number on the box of tests to identify the correct expiration date (lot numbers on individual tests are used by Abbott internally).

Shipment

Please allow up to **two weeks** for processing and shipment.

(Tests are typically shipped out within 1-4 days of the order being received, but please allow up to two weeks for shipment).

If an outbreak is occurring and tests are needed immediately, this should be indicated on the ordering form, and the request will be elevated.

Reporting

Reporting remains a federal requirement.

All tests administered must be reported daily through the MDHHS antigen reporting portal, found here: Michigan Antigen Testing Results. LHDs have access to this reporting data through MDSS.

If your facility is federally mandated to report through the National Healthcare Safety Network (NHSN), you **DO NOT** need to report through the Michigan Antigen Testing Results portal as well. Reporting through NHSN meets both state and federal reporting requirements.

CLIA Waivers

A Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver (CoW) is a certification that allows a facility to legally examine a person through waived tests in order to assess health, make a diagnosis or determine treatment.

The antigen tests provided by MDHHS require any facility that is administering these tests to obtain a CLIA waiver in order to legally preform the test.

No specific credentials are required to obtain a CLIA Waiver. The testing site administering the test must follow the guidelines specified under the Centers for Medicare and Medicaid Services (CMS).

To apply for a CLIA waiver, complete all sections of the CMS 116 CLIA Application.

Completed application can be submitted to:

LARA-BCHS-DHHS-COW-TESTING-APPLICATION@michigan.gov.

Questions?

MDHHS-COVIDTestingSupport@michigan.gov

Emergence of Omicron

Jan 12, 2022

Marty K. Soehnlen, PhD, MPH, PHLD(ABB)
MDHHS, Bureau of Laboratories
Director, Division of Infectious Disease

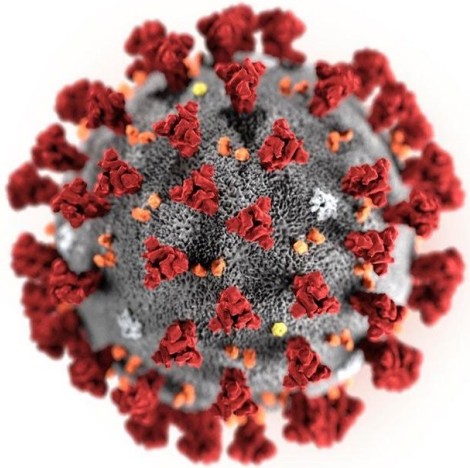
History of COVID – Outbreak Origins

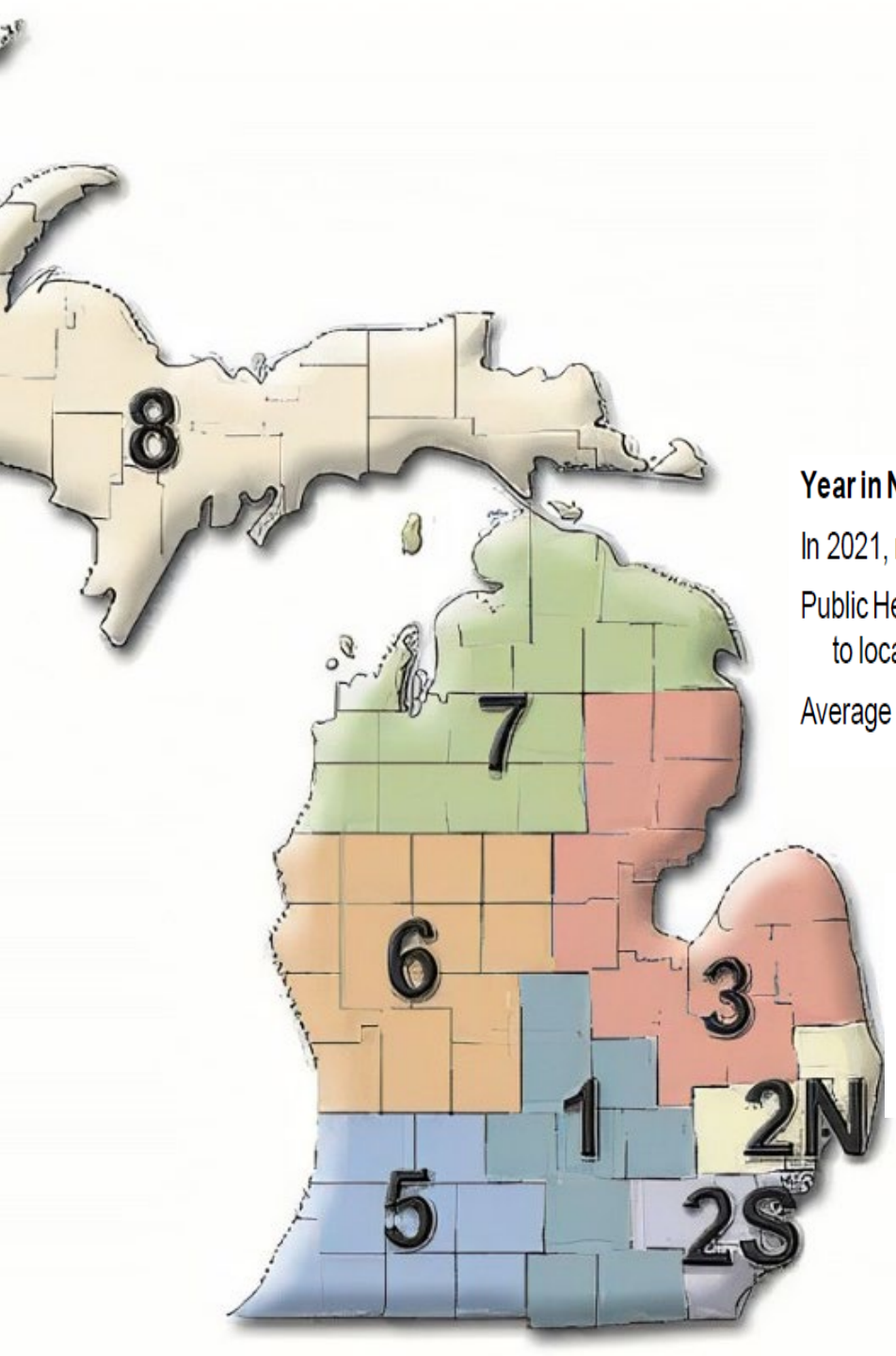
November 17, 2019: The first case, a 55-year-old, may have been known but not publicly acknowledged, according to the South China Morning Post, which tried to track the virus back to patient zero.

December 10, 2019: A 57-year-old seafood merchant in Wuhan's Huanan Seafood Wholesale Market began feeling ill and 8-days later, is hospitalized.

December 31, 2019: China informs the World Health Organization it has detected unusual pneumonia cases in Wuhan, which has a population of 11 million. China says that the cause is unknown.

