COVID-19 Testing Proposal

Learning and Operational Plan for the 2020-21 School Year

Tuesday, October 13, 2020

Testing Exploration Process

- Partnered with other school districts, including New Trier High School District, to explore the possibility of implementing routine COVID-19 testing for students and staff.
- Engaged with multiple testing providers offering both lab and non-lab based tests including Abbott Laboratories, Elysian, Loyola University, and the University of Illinois.
- Considered tests that:
  - Utilized saliva-based and nasal swab (non-invasive) samples;
  - Could be self-administered;
  - Required assistance and/or supervision by licensed medical professionals;
  - Had the ability to detect the presence of active COVID-19, as opposed to the presence of COVID-19 antibodies; and
  - Offered the ability for the school district to have access to positive test results to support our students, and activate contact tracing activities.

Testing Exploration Process

- Surveyed the school community regarding interest in potential routine COVID-19 testing:
  - Parent Responses
    - No - 11% (331)
    - Yes - 89% (2,687)
  - Staff Responses
    - No - 8.1% (56)
    - Yes - 91.9% (633)
- Requested quotations from testing providers and potential timelines to begin testing. Per-test costs ranged from $5 - $150, with timelines as soon as the beginning of November.
- All providers require a level of testing commitment (e.g., a number of tests over a period of time), which average 4 weeks.

