

Holland Central School District District Office

103 Canada Street Holland, NY 14080 P: 716-537-8200 F: 716-537-8203

www.hollandcsd.org

Proximal and Surveillance Testing

Dear Holland Families,

Holland CSD is providing an opportunity through the Erie County Department of Health (ECDOH) in collaboration with Quadrant BioSciences, Inc. for your child to participate in two COVID-19 testing programs for students this year. The testing programs are completely voluntary. Both testing programs use a swab in the mouth that children can do themselves with the supervision of a medical professional if they are over the age of 3. If you child is under the age of 3 or needs assistance, ECDOH is providing a medical professional to your school district who is trained and can complete the swabbing for them.

The first COVID-19 testing program is called Proximal Testing. Proximal Testing happens when there is a positive COVID-19 case in a classroom. If your child is in the same room as someone who recently tested positive for COVID-19, they will have the opportunity to have a COVID-19 test done 3-5 days after the last day they were around the COVID-19 positive person. Proximal Testing is offered 3-5 days later since that is the incubation period of the COVID-19 Delta Variant, which is the variant making up most of the cases in our county.

The second COVID-19 testing program is called Surveillance Testing. Surveillance Testing happens on a weekly basis. Each week, we will be randomly selecting and testing a group of those who have consented to participate in this program. This means that your child will not be tested every week.

If you are interested in enrolling your child in either program or want to learn more, please visit the following website: https://www3.erie.gov/covid-19-proximal-testing-and-surveillance-testing-schools

Sincerely,

Superintendent of Schools



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Proximal and Surveillance Testing Information

Please see the updated information regarding the accuracy of the Clarifi COVID-19 Test Kit utilized by Quadrant BioSciences, Inc. below.

"Sensitivity: The ability of surveillance to detect the health problem that it is intended to detect." (Centers for Disease Control and Prevention A, 2012) Retrieved

from: https://www.cdc.gov/csels/dsepd/ss1978/lesson5/appendixa.html

"Specificity: Measures a test's ability to correctly generate a negative result for people who don't have the condition that's being tested." (CDC B, 2012) Retrieved

from: https://www.cdc.gov/csels/dsepd/ss1978/lesson5/appendixa.html

False Positive: When a test result indicates that a person has a condition (COVID-19) when the person truly does not have the condition "(National Cancer Institute, 2021). Retrieved

from: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/false-positive-test-result

Limitation of Detection (LoD): The lowest concentration of COVID-19 genetic material that can be detected on a test 95% of the time (CDC C, 2021). Retrieved from: https://www.fda.gov/media/134922/download

The Specificity of the Clarifi COVID-19 Kit is 100% and the Sensitivity of the Clarifi COVID-19 Kit is 95% (CDC C, 2021). Retrieved from: https://www.fda.gov/media/134922/download

In reference to the table below, "a lower LoD represents a test's ability to detect a smaller amount of viral material in a given sample, signifying a more sensitive test." (U.S. Food and Drug Administration, 2020) Retrieved from: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data

Essentially, the Clarifi COVID-19 Test Kit is the most sensitive test currently being used for oral, saliva swabs and there is a lower likelihood of a false positive than the other tests on the market. Retrieved

from: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data

Table 2C-Saliva

Corroborated negative saliva is pooled. The volume of saliva that goes into the collection device is then spiked with the material at the same dilution as indicated for NP swabs (considering the replicates needed and an excess volume for the serial dilution). If the collection device is a dry container with nothing in it, the saliva is spiked and tested. However, if the collection device contains liquid, the saliva is mixed with virus and then the

normal volume of collected saliva is added to the container to mimic the workflow. The volumes in the FDA-proposed dilution protocol may need to be adjusted to follow the device Instructions for Use.

Note: NDU/mL = NAAT Detectable Units/mL

Search:

Product LoD (NDU/mL)	Developer	Test
18000	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	SalivaDirect
600	Quadrant Biosciences Inc.	Clarifi COVID-19 Test Kit
18000	Phosphorus Diagnostics LLC	Phosphorus COVID-19 RT- qPCR Test
54000	Fluidigm Corporation	Advanta Dx SARS-CoV-2 RT- PCR Assay
180000	Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory	Express Gene 2019-nCoV RT- PCR Diagnostic Panel
3600	DxTerity Diagnostics, Inc.	DxTerity SARS-CoV-2 RT-PCR Test
5400	Clinical Reference Laboratory, Inc.	CRL Rapid Response

For more information, please view the following links:

https://f.hubspotusercontent20.net/hubfs/7307728/Quadrant Biosciences June 2021/Pdf/Clarifi-COVID-19-Test-Kit-Instructions-for-Use-May-6-2021.pdf

https://f.hubspotusercontent20.net/hubfs/7307728/Quadrant Biosciences June 2021/Pdf/Patient-Fact-Sheet-May-6-2021.pdf

https://quadrantbiosciences.com/covid-pooling/?hsLang=en