March 10, 2020: First cases identified in Michigan





Epidemiology of the Pandemic

Year in Numbers

In 2021, nearly 1 in 10 Michiganders were reported with COVID-19, and more than 1 in 1,000 Michiganders died from COVID-19

Public Health responded with over 14.0 million COVID vaccines administrated, 4.6 million rapid antigen tests distributed, and $275 million allocated to local health departments to support COVID-19 efforts

Average mobility and encounter density are both above pre-pandemic baseline levels

In October, unvaccinated persons had:

5X
Risk of Testing Positive for COVID-19

AND

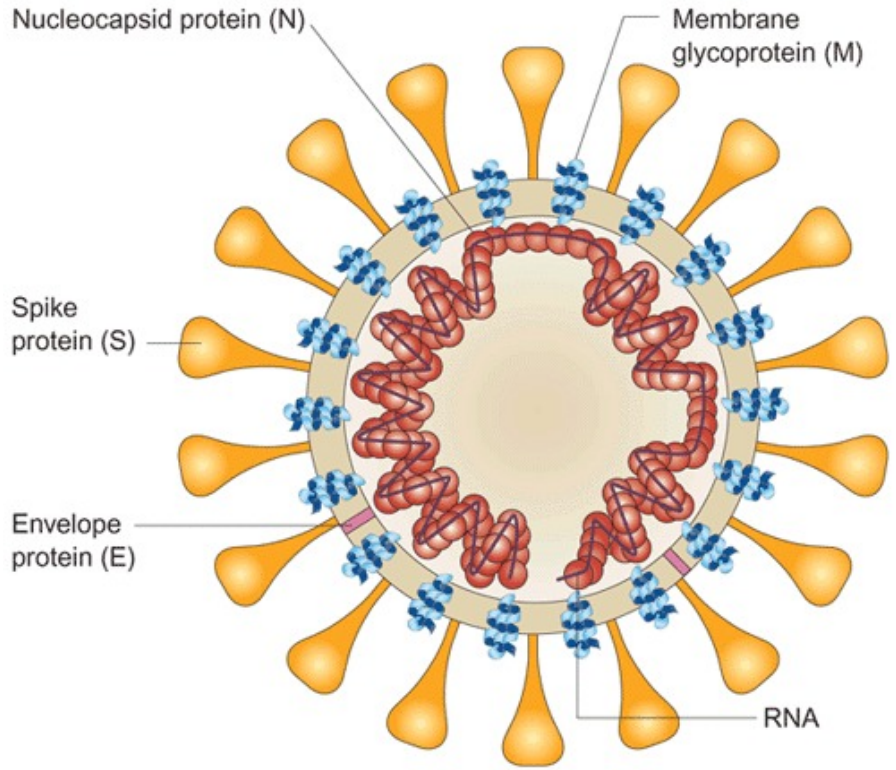
14X
Risk of Dying from COVID-19

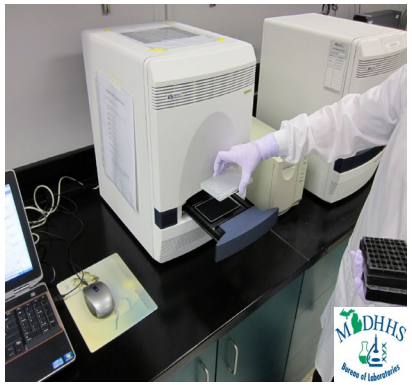
compared to fully vaccinated persons

Types of Tests

Types of COVID Tests

- Real-time reverse transcription PCR
- Rapid direct detection iso-thermal PCR
- Rapid Antigen Detection
- Serology



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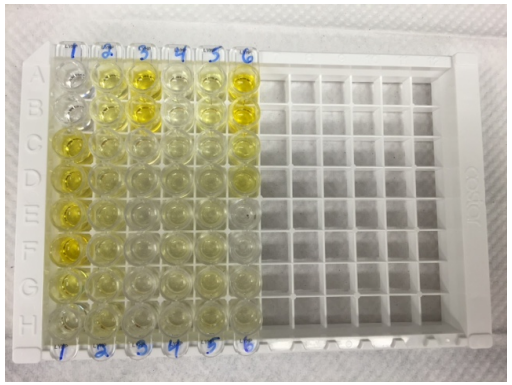
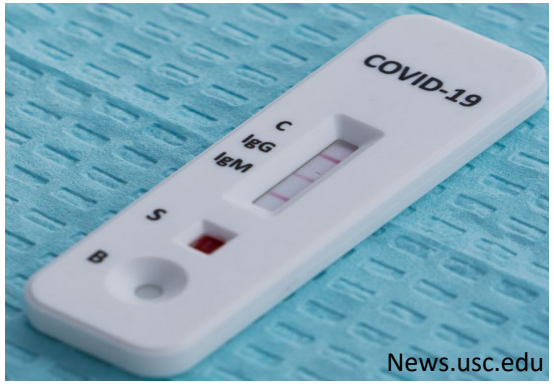




News.usc.edu

The Current Testing Market

(as of December 2021)

All Available

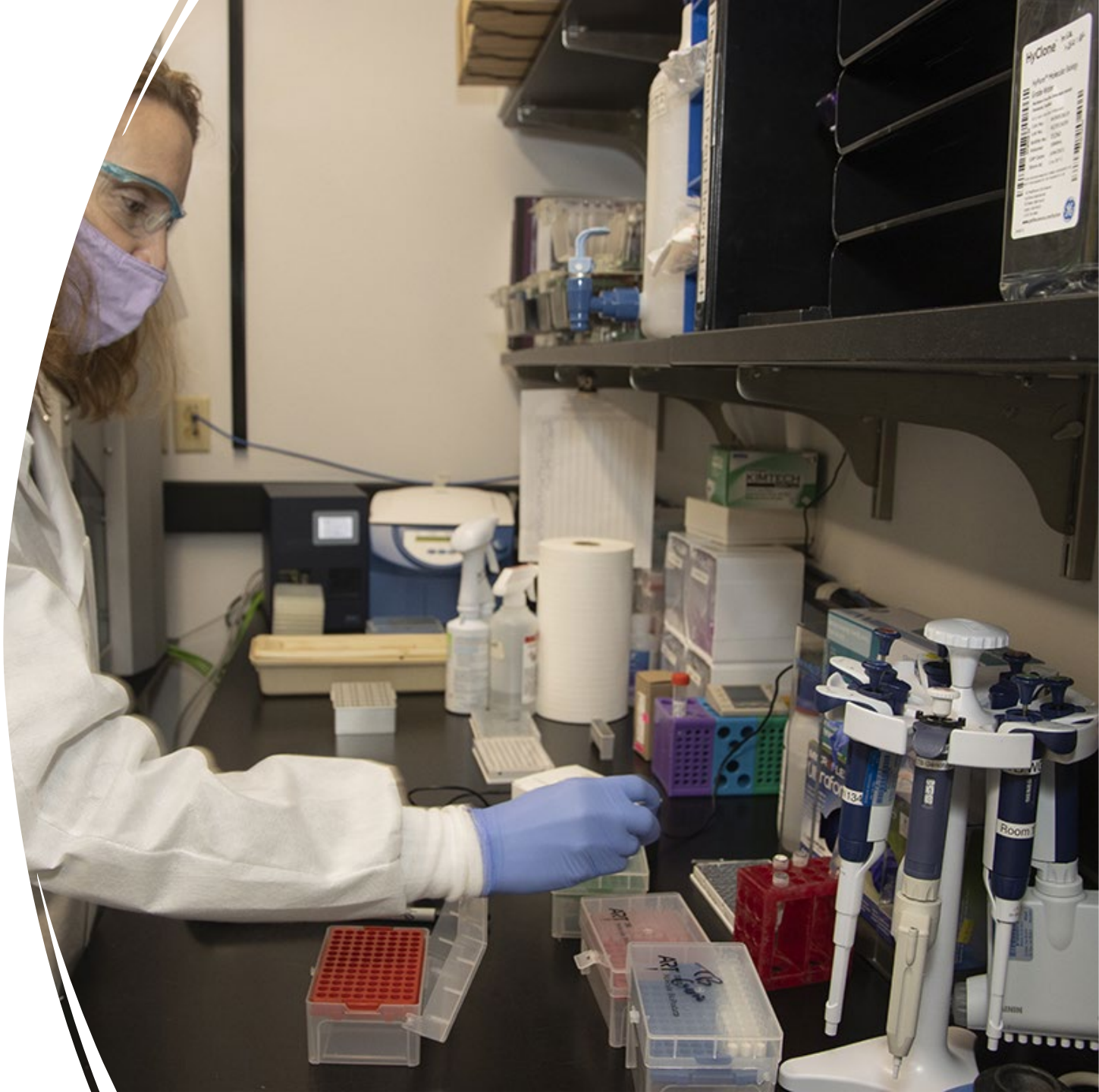
- 293 FDA EUA molecular tests and sample collection devices
- 90 Antibody and immune response tests
- 40 Antigen tests

