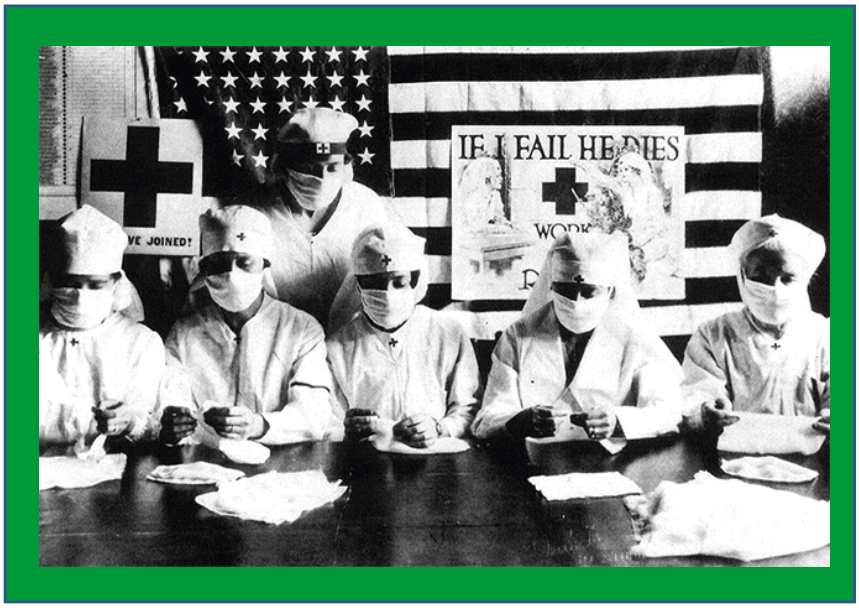


WISCONSIN DEPARTMENT OF PUBLIC INSTRUCTION

School Nurse UPDATE

#9 January 13, 2022

Greetings!

I wish I knew some good surfing lingo as we ride this current wave of COVID. It is definitely putting additional strain on all of you. I wish it were otherwise. Because this is the first newsletter since Winter Break and because of all the changes since Break and the last newsletter most of this Update is COVID related. I wish it were otherwise.

I had a meeting with those new school nurses who attended the October 2021 New School Nurse Orientation. Most of that conversation was sharing how they are dealing with the new guidelines and the continuing questions and second guessing of their recommendations. It is difficult at this moment of peak everything to find a bright spot. I do hope what I share in **my Practice Points gives you a new perspective in which to frame your work.**

As the need for PPE continues and the wearing of well-fitting masks is stressed to protect against the more easily transmitted Omicron variant of SARs-CoV2, school districts are looking for sources of masks and equipment. I am not aware of any statewide initiative at this time, but I noted **this Department of Health Services webpage where schools can ask for PPE supplies.** https://www.dhs.wisconsin.gov/covid-19/ppe.htm

We are all frustrated by the shortage of rapid antigen test kits. As noted under the DHS News, **DHS is holding off on starting a Test to Stay (TTS)** program because of this shortage.

We have received notice here that DPI staff travel will continue to be restricted to travel essential to the job until May 2, 2022. I therefore will not be able to schedule any in-person meetings or events until after that date (or later if it is extended). Like you, I long for gathering and greeting you in person – someday! Until then, "see" you at the virtual network meeting next week.

Louise

FEATURED STORIES

SAVE THE DATE

WASN Spring Conference- April 28-29, 2022- Green Bay, WI

Next DiSH- WI Session – January 19, 2022

School Nurse Network Meeting- January 18, 2022 3:30-4:30 PM (reminder link will be sent out the day prior)

DPI supports best practices/evidence-based resources but does not vet or endorse products/services. User is responsible to evaluate the resource and how it meets local needs. Some pictures courtesy of Unsplash.

DPI News

State Superintendent Issues Statement to Keep Our Children Healthy and Engaged in Learning
State Superintendent Dr. Jill Underly issued the following statement on January 10, 2022, relating to COVID-19 mitigation measures in K-12 schools.

"Earlier today, Wisconsin Chief Medical Officer Dr. Ryan Westergaard and Wisconsin State Health Officer Paula Tran sent a letter to all district and school administrators in our state. The letter addressed the current surge in COVID-19 cases and provided further resources and support to implement layered mitigation measures.

"I fully support this letter and the strategies it recommends, and I call on all district and school administrators to follow these recommendations. As the state official entrusted with the quality of Wisconsin's public education, I am proud to partner with the Department of Health Services, the state agency charged with protecting the health of all Wisconsin residents. We cannot keep our children engaged in learning if we cannot keep our children and our school staff healthy. To that end, in addition to calling on all school administrators to implement these mitigation measures, I also ask all Wisconsinites for their help in keeping our children and school staff healthy and safe. We must work together to achieve the common goal of healthy kids, healthy educators, and safe schools."

For the full statement and news release, visit https://dpi.wi.gov/news/releases/2022/underly-covid-schools-statement-dhs

We cannot keep our children engaged in learning if we cannot keep our children and our school staff healthy. To that end, in addition to calling on all school administrators to implement these mitigation measures…

2021-2022 Wisconsin School Health Award
Equitable schools create a learning environment where students are healthy, safe, engaged, supported, and challenged. To improve schools and school systems, the Wisconsin School Health Award aims to support collaborative engagement to minimize achievement gaps. In addition, the Wisconsin School Health Award is a way to recognize and celebrate schools with policies, programs, and the infrastructure to promote and sustain a healthy learning environment.
This award is LIVE! The final step, the application, is due by 3/31/2022. Follow this four-step process to register, complete and apply for the award.

Step 1: Coordinate, Review and Register
Step 2: Assess by completing the Action for Healthy Kids Assessment and the DPI Supplemental Questions
Step 3: Examine school results and create an Action Plan
Step 4: Complete application to be considered for the award

Reach out to Tacara Lovings, Tacara.Lovings@dpi.wi.gov with any questions.