Proposed Testing Framework

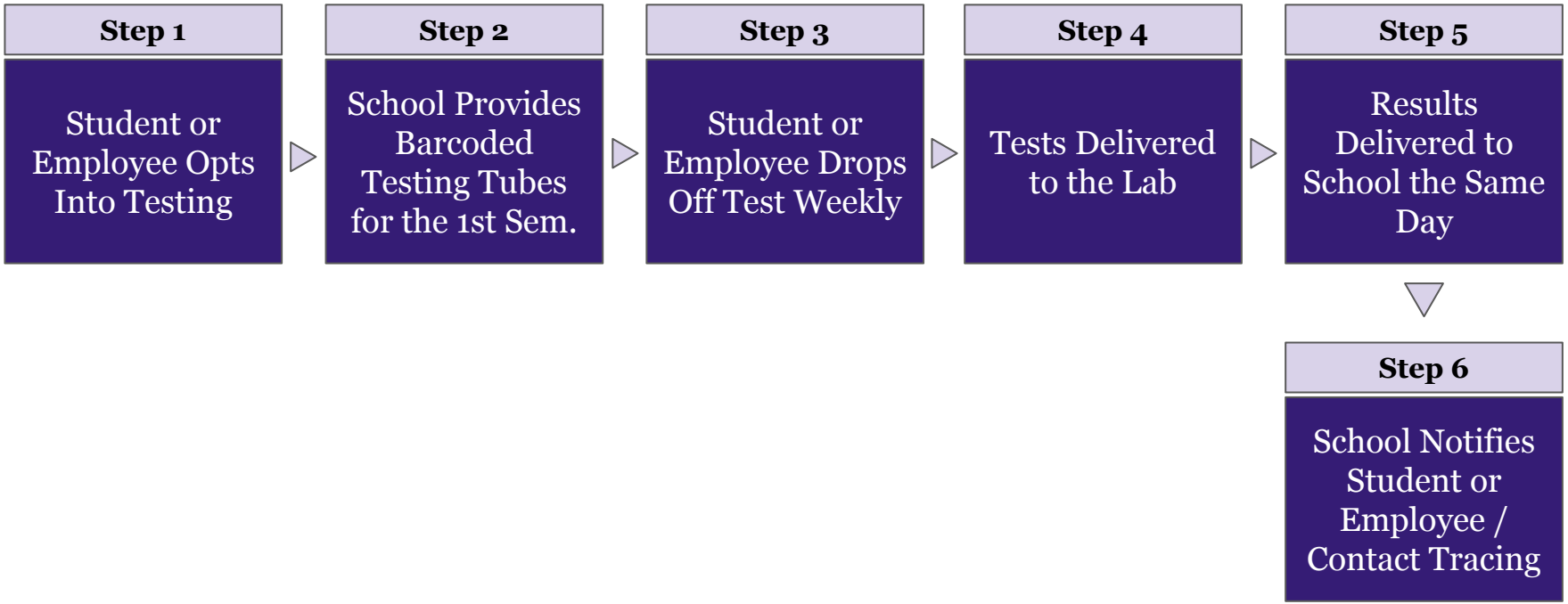
Voluntary Participation

Self-Administered,
Saliva-Based Test at Home

Weekly Testing

Confidential

Testing Workflow



Testing Cost Projections

Per Test

$11.00

Per Week

All Students and Staff Present and Participating:
850 Staff + 5,200 Students = 6,050 Total Tests = $66,550 per Weekly Test

All Students Currently Opting-Into In-Person and All Staff Present Participating:
850 Staff + 3,365 Students = 4,215 Total Tests = $46,365 per Weekly Test

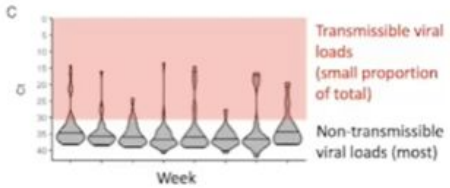
Per Year (Start Testing the Week of November 9th)

All Students and Staff Present and Participating:
$66,550 per Weekly Test x 27 Weeks = $1,796,850

All Students Currently Opting-Into In-Person and All Staff Present Participating:
$46,365 per Weekly Test x 27 Weeks = $1,251,855

Test Overview
RT-LAMP Surveillance Testing

Testing sensitivity concepts about COVID-19 testing



Representative samples of viral loads in last 8 weeks in MA

Michael Mina talk Vumedi

COVID TEST TABLE

RNA copy number	Ct value/Testing Modality/Relevance
<1000	39/RT-PCR/Outside Infectiousness Period
>1000	36/NAAT Methods/Outside Infectiousness Period
4,000	34/Abott ID Now/ Outside Infectiousness Period
50,000	30/Rapid Antigen Tests/ Outside Infectiousness Period
3,000,000	24/All modalities/**Infectious**

References for table(1-4)

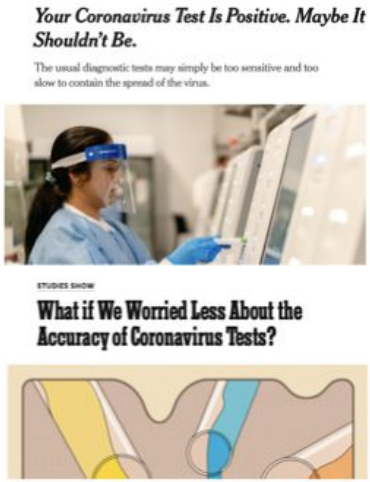
TWIV 654, Daniel Griffin MD/PhD

America's Approach
Sensitivity
Cost
Speed

What the data say
Cost
Speed
Sensitivity

Science 09-30-20

70% of infected people didn't transmit to other contacts

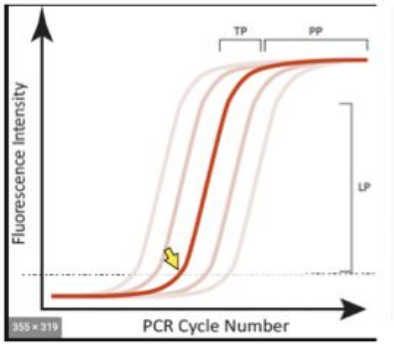


nytimes.com/2020/08/29
New York Times/2020/08/20

Test Overview
RT-LAMP Surveillance Testing

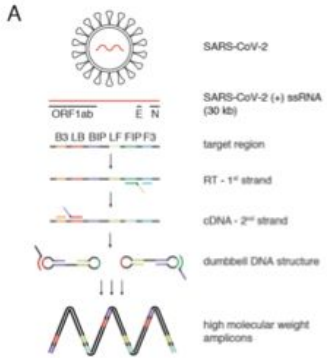
How does RT-LAMP compare to other comparable assays