Style

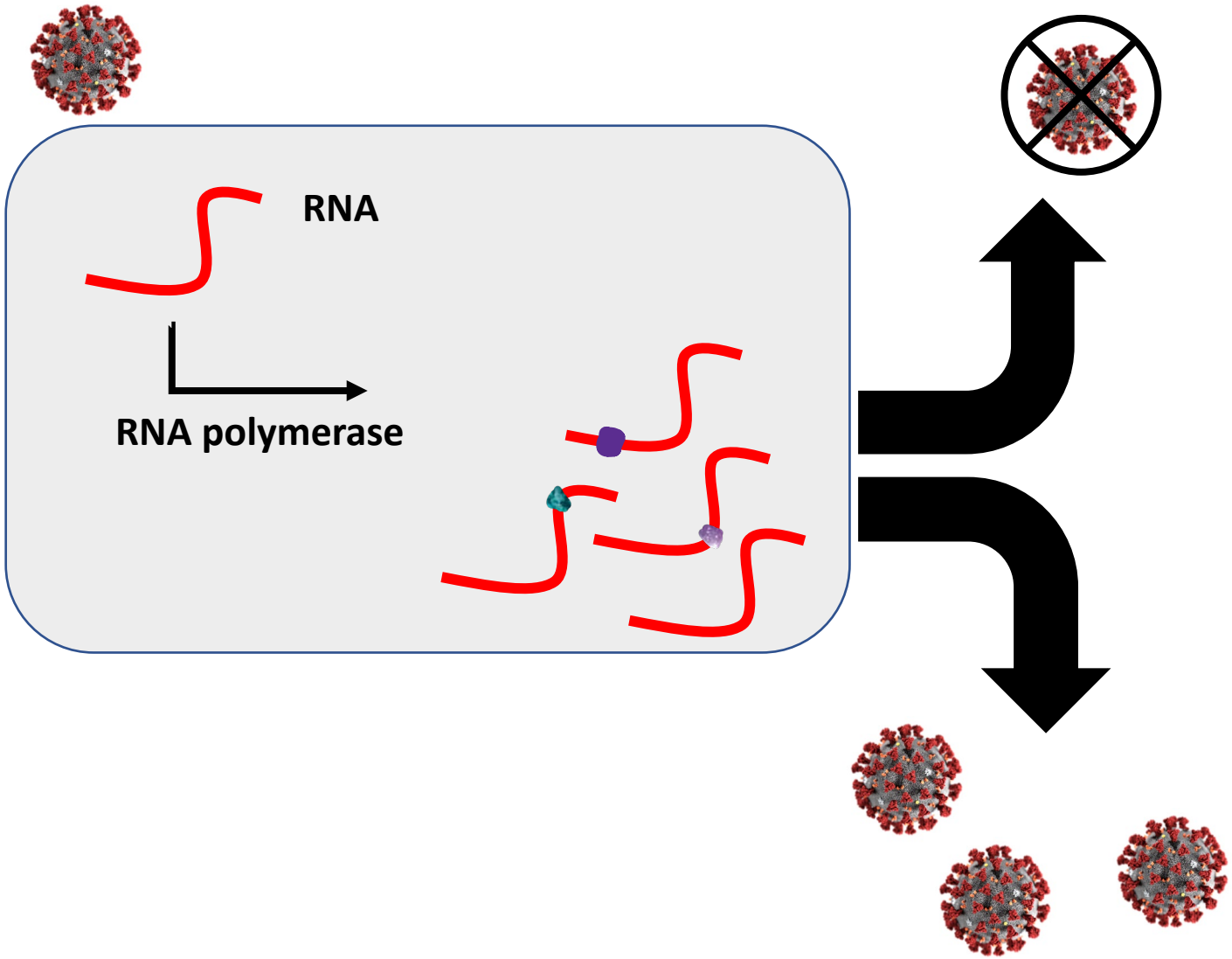
- 66 molecular and 1 antibody test are authorized for at-home collected samples
- 1 molecular for Rx at-home test
- 3 Antigen tests for Rx at-home tests
- 11 Antigen over-the-counter (OTC) tests
- 3 molecular OTC tests

Other Test Considerations

- Saliva testing
- Pooled Samples
  - Up to 3, up to 5, or up to 10
  - Media vs swab pools
- Serial testing options
- An available 510k pathway has been established