DPI News

DPI's COVID-19 Infection Control and Mitigation Measures for Wisconsin Schools 2021/2022 Revised

On January 10, 2022, the COVID-19 Infection Control and Mitigation Measures for Wisconsin Schools 2021/2022 was revised and posted to the DPI COVID-19 Information for School Health Services webpage. The revised guidance is reflective of the CDC's Quarantine and Isolation (January 9, 2022), CDC's Guidance for COVID-19 Prevention in K-12 Schools (January 6, 2022), CDC's Overview of COVID-19 Isolation for K-12 Schools (January 6, 2022), CDC's Overview of COVID-19 Quarantine for K-12 Schools (January 6, 2022), CDC's Responding to COVID-19 Cases in K-12 Schools: Resources for School Administrators (January 6, 2022) and CDC's What You Should Know About COVID-19 Testing in Schools (January 6, 2022).

DHS's Guidelines for the Prevention, Investigation, and Control of COVID-19 Outbreaks in K-12 Schools in Wisconsin (August 2021) is under revision at this time. Once the DHS revision is published, the DPI guidance will be revised to include new information.

In this update DPI calls on districts to use evidence-based public health measures and that student and staff safety be the priority in decision making. The burden of contact tracing is addressed. DPI recommends installing high efficiency air filters (MERV 13 or better), and/or increasing ventilation, as a proven and safe method for removing pathogens and other contaminants with the HVAC system. Additional ventilation are resources listed.

In this update DPI calls on districts to use evidenced-based public health measures and that student and staff safety be the priority in decision making.

Act 90 (Addition to Human Growth and Development)

Recent updates to the Human Growth and Development requirements now include Act 90. The Health Educator must now also explain the process of relinquishing a newborn. Please review the statute as this requirement must be added to your Human Growth and Development instruction effective immediately.

DPI News

Recording of DHS/DPI COVID-19 Webinar for Local Public Health and School Stakeholders
The recording of the Wednesday, December 15, COVID-19 Webinar for Local Public Health and School Stakeholders, presented by the Wisconsin Department of Health Services (DHS) and the Department of Public Instruction (DPI) is posted. The recording of this webinar can be found on the DHS COVID-19 Schools webpage under "Webinars for Local Public Health and School Stakeholders."
For additional information, reference these resources and studies that were discussed by the webinar speakers.

Resources:
Dr. Ryan Westergaard, DHS Chief Medical Officer:
Online Resources

- DHS New Confirmed Cases by Date Confirmed, and 7-day Average
- Wisconsin SARS-CoV-2 Genomic Dashboard
- CDC Where Has Omicron Been Detected in the United States
- CDC COVID Data Tracker: Monitoring Variant Proportions

Dr. Jordan Mason, DHS Bureau of Communicable Diseases:
BCD Memos

- Considerations for Confirmatory Testing of COVID-19 Point-of-Care Tests
- Public Health Reporting Requirements for At-Home COVID-19 Tests

Louise Wilson, DPI School Nurse Consultant:
Online Resources

- COVID-19 Information for School Health Services
- COVID-19 Infection Control and Mitigation Measures for Wisconsin Schools 2021/2022
- Logistical Considerations for Hosting School-Located COVID-19 Vaccination Clinics for Students (11.11.21)

TRAUMA SENSITIVE SCHOOLS PROJECT '21-'22 MIDWINTER EVENT
Our virtual Trauma Sensitive Schools (TSS) Mid-winter event on February 15th from 12-2pm is now open for anyone to register, including individuals at the local or state level who are not involved in our other TSS support and offerings. This event will feature presenters Antoine Moore and Jen Leland from the "School Crisis Recovery & Renewal (SCRR) Project" on the topic of "Trauma Informed Communication."

This session is free to all participants. Due to the interactive nature of the workshop, it will **not be recorded**. Please attend live ready to participate.

We would encourage teams to attend this event together. However, participants should register individually, as that will give them access to the zoom link on their device.

We are encouraging participants to bring examples of past communications that they have created or used. This will enable them to actively engage in the learning and apply the trauma -nformed strategies to their communications going forward.

DPI News

New Mental Health and Social and Emotional Learning (SEL) Resources
Join the Wisconsin Department of Public Instruction (DPI) on **January 19, 10 – 10:45 a.m.** to learn about some new mental health and social and emotional learning (SEL) resources. From the revised Mental Health Framework, to the Stigma Reduction Toolkit, Mental Health Literacy units, an SEL Roadmap, SEL Guiding Principles, DPI's SEL Framework and Theory of Action, to various training and learning opportunities, DPI hopes to provide you with valuable tools to help you advance your wellness work with students, staff, families, and communities. Time will be available to ask questions.

Note that the webinar will be recorded, posted on our websites, and closed captioned for future viewing.

Join Zoom Meeting
https://us02web.zoom.us/j/84432334128

Meeting ID: 844 3233 4128
One tap mobile
+13017158592,,84432334128# US (Washington DC)
+13126266799,,84432334128# US (Chicago)

NASN News

Vaping Toolkit Provides Resources for Your Schools
To assist school nurses in addressing the vaping issue, NASN has assembled a toolkit of information and resources to support school nurses in implementing evidence-based programs in their schools, including planning for sustainability and building collaborations with key stakeholders to successfully engage their school communities in tackling the topic of vaping head on. Here is what's included in the toolkit:

- An Implementation Manual
- Questions and Answers about Vaping for Parents and Administrators
- Slide Deck Template: Sample presentation regarding vaping
- Learning Microburst: Applying NASN's Framework for 21st Century School Nursing Practice™ to address the vaping crisis

Toolkit access

To assist school nurses in addressing the vaping issue, NASN has assembled a toolkit of information and resources to support school nurses in implementing evidence-based programs in their schools.