- **RT-PCR**



Highly sensitive
Quantitative
Comparatively Expensive

- RT-LAMP Reverse Transcription Loop-mediated Isothermal Amplification-(RT-LAMP)

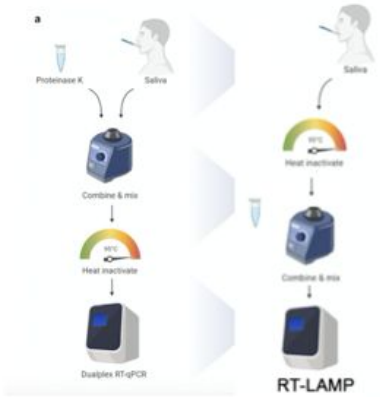


Less Sensitive
Binary Readout: Yes/No
Cheap
FAST

Test Overview
RT-LAMP Surveillance Testing

Saliva Direct vs RT-LAMP

- Diagnostic Assay
  - FDA Emergency Use Authorization
- Required CLIA certified lab
  - Cost associated with this

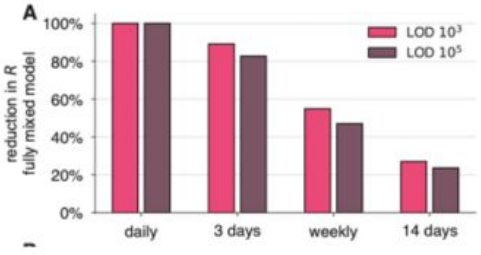


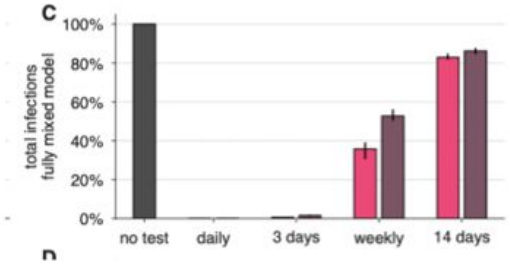
- "Non-diagnostic" Assay
  - Participants are notified of a finding of potential clinical significance and referred to a physician
- Does not require CLIA certified lab

Vogels et al, MedRXIV 2020

Test Overview
RT-LAMP Surveillance Testing

Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance





Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance

Daniel B. Larremore[†1,2], Bryan Wilder[3], Evan Lester[4,5], Soraya Shehata[4,5], James M. Burke[6], James A. Hay[7,8], Milind Tambe[3], Michael J. Mina[†7,8,9,*], and Roy Parker[†4A,10,2,*]

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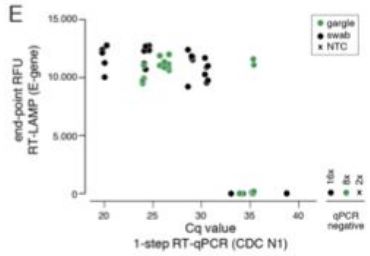
[2]BioFrontiers Institute, University of Colorado at Boulder
[3]Center for Research on Computation & Society, Harvard John A Paulson School of Engineering and Applied Sciences, Harvard University
[4]Department of Molecular, Cellular and Developmental Biology, University of Colorado
[5]Medical Scientist Training Program, University of Colorado Anschutz Medical Campus
[6]Department of Biochemistry, University of Colorado Boulder
[7]Center for Communicable Disease Dynamics, Department of Epidemiology, Harvard T.H. Chan School of Public Health
[8]Department of Immunology and Infectious Diseases, Harvard T.H. Chan School of Public Health
[9]Department of Pathology, Brigham and Women's Hospital, Harvard Medical School
[10]Howard Hughes Medical Institute
[*]These authors contributed equally.