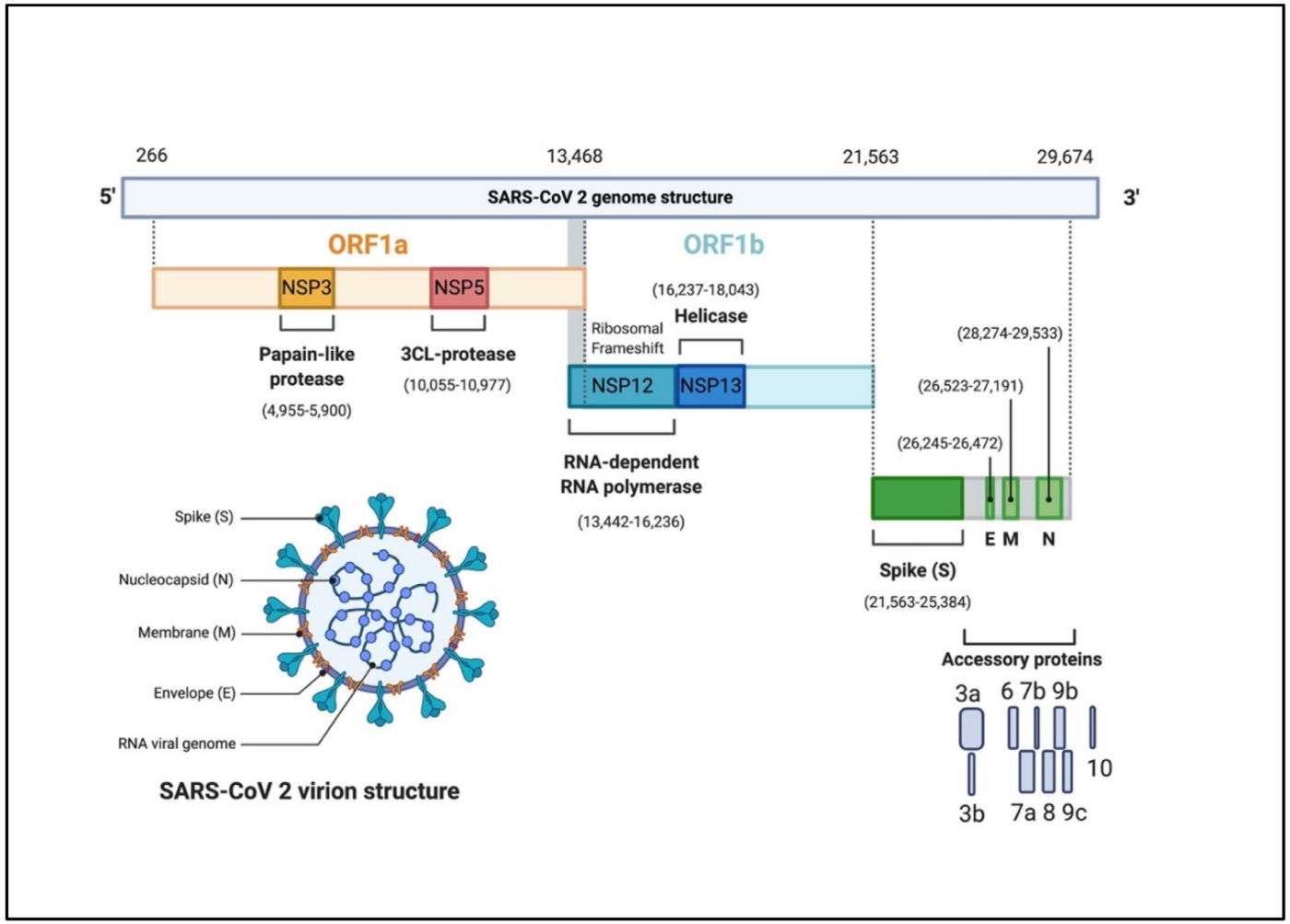
SARS-CoV-2 Whole Genome Sequencing



- RNA viruses infect human (and other eukaryotic) cells because they lack the ability to replicate themselves
- The RNA polymerase is highly error prone and can result in mutations in the genome
- Most mutations will not affect the virus due to:
  - Redundancy in genetic code
  - No longer viable virus
  - Slight change in protein

Genome

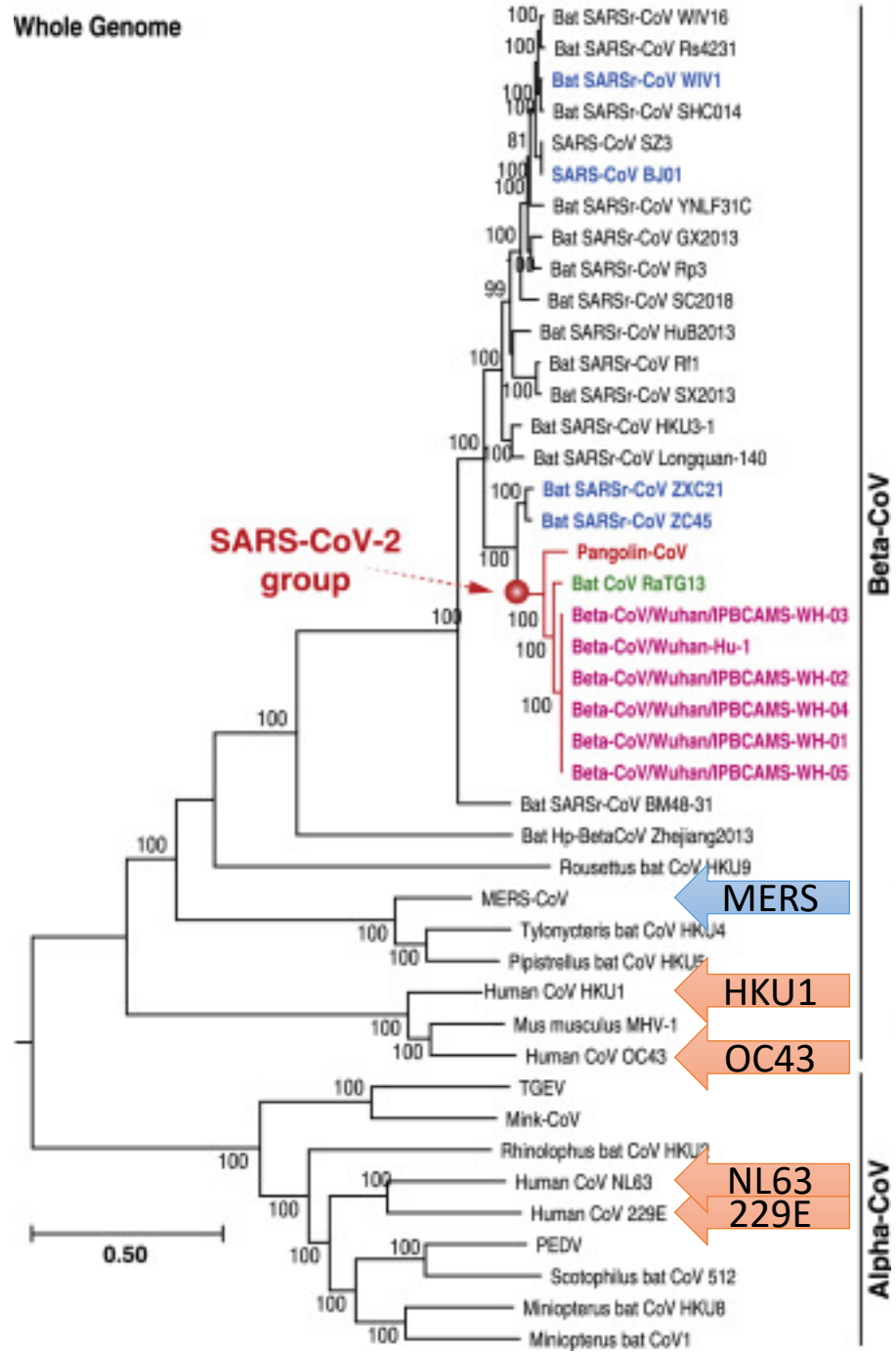
- 4 main structural proteins that are highly related based on sequence similarity to SARS-CoV-2 and MERS
  - S: spike
  - N: Nucleocapsid
  - E: Envelope
  - M: Membrane
- 11 protein coding genes and 12 expressed proteins
- ORF1a and ORF1b – replication and protein modification



Alanagreh et al (2020) Pathogens

SARS-CoV-2 Genetic Origins

- Origin is hypothesized to be bat or pangolin coronavirus
- 89% sequence identity to other coronaviruses
- Common cold coronaviruses highlighted in green
- Uniqueness made it hard to identify genomic material for reference and positive control at the start of the pandemic

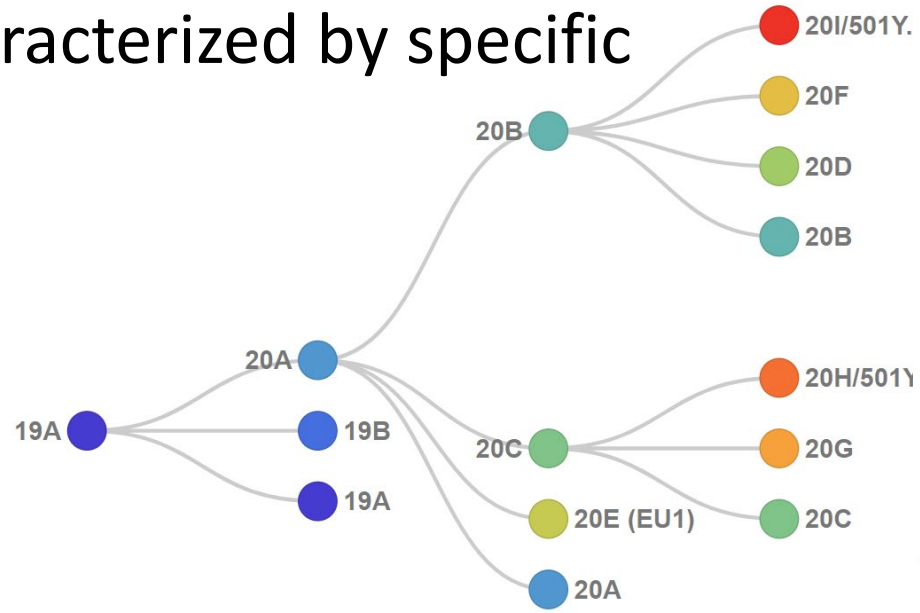


Adapted from Zhang et al (2020) Current Biology.