DHS News

Evers Administration, DHS, DPI Remind Schools of Support, Resources Available to Help Keep Kids and Educators Safe in School as Omicron Spreads

DHS and the Evers Administration sent a letter to all public, private, and independent charter schools detailing the tools that DHS and the Department of Public Instruction (DPI) have made available to schools to help keep people safe and in school. Schools have multiple mitigation strategies available to help stop the spread of COVID-19.

We urge parents to support these approaches to keeping their children safe:

- Enrollment in the DHS School-Based Testing Program: We have secured funding to provide in-school testing through appropriate vendors as a way to help schools protect everyone in their buildings.
- Host a school-based vaccination and booster clinic during drop-off and pick-up times: All children ages 5 years and older are eligible for a COVID-19 vaccine, and all children ages 12 and older are now eligible to receive a booster. COVID-19 vaccines are safe, effective, and provide the best protection from getting seriously sick, being hospitalized, or dying from COVID-19.
- Require masks in schools: Well-fitting, multi-layered masks have been shown to restrict respiratory droplet spread, helping to reduce the spread of COVID-19.
- DHS supports the Centers for Disease Control and Prevention's (CDC) updated isolation and quarantine strategies: Students, teachers, and staff should get tested and isolate at home when they are sick, or quarantine and get tested if they have been in close contact with someone diagnosed with COVID-19. They should also wear a mask following their isolation and quarantine period. When isolation and quarantine measures are not implemented, COVID-19 can spread throughout a school and cause illness that could lead to hospitalization and death.

To learn more what parents and guardians can do to help slow the spread of COVID-19 and the Omicron variant and keep children safe in schools, see the recent DHS news release or visit the COVID-19: Healthy Kids page

DHS and the Evers Administration sent a letter to all public, private, and independent charter schools detailing the tools that DHS and the Department of Public Instruction (DPI) have made available to schools to help keep people safe and in school.

DHS News

COVID-19 Testing Support for K-12 Schools - BinaxNOW Supply Shortage Update
The nationwide shortage of BinaxNOW antigen rapid test kits combined with a sharp increase in testing demand across the country has significantly affected our ability to fulfill orders.

At this time, schools/districts that do receive BinaxNOW test kits may use them only to test teachers and staff.

Given that PCR supplies and processing capacity are plentiful, students should be tested using lab-based PCR tests that can be ordered through your school/district's vendor. The processing of PCR tests generally takes 2-3 days (heightened demand may increase this timeframe).

DHS is closely monitoring the situation and will provide more information as it becomes available.

Test to Stay Program Update
DHS supports Test to Stay Programs as an optional strategy for schools, however due to supply chain constraints, the state cannot guarantee rapid antigen tests for schools that may be interested in implementing these programs.

A survey will be issued within the next week to gather information from schools about their interest in Test to Stay programs. The data gathered will advance the State's efforts to support schools interested in implementing Test to Stay based on the best available evidence and current CDC guidance.

DHS Recommends COVID-19 Vaccine Booster Dose for Everyone Ages 12 and Older
DHS supports the Centers for Disease Control and Prevention's (CDC) recommendation that 12- to 15-year-olds should receive a single booster dose of the Pfizer COVID-19 vaccine. DHS also supports CDC's recommendations to shorten the booster interval from 6 months to 5 months for people who received the Pfizer and Moderna COVID-19 vaccines and that moderately or severely immunocompromised 5- to 11-year-olds receive an additional primary dose of vaccine 28 days after their second shot.
With the record-high level of disease transmission in Wisconsin, DHS strongly recommends that everyone who is eligible to get a booster should get one as soon as possible. The booster dose can strengthen and extend their protection against infection, serious illness, hospitalization, and death from COVID-19.

To find a COVID-19 vaccine provider in your community, visit Vaccines.gov, or call 211 or 877-947-2211. For additional information about booster doses, additional doses, and help accessing your COVID-19 vaccine record to determine when you may be recommended for a booster, visit the DHS Additional Doses and Booster Doses webpage.

2022 Joint Webinars for Public Health and School Stakeholders
Dates for the 2022 Joint Webinars for Public Health and School Stakeholders have been confirmed through May. All webinars take place from 4 to 5 p.m. on a Wednesday.
The first webinar this year is on Wednesday, January 26, from 4 to 5 p.m. A registration link and information regarding speakers will be sent a week before the webinar.
Here is the schedule for 2022:

- January 26
- February 23
- March 23
- April 20
- May 18

Past recorded webinars are available for viewing.

DHS News

Respiratory Report
The Weekly Respiratory Report is available and updated bi-weekly.

Wisconsin Receives Oral Antiviral COVID-19 Treatments
Initial supply of Molnupiravir and Paxlovid is limited, both drugs require a prescription
The Wisconsin Department of Health Services (DHS) announced today that they have received the first allocation of oral antiviral COVID-19 treatments Molnupiravir and Paxlovid to treat patients diagnosed with mild to moderate COVID-19. The initial supply available to states from the federal government is extremely limited. Under guidance developed by the National Institutes of Health, health care providers are encouraged to prioritize prescribing these new therapeutics to those patients at greatest risk of serious illness or hospitalization from COVID-19. Wisconsinites who may be eligible for these treatments should talk with their health care provider.

"While these new antiviral pills may help treat COVID-19, it's important to remember these drugs are not a substitution for protecting yourself by getting vaccinated and wearing a mask in public places," said DHS Secretary-designee Karen Timberlake. "We anticipate high demand for these medications, and we know that the initial supply we are receiving will be extremely limited. Please be patient as providers will prioritize people at highest risk for developing serious illness from the virus. We are committed to distributing these pills equitably across the state, and access will increase as Wisconsin receives more allocations from the federal government."

View the entire news release

"While these new antiviral pills may help treat COVID-19, it's important to remember these drugs are not a substitution for protecting yourself by getting vaccinated and wearing a mask in public places."

American Nurses Association

ANA Releases Video About Ethical Considerations Regarding Mandatory Vaccinations for Nurses
One of the most important foundational documents for the nursing profession is the Code of Ethics for Nurses with Interpretive Statements (The Code). The Code was developed as a guide for nurses to use in ethical analysis and decision-making and establishes the ethical obligations of the profession.

The American Nurses Association has released COVID-19 Vaccines: Ethical Considerations for Nurses**, a free 40-minute video about the ethical considerations used to inform policy decisions regarding mandatory vaccinations for nurses.** This educational resource outlines and analyzes the competing ethical arguments and alternative points of view regarding mandatory COVID-19 vaccination. In this video, an expert panel of nurse ethicists describes skills for ethical decision-making and addresses critical issues of autonomy, patient safety, and collective interests.

CDC

Why CDC Shortened Isolation and Quarantine for the General Population
CDC has been monitoring the emerging science on when and for how long a person is maximally infectious with Omicron, as well as the effectiveness of COVID-19 vaccines and booster doses against Omicron infection. Data related to the mental health effects of the pandemic and adherence to prevention interventions have also been considered.

Data, including a review of 113 studies from 17 countries, show that most SARS-CoV-2 transmission occurs early in the course of infection . Infectiousness peaks around one day before symptom onset and declines within a week of symptom onset, with an average period of infectiousness and risk of transmission between 2-3 days before and 8 days after symptom onset. These data are from studies of prior SARS-CoV-2 variants, including Delta. The science is evolving, particularly for the Omicron variant, and some reports suggest that compared with previous variants, Omicron has a shorter incubation period (2-4 days), defined as the time between becoming infected and symptom onset.

On January 4, CDC updated COVID-19 isolation and quarantine recommendations with shorter isolation (for asymptomatic and mildly ill people) and quarantine periods of 5 days to focus on the period when a person is most infectious, followed by continued masking for an additional 5 days. These updated recommendations also facilitate individual social and well-being needs, return to work, and maintenance of critical infrastructure. Read more.

Updated COVID-19 Quarantine and Isolation Guidance
On Tuesday, January 4, 2022, the CDC posted the updated COVID-19 quarantine and isolation guidance to their website. With the Omicron variant surging throughout Wisconsin and the United States, these recommendations are motivated by the latest science on the severity of disease, when transmission occurs, and for how long a person is maximally infectious. The new quarantine and isolation guidance also reflects the societal impacts the pandemic is having on families and employers across the country.

This new guidance applies to the general population in the community, including workplaces and K-12 schools. To accompany the guidance, the CDC has developed a corresponding rationale and FAQs.

The science is evolving, particularly for the Omicron variant, and some reports suggest that compared with previous variants, Omicron has a shorter incubation period (2-4 days), defined as the time between becoming infected and symptom onset.

AAP

Updated Interim Guidance – Management Strategies for Children With Mild to Moderate COVID-19
The AAP strongly supports the equitable distribution and availability of therapeutic medications and vaccinations to eligible children and adolescents. Given rapidly emerging data and changes in monoclonal antibody indications, while simultaneously acknowledging that mAb may be in short supply or not readily accessible in all geographic areas and that there continues to be a paucity of pediatric-specific data regarding the safety, efficacy, and pharmacokinetics of mAb across all age groups, this updated interim guidance is intended to help navigate management challenges and considerations and summarize currently available recommendations for the outpatient management of COVID-19 in children and adolescents.

- Updated Interim Guidance: Management Strategies in Children and Adolescents with Mild to Moderate COVID-19
- AAP News: AAP updates treatment guidance
- HealthyChildren.org: When can kids get the COVID-19 vaccine or a booster?

Prevent Blindness

NCCVEH Webinar Series: Vision Health of Children with Special Needs
Join us for our first webinar of the "Year of Children's Vision" to learn why referral for some children with special needs to eye care is best practice and how a comprehensive system of care can be structured for these children. You will also learn about vision-related components of the federal Individuals with Disabilities Education Act. Finally, you will gain skills to address barriers to eye care for children with special needs and strategies for working with families, eye care providers, special education staff, and healthcare providers. Attached to the newsletter is the flier with registration information for this FREE 90-minute webinar hosted by Prevent Blindness as part of their NCCVEH Webinar series. **Registration is required.**

Wednesday, January 19, 2021, 3:00 p.m. – 4:30 p.m., Central Time Zone
The Facts, The Law, and Best Practices

Wisconsin Prevent Blindness Requires Lion Club Members to Be Certified.
The Board of Directors for Prevent Blindness Wisconsin voted that, as of January 2022, Wisconsin Lions Club members will need to pay to receive Prevent Blindness Wisconsin's certification course. Many school nurses rely on Lions Club members for support of their vision screenings so Prevent Blindness Wisconsin will be reminding nurses to check for certification cards.

Medscape Nurses

Swab Nose, Throat, or Both for COVID-19 Rapid Tests?
Many Americans are familiar with the rapid antigen tests for COVID-19 that involve swabbing the nose. But some new evidence suggests a saliva sample could boost the tests' accuracy.

Experts agree on one thing — if you're going to test both the nose and throat, swab the throat first. In terms of an official stance, the FDA says to follow the test instructions. In other words, stick to the nose for now. Read more.