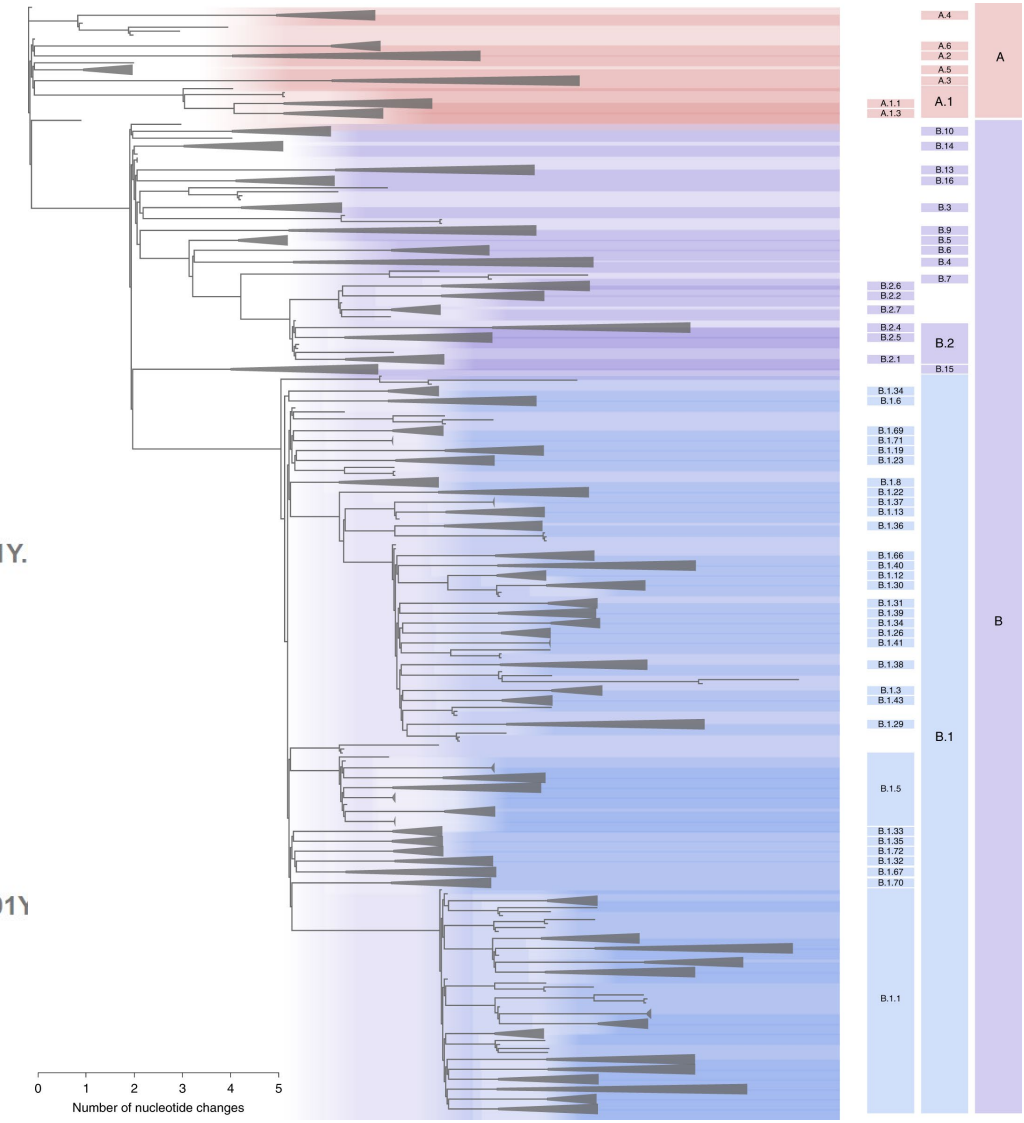
Clades (Typing)

- Differences in clade classification may have varying levels of discrimination among isolates

- Each clade is characterized by specific mutations



Nextclade/Nextstrain



Pangolin

CMS Guidance for SARS-CoV-2 Sequencing

- De-identified samples
- Report to Public Health only
- Validated (LDT) test

- Reports do not go back to patients or providers for clinical care use unless under LDT

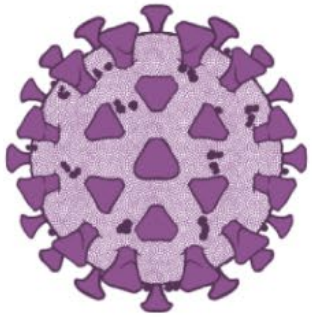
CLIA SARS-CoV-2 Variant Testing Frequently Asked Question
Date: 3/19/2021

Does a facility that performs surveillance testing to identify SARS- CoV-2 genetic variants need a CLIA certificate?

CMS is temporarily exercising enforcement discretion under CLIA for SARS-CoV-2 genetic variant testing on identified specimens in which patient-specific results are reported to State or local Public Health Departments. As defined by Centers for Disease Control and Prevention (CDC), public health surveillance testing for SARS-CoV-2 is intended to monitor community- or population-level outbreaks of disease, or to characterize the incidence and prevalence of disease. Public health surveillance testing is performed on de-identified specimens, and thus results are not linked to individuals. Public health surveillance testing cannot be used for individual decision-making. See CDC's Testing Strategies for SARS-CoV-2 (Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories).

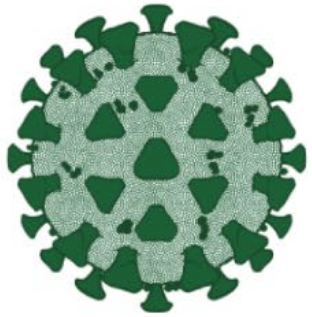
Generally, surveillance testing using sequencing technology to identify SARS-CoV-2 genetic variants can be performed in a facility that is NOT CLIA certified, provided that patient-specific results are **not** reported to (1) the individual who was tested or (2) their health care provider. If at any time a facility

Variants of Concern



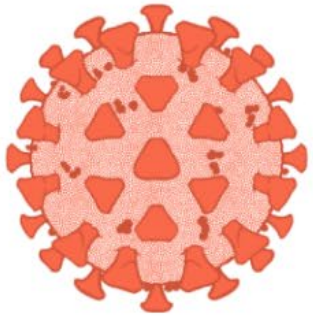
'The U.K. Variant,' B.1.1.7

- 50% more transmissible
- Likely causes more severe disease
- Vaccines are still effective



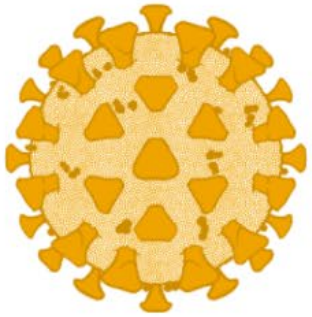
'The South Africa Variant,' B.1.351

- 50% more transmissible
- Unknown if it causes more severe disease
- Vaccines are less effective