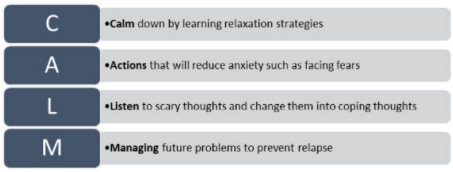
Miscellaneous

Exciting Volunteer Opportunity for School Nurses to Help Students with Anxiety

Due to the pandemic, we expect more students than ever before to visit their school nurse with symptoms of excessive anxiety (including stomach aches, headaches, dizziness) that impair their academic, social, and emotional functioning. To address this critical student mental health problem (and with funding from the US Department of Education), a research project called CALM (Child Anxiety Learning Modules) has been offering free training to school nurses (we actually pay them!) to enhance their capacity to identify and help manage anxiety in their students. The study is completely voluntary, and all nurses are compensated for their participation (all school training is done virtually and not during the school day). The COVID-19 pandemic has highlighted mental health challenges for many, and resources to support students struggling with anxiety are needed now more than ever. To set up a time to learn more about this study, you can email CALM@uchc.edu

This opportunity is coming from:

Golda S. Ginsburg, Ph.D. (she/her)
Professor
Department of Psychiatry
University of Connecticut School of Medicine
Adjunct Professor of Psychiatry The Johns Hopkins University School of Medicine



COVID-19 Survey – School Nurse Moral Distress and More

School nurses are invited to take this survey, which is designed to learn more about school nurses' moral distress and information needs about the COVID-19 virus and vaccine, especially relating to school nurse case management and how to respond to family questions and concerns about the vaccine. It should take you 15-20 minutes to complete. If you have questions about the survey, please contact Christina Baker at 720-220-8571 or email: **christina.baker@cuanschutz.edu**. Survey link

School nurses are invited to take this survey, which is designed to learn more about school nurses' moral distress and information needs about the COVID-19 virus and vaccine…

Approval of At Home Test Kits

FDA approved two new at home test kits for emergency use authorization (EUA). See EUA approval letters attached to this newsletter for information regarding how these test kits are used.

Miscellaneous

The National Board for the Certification of School Nurses Applications Open for Spring 2022 Exam

NBCSN is now accepting applications for the Spring 2022 exam. Applications must be submitted by February 3, 2022.

As of January 1, 2022, NBCSN will be changing the price of the NCSN exam:

- $360 for applications submitted no later than December 31, 2021.
- $370 for applications submitted between January 1 - 19, 2022.
- $390 for applications submitted between January 20 - February 3, 2022.

February 3, 2022, is the last day in the Spring exam registration window. Applications submitted after February 3, 2022, will charged a late fee of $100.

The Spring Exam Testing Window has also now been extended. The new dates for the testing window are:

March 3, 2022 - April 3, 2022
LEARN MORE

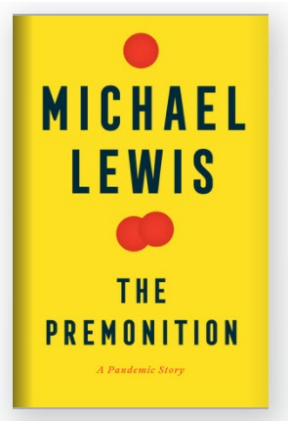
What can schools do to navigate the effects of long COVID?
"Chronic post-COVID symptoms may qualify students for Section 504 and IDEA coverage or change their existing status. Schools have become accustomed to flexing protocols to respond to the rapidly changing pandemic environment, but navigating "long COVID" — persistent and recurring post-COVID conditions experienced for four or more weeks after initial infection — remains uncharted territory. In July, the White House classified the lingering effects of chronic post-COVID syndrome a disability, which means employers and schools have to provide needed accommodations in compliance with Section 504 and the Individuals with Disabilities Education Act." Read more...

Chronic post-COVID symptoms may qualify students for Section 504 and IDEA coverage or change their existing status.

Updated Toolkit: Children and COVID-19 Vaccination
Made to Save and the de Beaumont Foundation tested messaging with parents/guardians of children ages 5-11 and found that messages about health and community were most effective at increasing support for COVID-19 vaccination of this age group. Download the full tip sheet.

PRACTICE POINTS

By Louise Wilson



Doing the Right Thing

I intended to write this PRACTICE POINTS on the data points and voluntary Wisconsin School Health Services survey I will be requesting districts submit data to this May. With the current state of COVID and its overwhelming impact on schools and school nurses that did not seem like a timely subject for this issue! I will share information on data collection (what will be collected will be short and sweet) in a future newsletter.

What I will share instead, is an insight I obtained from reading "The Premonition - A Pandemic Story " by Michael Lewis. This book was on my Christmas wish list which I received as a gift and read over Winter Break. I highly recommend the book! It is a fascinating read of decades-long behind-the-scenes work by individuals who had the foresight and courage to "do the right thing." It gives insight into the pandemic planning or lack thereof, for our nation and how and why the national, state, and local public health departments responded as they did to the SARS-CoV2 pandemic.

What struck me over and over is the fact that it was not systems, agencies or public policies that protected our nation and its citizens from what could have been a worse situation. It was individuals, in the right place at the right time, diligently doing their jobs often at the threat of losing those jobs, that made all the difference. I found that an incredibly powerful insight. I recently shared that insight with a local public health official feeling hopeless in the face of this COVID surge and school districts not using layered mitigation strategies as recommended.

... the fact that it was not systems, agencies or public policies that protected our nation and its citizens ... It was individuals, in the right place at the right time, diligently doing their jobs often at the threat of losing those jobs, that made all the difference.

What I shared and have come to embrace is that I must do my very best given the circumstances, choose to do the right thing because it is the right thing, and be courageous. I cannot necessarily rely on others to do the right thing but that does not stop me from doing it.

The stories of these remarkable individuals have renewed both my courage and my endurance to not just survive but thrive through this long continuing pandemic. This applies to both my professional and personal lives. It reminds me of this Maya Angelo quote I have on my social media page. "My mission in life is not merely to survive, but to thrive; and do so with some passion, some compassion, some humor and some style."

I fear there is yet a long road ahead for school nurses and public health departments and staff. Is it worth writing, updating, publishing and making public health recommendations when one knows it might be ignored? Is it worth promoting science and seeking to educate others to base their decisions and actions on science and the greater good? I think it is.

If not us, who will stand to defend our students, school staff, and communities? While it may seem you are alone, you are not. There have always been and will continue to be people with integrity and foresight and perseverance. When I look back and tell my granddaughter what I did during the COVID-19 pandemic I want to tell her I did what was right even though it was not easy.

While it may seem you are alone, you are not. There have always been and will continue to be people with integrity and foresight and perseverance.

This publication is available from:
Learning and Support
Student Services Prevention and Wellness Team
(608) 266-8857
https://dpi.wi.gov/sspw/pupil-services/school-nurse
January 2022 Wisconsin Department of Public Instruction

NCCVEH Webinar Series: Vision Health of Children with Special Needs

The Facts, The Law, and Best Practices

Wednesday, January 19, 2021, 4:00 p.m. – 5:30 p.m., Eastern

Join us for our first webinar of the "Year of Children's Vision" to learn why referral for some children with special needs to eye care is best practice and how a comprehensive system of care can be structured for these children. You will also learn about vision-related components of the federal Individuals with Disabilities Education Act. Finally, you will gain skills to address barriers to eye care for children with special needs and strategies for working with families, eye care providers, special education staff, and healthcare providers.

Presenters

- Sandra Block, OD, MPH, MEd
  Professor Emeritus, Illinois College of Optometry
  President-Elect, World Council of Optometry
- Rebecca Sheffield, PhD
  Education Program Specialist, Research to Practice Division
  Office of Special Education Programs, U.S. Department of Education
- MaryAnn Strawhacker, MPH, BSN, RN
  Nurse Consultant, Heartland Area Education Agency (Iowa)
- Rachel A. "Stacey" Coulter, OD, MS, FAAO, FCOVID
  Diplomate, Binocular Vision, Perception and Pediatric Optometry and
  Professor, Nova Southeastern University College of Optometry

Target Audience

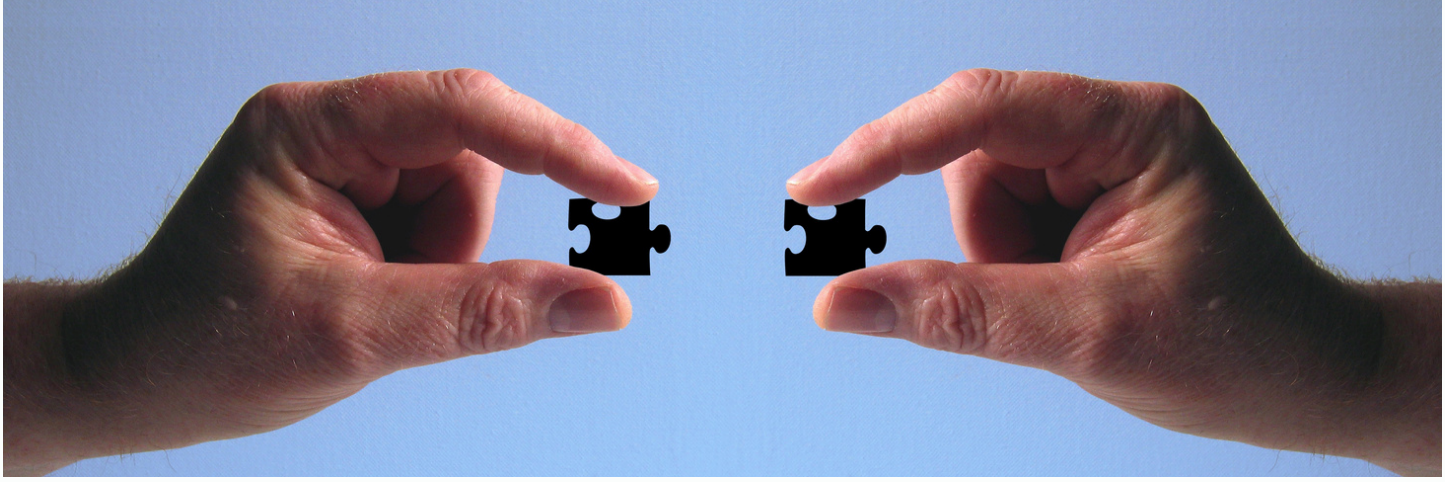
Individuals who work with children ages 3 through elementary school

- Child Care Health Consultants
- Early Childhood Education and Care Professionals
- Head Start Health Managers and staff
- Home visitors
- Medical Care Providers
- School Nurses
- Special Education staff

Register at: NCCVEH Webinar Series: Vision Health of Children with Special Needs The Facts, The Law, and Best Practices - National Center (preventblindness.org)

For more information, please contact dfishman@preventblindness.org

Certificates of Attendance will be available



TRAUMA SENSITIVE SCHOOLS PROJECT '21-'22
MIDWINTER EVENT

Tuesday, February 15, 2022 12pm-2pm

TRAUMA INFORMED COMMUNICATION

Have you ever sent or received a communication around a crisis/school event that didn't go as you intended and that induced stress in you or someone you sent it to?

Often efforts to avert miscommunication problems focus great attention on communicating clearly. This assumes that an upfront investment in spelling out the critical details of who, what, when, and where will ward off problems. While this strategy makes sense, it may not adequately consider that often the problems of communication are **not about how information is delivered but rather how information is received**. It is helpful to be aware that sometimes what really matters is the meaning-making process that is taking place inside the recipient of information. From that perspective, communication is not simply about providing **accuracy**, it is also about shaping a person's **experience**.