'The Brazil Variant,' P.1

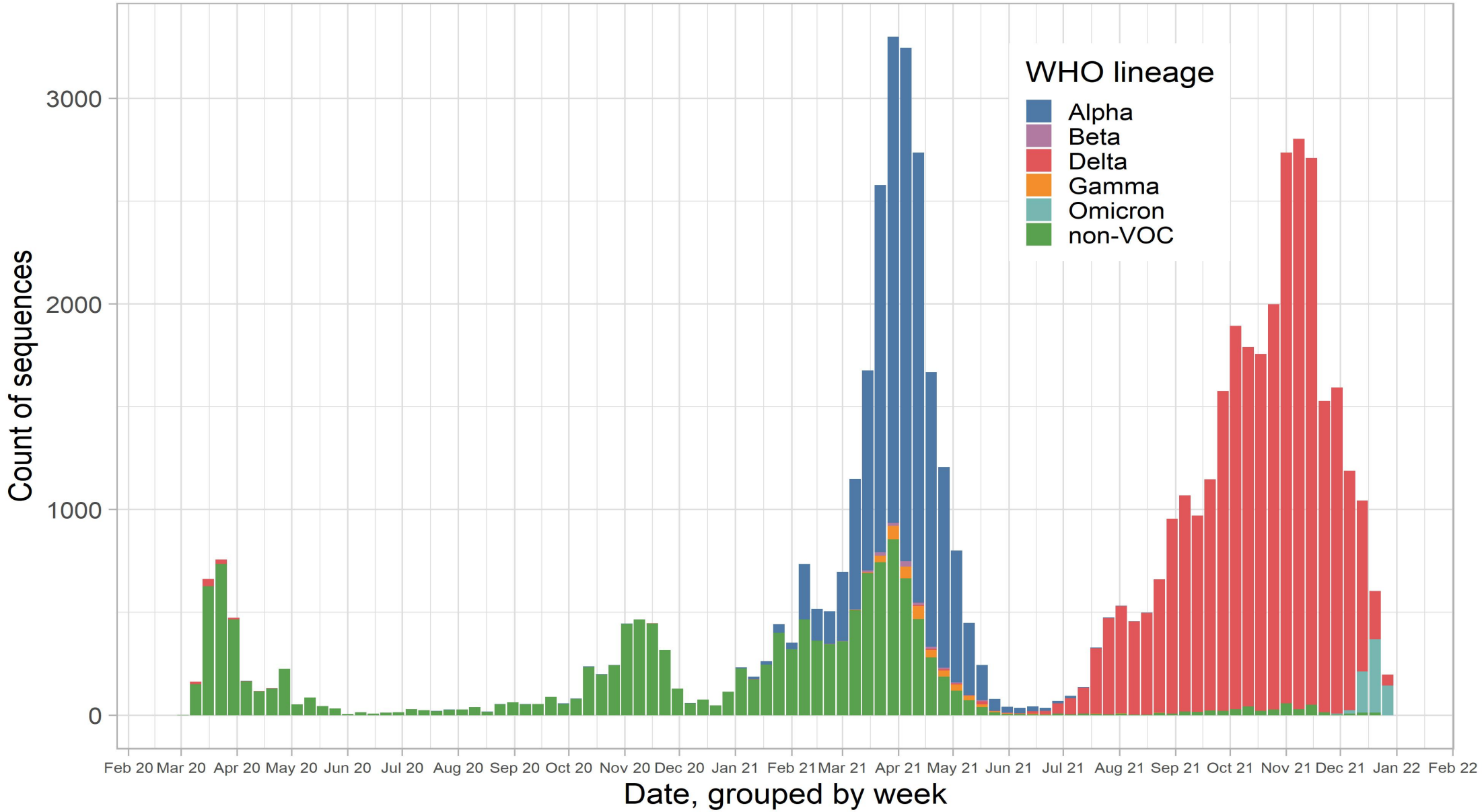
- Believed to be more transmissible, but more research needed
- Unknown if it causes more severe disease
- Vaccine efficacy is unknown



'The California Variant,' B.1.427/B.1.429

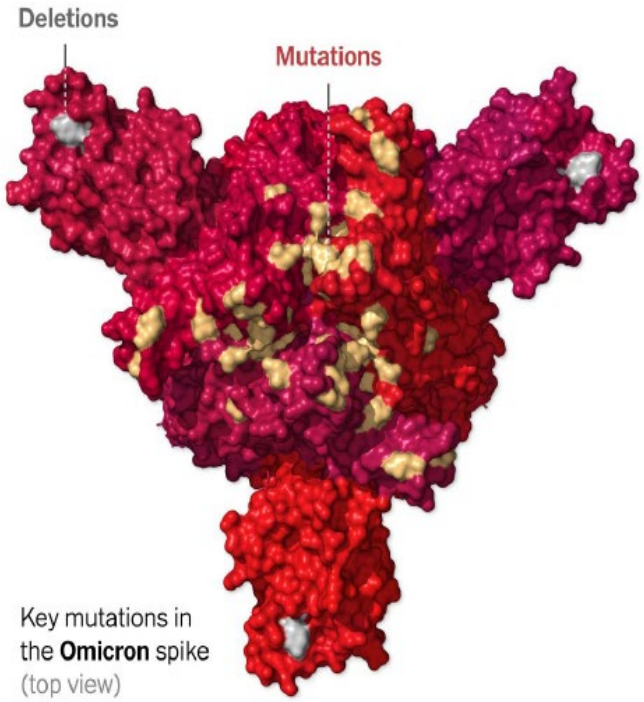
- 20% more transmissible
- May cause more severe disease, but more research needed
- Vaccines are likely still effective

Changes of Lineage over Time



Omicron (B1.1.529)

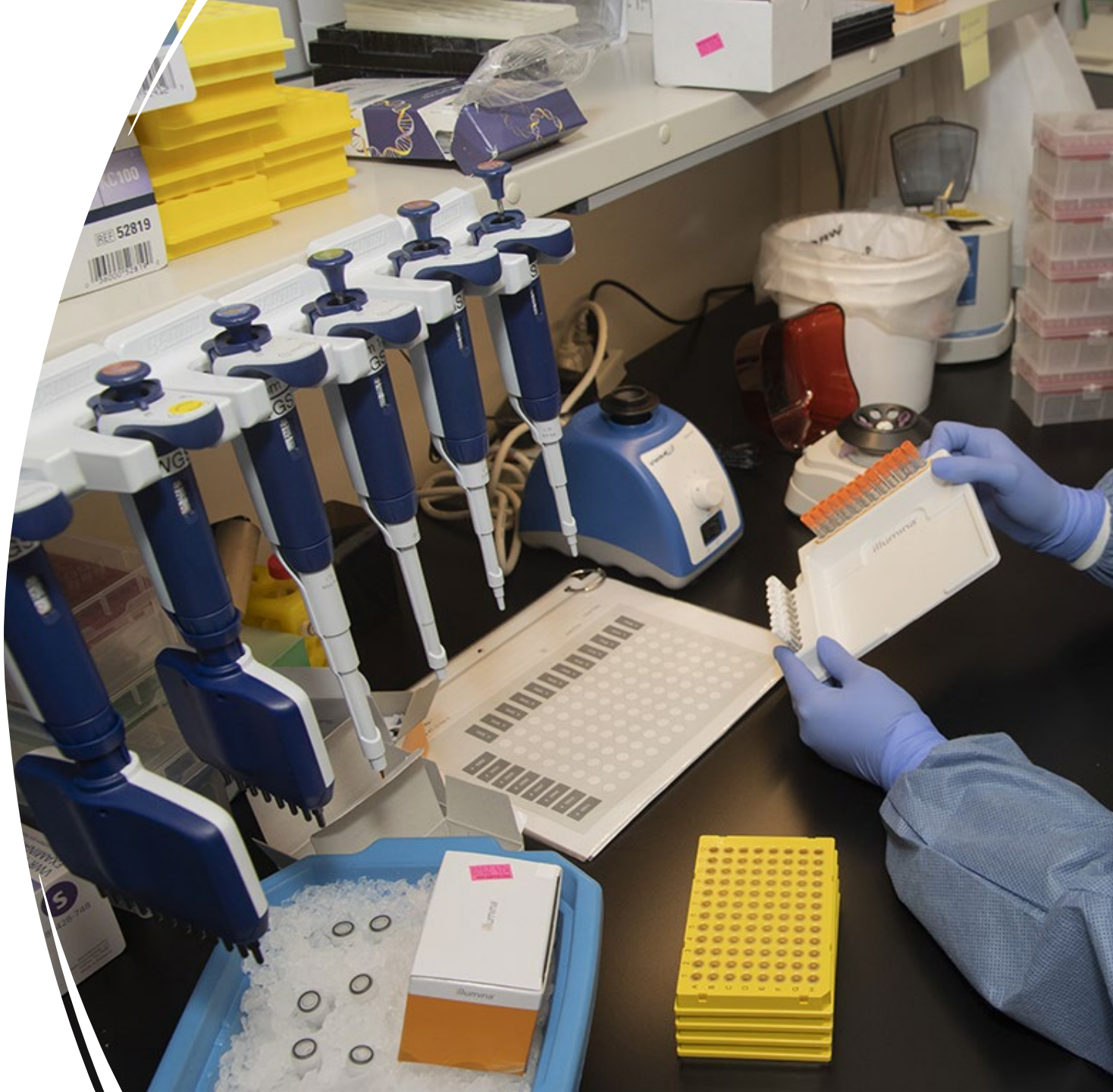
- 52 mutations; 32 present to identify; 36 mutations in the spike protein
- Spike protein mutations found in other Variants of Concern believed to lead to higher transmissibility
  - D614G, N501Y, K471N