This session, **presented by the The School Crisis Recovery & Renewal (SCRR) Project,** will include:

- Key factors that tend to induce stress and/or reduce stress in our communication
- Learn how to apply 3 trauma-informed communication strategies
- 1-2 strategies for what to do if communication goes amiss or causes distress

BRING TO THIS SESSION

A communication after a crisis
A communication to all staff
A communication to parents

Participants are invited to bring ideas, stories, and ACTUAL communications that may have inadvertently induced stress or just not gone as intended for case consultation and practice.
Participants will be actively engaged in this session, learning a useful rubric for how to reduce stress and promote healing-centered communication.

This session is **free** to all participants. Due to the interactive nature of the workshop, it will not be recorded. Please attend live ready to participate.

Register Now! (Click here)

Session questions? Contact:
Alissa Darin, WISH Center Regional Coordinator adarin@cesa1.k12.wi (262-787-9786) **or**
Julie Incitti, School Social Work Consultant, DPI julie.incitti@dpi.wi.gov (608) 266-0963

Wisconsin Safe and Healthy Schools Center
wishschools.org

Wisconsin Department of Public Instruction
https://dpi.wi.gov/sspw

December 29, 2021

Robert Zinck, M.S.
Regulatory Affairs Manager
Siemens Healthineers
511 Benedict Avenue
Tarrytown, NY 10591

Device:	CLINITEST Rapid COVID-19 Antigen Self-Test
EUA Number:	EUA210639
Company:	Siemens Healthineers
Indication:	Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with: Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. Adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Dear Mr. Zinck:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Siemens Healthineers.
[2] For ease of reference, this letter will use the term "your product" to refer to the CLINITEST Rapid COVID-19 Antigen Self-Test used for the indication identified above.

emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)" (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details
Your product is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. The CLINITEST Rapid COVID-19 Antigen Self-Test does not differentiate between SARS-CoV and SARS-CoV-2.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or coinfection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with your product should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention.

Your product is performed using anterior nasal (nares) swab samples from individuals aged 2 years and older. When using your product, the individual places the tube in the tube holder and

removes the seal from the tube. The swab is then removed from its packaging and the individual collects an anterior nasal swab sample by inserting the swab into the nostril and rubbing the insides of the nostril in a complete circle at least 5 times, taking at least 15 seconds to collect the specimen (including any nasal drainage) before repeating the process in the second nostril. The swab is then immediately inserted into the liquid inside the tube. The tube is mixed vigorously by rolling the swab tip at least 6 times on the bottom and sides of the tube. The tube is placed back in the tube holder (with the swab in place) and allowed to sit for one minute. After one minute the swab is removed from the tube while squeezing the swab tip from outside the tube to release as much liquid from the swab as possible. The swab is discarded and the tube capped with the tube tip. The test device is removed from the pouch and placed on a flat surface. Four drops of the solution are applied into the sample well of the test device. The individual then starts the 15 minute timer. If the extracted specimen contains SARS-CoV-2 antigens, a pink/red-colored T (Test) Line, along with a pink/red-colored C (Control) Line will appear on the test device indicating a positive result. This control line indicates that the test was performed correctly. Test results are interpreted visually after 15-20 minutes based on the presence or absence of visually detectable colored lines at the control line (C) and/or test line (T). Test results should not be read after 30 minutes.

The CLINITEST Rapid COVID-19 Antigen Self-Test includes the following materials or other authorized materials (as may be requested under Condition L. below): test device, sterile swab, extraction tube with buffer and tip, tube holder, and "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" (QRI).

Your product includes an internal control line (C) that must generate the expected result for a test to be considered valid, as outlined in the "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)" and the "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" (QRI).

The labeling entitled "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)", and the "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" (QRI), (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the two CLINITEST Rapid COVID-19 Antigen Self-Test box labels (1-, or 5-pack) and the following fact sheet pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers:[5] Siemens Healthineers - CLINITEST Rapid COVID-19 Antigen Self-Test

The above described product when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

[5] Note that the information typically found in a Fact Sheet for Individuals is contained in the QRI that will be available to end users as set forth in the Conditions of Authorization (Section IV).

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Siemens Healthineers (You), and Authorized Distributor(s)[6]

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any

[6] "Authorized Distributor(s)" are identified by you, Siemens Healthineers in your EUA submission as an entity allowed to distribute your product.

available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" for your product in the shipped kit using the CLINITEST Rapid COVID-19 Antigen Self-Test box labels (1-, or 5-pack) and make the "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)", and the "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" available electronically on your website(s).

C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributors using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Siemens Healthineers (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)" and the Fact Sheet for Healthcare Providers electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)" and Fact Sheet for Healthcare Providers in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[7] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must evaluate the clinical performance of your product to support the serial screening claim in an FDA agreed upon post authorization clinical evaluation study

[7] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

S. You must submit to FDA a summary report within 90 calendar days of product launch summarizing the results of any testing performed using your product during that timeframe, including how many products were distributed, the positivity rate for specimens tested with your product, and how many individuals reported results to their healthcare provider as encouraged by the "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" (QRI) along with any proposed corrective action, as necessary.

T. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

V. You must submit your product for any FDA-recommended independent evaluation to confirm the performance characteristics of your test, if requested by FDA. After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

W. You must further evaluate the clinical performance of your product in pediatric individuals <14 years of age, an FDA agreed upon post authorization clinical evaluation study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update authorized labeling to reflect the additional testing. Such labeling

updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

X. You must develop a mobile phone application or website to further facilitate results reporting by the individual using your product and submit to FDA such application or website within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the mobile phone application or website to, and review of and concurrence with the developed mobile phone application or website by FDA, you must update the authorized labeling. Such labeling updates will be made in consultation with, and require concurrence of, FDA.

Conditions Related to Printed Materials, Advertising and Promotion

Y. All descriptive printed matter, including advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

Z. No descriptive printed matter, including advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

AA. All descriptive printed matter, including advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure

December 24, 2021

SunYoung Jeong
SD Biosensor, Inc.
C-4th & 5th, 16, Deogyeong-Daero,
1556beon-Gil, Yeongtong-Gu,
Suwon-si, Gyeonggi-Do,
Republic of Korea 16690

Device:	COVID-19 At-Home Test
EUA Number:	EUA210661
Company:	SD Biosensor, Inc.
Indication:	Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with: Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 6 days of symptom onset. Adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 6 days of symptom onset. Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Dear SunYoung Jeong:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health

[1] For ease of reference, this letter will use the term "you" and related terms to refer to SD Biosensor, Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the COVID-19 At-Home Test used for the indication identified above.

emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the "COVID-19 At-Home Test Healthcare Provider Instructions for Use" (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details
Your product is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.

---

[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 6 days of symptom onset. This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. The COVID-19 At-Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or coinfection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with your product should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention.

Your product is performed using anterior nasal (nares) swab samples from individuals aged 2 years and older. When using your product, the individual first opens the foil pouch containing the test device and places it on a flat surface. The individual then opens the foil pouch containing

the tube (with liquid), opens the seal of the tube and places the tube in the tube holder. The swab is then removed from its packaging and the individual collects an anterior nasal swab sample by inserting the swab into the nostril and firmly and slowly rotating the swab against the insides of the nasal wall in a circular motion at least 5 times, taking at least 15 seconds to collect the specimen, before repeating the process in the second nostril. The swab is then immediately inserted into the tube, the tube is squeezed and the swab is stirred in the liquid at least 15 times. The swab is then removed while squeezing it against the sides of the tube to extract the liquid from the swab. The swab is discarded and the tube capped with the nozzle cap. The liquid in tube interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in your product. Four drops of the solution are applied into the sample well of the test device. The individual then starts the 20 minute timer. If the extracted specimen contains SARS-CoV-2 antigens, a magenta-colored T (Test) Line, along with a magenta-colored C (Control) Line will appear on the COVID-19 Test Card indicating a positive result. This control line indicates that the sample has migrated across the membrane as intended and indicates that the test was correctly performed. Test results are interpreted visually after 20 minutes based on the presence or absence of visually detectable colored lines at the control line (C) and/or test line (T). Test results should not be read after 30 minutes.

The COVID-19 At-Home Test includes the following materials or other authorized materials (as may be requested under Condition L. below): test device (inside a foil pouch), sterile swab, extraction buffer tube (inside a foil pouch) nozzle cap and tube holder, and "COVID-19 At-Home Test Quick Reference Instructions for Patients" QRI.

Your product includes an internal control line (C) that must generate the expected result for a test to be considered valid, as outlined in the "COVID-19 At-Home Test Healthcare Provider Instructions for Use" and the "COVID-19 At-Home Test Quick Reference Instructions for Patients".

The labeling entitled "COVID-19 At-Home Test Healthcare Provider Instructions for Use", and the "COVID-19 At-Home Test Quick Reference Instructions for Patients" (QRI), (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the two "COVID-19 At-Home Test" box labels (1-, or 25-pack) and the following fact sheet pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers:[5] SD Biosensor, Inc.- COVID-19 At-Home Test

The above described product when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that

[5] Note that the information typically found in a Fact Sheet for Individuals is contained in the QRI that will be available to end users as set forth in the Conditions of Authorization (Section IV).

the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

SD Biosensor, Inc. (You), and Authorized Distributor(s),[6] including Roche Diagnostics

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

[6] "Authorized Distributor(s)" are identified by you, SD Biosensor, Inc, in your EUA submission as an entity allowed to distribute your product. Roche Diagnostics is an authorized distributor.

B. You and authorized distributor(s) must make available the "COVID-19 At-Home Test Quick Reference Instructions for Patients" for your product in the shipped kit using the "COVID-19 At-Home Test " box labels (1-, or 25-pack) and make the "COVID-19 At-Home Test Healthcare Provider Instructions for Use", and the "COVID-19 At-Home Test Quick Reference Instructions for Patients" available electronically on your website(s).

C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributors using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

SD Biosensor, Inc. (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "COVID-19 At-Home Test Healthcare Provider Instructions for Use" and the Fact Sheet for Healthcare Providers electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "COVID-19 At-Home Test Healthcare Provider Instructions for Use" and Fact Sheet for Healthcare Providers in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[7] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must evaluate the clinical performance of your product to support the serial screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling

[7] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

S. You must submit to FDA a summary report within 90 calendar days of product launch summarizing the results of any testing performed using your product during that timeframe, including how many products were distributed, the positivity rate for specimens tested with your product, and how many individuals reported results to their healthcare provider as encouraged by the "COVID-19 At-Home Test Quick Reference Instructions for Patients" along with any proposed corrective action, as necessary.

T. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

V. You must submit your product for any FDA-recommended independent evaluation to confirm the performance characteristics of your test, if requested by FDA. After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

W. You must further evaluate the clinical performance of your product in pediatric individuals <14 years of age, an FDA agreed upon post authorization clinical evaluation study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

X. You must develop a mobile phone application or website to further facilitate results reporting by the individual using your product and submit to FDA such application or website within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the mobile phone application or website to, and review of and concurrence with the developed mobile phone application or website by FDA, you must update the authorized labeling. Such labeling updates will be made in consultation with, and require concurrence of, FDA.

Conditions Related to Printed Materials, Advertising and Promotion

Y. All descriptive printed matter, including advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

Z. No descriptive printed matter, including advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

AA. All descriptive printed matter, including advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure
Cc: Kelli, Turner, Senior Program Manager, Roche Diagnostics, U.S. Agent