	Omicron
Transmissibility	Likely increased
Severity	Mild illness reported in young, healthy individuals. Severity will need to be assessed on a population basis.
Prior infection	Possible increased risk of reinfection
Effectiveness of vaccines	Studies underway. Current vaccines protective against infection, severe disease and death from widely circulating strains.
Effectiveness of tests	PCR detects infection. Antigen manufacturers have released statements on test effectiveness.
Effectiveness of therapeutics	Steroids and IL6 receptor blockers still useful in severe COVID-19. Studies needed on mAB and other antivirals.

Omicron's Arrival

- Nov 23rd – S. Africa sequences new lineage B.1.1.529 with announcement of WHO on Nov 26th as a VOC
- Nov 29th – Cases confirmed or presumptive in Canada, Europe, Africa, Asia, Australia, and the Middle East
- Dec 1st – 1st US confirmed case announced by CDC out of California
- Dec 2nd – MN announces confirmed case in domestic traveler



Transmission of Omicron

- The Omicron variant likely will spread more easily than the original SARS-CoV-2 virus
- Omicron spreads compared to Delta remains unknown
- CDC expects that anyone with Omicron infection can spread the virus to others, even if they are vaccinated or don't have symptoms
- **2.7 to 3.7 times more infectious than Delta variant**

Disease Severity

- More data are needed to know if Omicron infections, and especially reinfections and breakthrough infections in people who are fully vaccinated, cause more severe illness or death than infection with other variants.
- The current limited and preliminary evidence suggests that Omicron has a less severe clinical presentation.

Vaccine Efficacy

- Current vaccines are expected to protect against severe illness, hospitalizations, and deaths due to infection with the Omicron variant.
- Preliminary data from UK and Denmark: A booster dose confers a stronger protection against symptomatic disease due to the Omicron VOC compared to two doses of vaccine.
- Information on the extent and duration of viral shedding from vaccinated individuals infected with Omicron VOC is currently missing or very preliminary.

References/Recommended Reading

https://www.michigan.gov/coronavirus

In Vitro Diagnostics EUAs | FDA

MI COVID response Data and modeling update (michigan.gov)

112921_APHL_CDC_COVID19_National_PHL_Call_Notes.pdf

SARS-CoV-2 Variant Classifications and Definitions (cdc.gov)

Questions or Comments

SoehnlenM@Michigan.gov

What's new in COVID-19 Treatment?

Wendy Snyder MSN, RN

Healthcare Preparedness Program

Division of Emergency Preparedness and Response (DEPR)

Bureau of EMS, Trauma, and Preparedness (BETP)

Michigan Department of Health and Human Services (MDHHS)

Review: Monoclonal Antibodies (mAb)

- Given to non-hospitalized high-risk residents as soon as possible after positive viral testing for COVID-19 and within 10 days of symptom onset
- May improve symptoms and reduce risk of hospitalizations and death associated with COVID-19
- May also be used following exposure to COVID-19 for some high-risk individuals
- **Not a substitute for vaccination.**

What Are Monoclonal Antibodies?

- Proteins developed in a laboratory
- Act like natural antibodies – attack and neutralize virus
- Administered either by IV or through subcutaneous injection by a health care provider
- Bamlanivimab, etesevimab, sotrovimab, REGEN-COV
    - Currently, with the prevalence of OMICRON variant, sotrovimab is the preferred mAb, as it is the most effective treatment against OMICRON

Who Qualifies for Monoclonal Antibody Treatment?

- High risk individuals who have tested positive and who have had symptoms for less than 10 days
  - Are older in age (e.g., age > 65 years of age)
  - Are obese (Body Mass Index >35) or are overweight
  - Are pregnant
  - Have chronic kidney disease, diabetes, or a condition that weakens the immune system
  - Have immunosuppressive disease or are receiving immunosuppressive treatment
  - Have heart disease, high blood pressure, or chronic lung disease
  - Other medical conditions or factors that may place the resident at high risk for progression to severe COVID-19

New Monoclonal Antibody Medication for the Treatment of COVID-19: Evusheld

- On 12/08/2021, the FDA issued an Emergency Use Authorization (EUA) for the medication Evusheld (tixagevimab/cilgavimab). Evusheld is a monoclonal antibody (mAb) therapy used for prevention, also known as pre-exposure prophylaxis (PrEP) of COVID-19 in adults and children >12 years and weighing at least 40kg.
- A physician will determine whether Evusheld is an appropriate treatment and when an individual will receive the medication. For those who have received a COVID-19 vaccine, Evusheld may be given two weeks following vaccination.

How Does Evusheld Work?

- Unlike other mAb medications use for COVID-19, Evusheld is not a treatment for COVID-19. Instead, it is given as a preventative medication.
- Evusheld keeps the SARS-CoV-2 virus from entering the cells of the body, preventing illness.

Who is a Candidate for Evusheld?

- Have not had known exposure to someone who has COVID-19
- Are moderate to severely immunocompromised, and MAY not develop an adequate immune response to COVID-19 vaccination
- Are undergoing chemotherapy or other treatments that may depress the immune system
- Have undergone organ transplant and are taking immunosuppressant therapy
- Have undergone CAR-T-cell or stem cell transplant within two years
- Have moderate to severe immunocompromise due to a medical condition such as DiGeorge Syndrome, Wiskott-Aldrich syndrome, etc.
- Have advanced or untreated HIV infection (CD4 cell counts of <200; AIDS-defining illness, or symptomatic HIV)
- Are being treated with high dose corticosteroids such as prednisone

How is Evusheld Administered and What are the Side Effects?

- A physician will determine whether an individual is eligible for Evusheld, as well as when the medication should be given
- Evusheld is given by injection
- Repeat injections should be given 6 months later for continued prevention of COVID-19 while the virus remains in circulation
- Common side effects may include hypersensitivity to the medication, bleeding from the injection site, headache, fatigue, and nausea

New Antiviral Medications for the Treatment of COVID-19: PAXLOVID and Molnupiravir

22 Dec. 2021	23 Dec. 2021
• the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the medication PAXLOVID for the treatment of mild-to-moderate COVID 19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death	• On December 23, 2021, the FDA issued an EUA for molnupiravir (MERCK) for the treatment of mild-to-moderate COVID 19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death

New Antiviral Medications for the Treatment of COVID-19: How Do They Work?

PAXLOVID

- PAXLOVID keeps the SARS-CoV-2 virus from copying itself within the cells, which neutralizes the virus

Molnupiravir

- If taken within 5 days of symptom onset, Molnupiravir works by causing the SARS-CoV-2 virus to mutate, which causes the virus to become unable to copy itself.
- When this happens, the virus becomes neutralized.

Who is Eligible for Antivirals ?

PAXLOVID

- PAXLOVID is an oral antiviral medication used for treating mild-to-moderate COVID-19 in adults and pediatric patients 12 years of age and older weighing at least 40 kg and who are at high risk for severe COVID-19, including hospitalization or death

Molnupiravir

- Adults who are at high risk for progression to severe COVID-19, including hospitalization of death
- Adults who have been having symptoms for less than 5 days
- Only someone who cannot take alternative COVID-19 medications is eligible for molnupiravir

How Are Antiviral Medications Given?

How is PAXLOVID given?

- Available by prescription only
- PAXLOVID is taken orally twice daily for 5 days
- If you feel worse, or do not feel better after 5 days, contact your physician
- Side effects may include liver problems, resistance to HIV medications, altered sense of taste, diarrhea, hypertension, and muscle aches

How is Molnupiravir given?

- Available by prescription only
- Molnupiravir is taken orally twice daily for 5 days, with or without food.
- Completion of the full 5-day treatment is recommended
- Common side effects include diarrhea, nausea, and dizziness

Supply vs. Demand

- To ensure equity, as COVID-19 infections continue to rise, the demand for COVID-19 medications has increased, causing a decrease in supply.
- As a result of the imbalance between supply and demand, the Michigan Department of Health and Human Services (MDHHS) has developed Priority Eligibility Criteria for administration of oral antivirals (paxlovid, molnupiravir) and monoclonal antibody medications (bamlanivimab/etesevimab, REGEN-COV, sotrovimab).
- Having prioritization criteria means medication administration is done based on age, medical history, and the possibility of progression to hospitalization due to COVID-19. If a resident begins having symptoms of COVID-19, and test positive, contact his/her physician immediately to determine whether the resident is a candidate for COVID-19 treatment.

Resources

- If you need assistance or have questions
  - Visit Michigan.gov/COVIDtherapy for more information.
  - Email mdhhs-covid-therapies@michigan.gov for monoclonal antibody questions and support

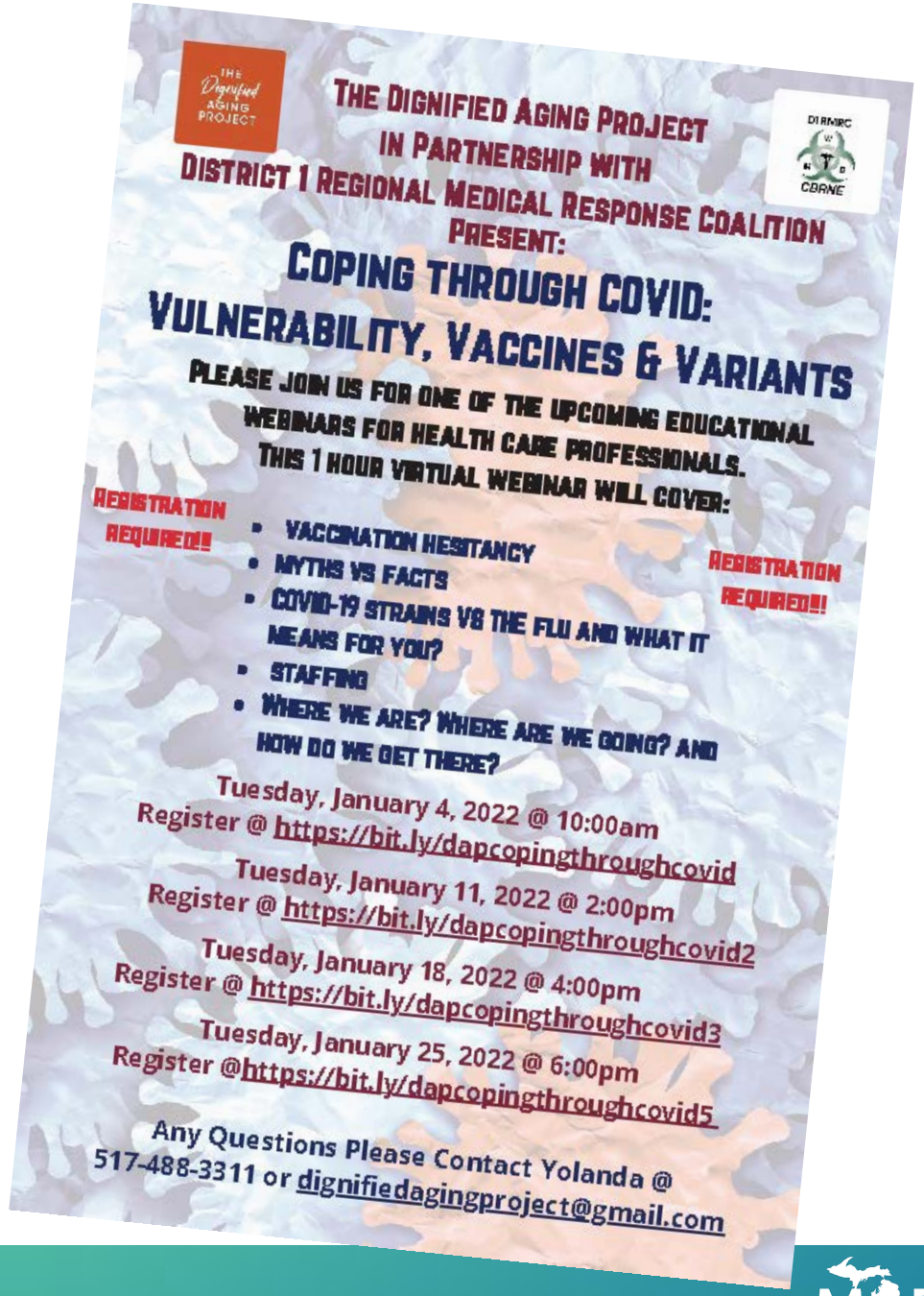
Dignified Aging Project
Webinar Series

COPING THROUGH COVID:
VULNERABILITY, VACCINES & VARIANTS

Two webinars left in the series:

Tuesday, January 18 at 4:00 p.m.
REGISTRATION
https://bit.ly/dapcopingthroughcovid3

Tuesday, January 25 at 6:00 p.m.
REGISTRATION
https://dapcopingthroughcovid5



Reminder

*** Our next presentation will be Wednesday, February 9 at 2pm**

A recording of today's presentation will be sent to the groups below, and they will email it to their members.

- Community Mental Health Association of Michigan
- Michigan Assisted Living Association
- Michigan Center for Assisted Living
- Leading Age of Michigan

You can also download the slides from our presentations at Michigan.gov/Coronavirus. Click the RESOURCES tab and select "For AFC and HFA Operators." Scroll to bottom of page.

Questions on other topics can be sent to:

Staffing: MDHHS-LTCStaffing@michigan.gov

Vaccines: MDHHS-COVID-Longtermcare@Michigan.gov

Testing: MDHHS-COVIDTestingSupport@michigan.gov

Emergency Orders: MDHHS-MSA-COVID19@michigan.gov

All Other Questions:
MDHHS-COVID-AFC-HFA-Response@michigan.gov

- Subscribe to correspondence at this link: Subscribe