Kelner et al, BioRXIV

Test Overview
RT-LAMP Surveillance Testing

Guidance from CMS on non-diagnostic screening

However, CMS is temporarily exercising enforcement discretion under CLIA for SARS-CoV-2 surveillance testing where patient-specific results are reported (e.g., SARS-CoV-2 surveillance testing that does not utilize a pooling strategy). Specifically, neither CMS nor the State survey agencies on its behalf will cite non-CLIA certified facilities, such as university laboratories, that are performing such testing, provided that the facility does not report actual test results, but only refers an individual with a presumptive positive or inconclusive test result to a CLIA-certified laboratory for further testing.

CMS update 08-28

Test Overview
RT-LAMP Surveillance Testing

Workflow of Saliva Collection from David and Shelby O'Connor

- David O'Connor
- UW Madison

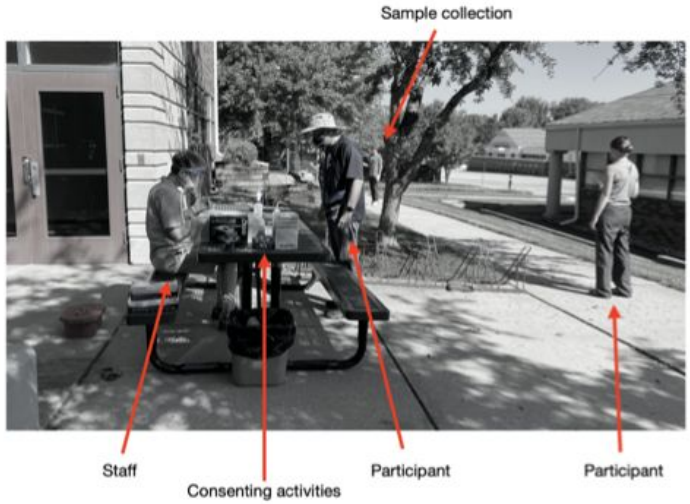
- Shelby O'Connor
- UW Madison

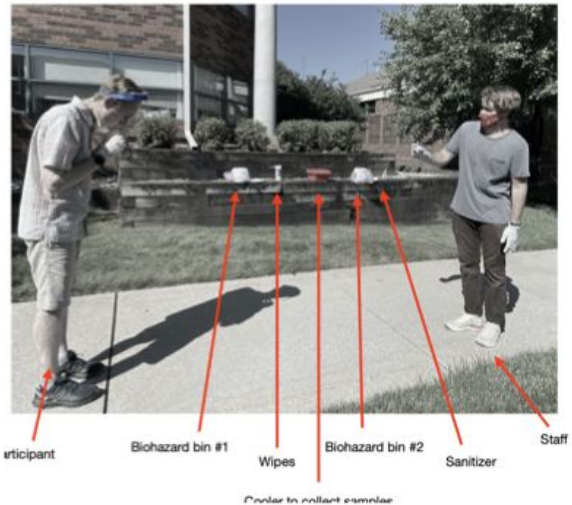
Item	Number
p1000 Pipet tips for spitting (boxes)	3
Eppendorf racks for each batch	2-4
Biopur tubes for spitting	100-200 (1 per spit sample)
Consent forms	stack
Labels	stack
Clipboards	2
pens	1 box
Sharpie marker	4
Something to clean pens between use	
hand sanitizer	
Lysol/bleach handwipes	
Insulated cooler to store tubes post spit	2-4 (1 per batch)
biohazard trash can for spit tips and lysol wipe waste	2
biohazard bags for trash can	2
Gloves nitrile small (boxes)	1
Gloves nitrile medium (boxes)	1
Gloves nitrile large (boxes)	1
Demo tubes containing 100ul of spit	1-4
Floor tape	1 roll
Table	1
10% bleach bottle	1
70% ethanol bottle	1
Wypalls	1 pack
Surgical masks (boxes) (for participants if needed)	1
Vaultz	1
Trash can for non-biohazardous waste	1
Sheet with site information (phone numbers, important info)	

Consent and Collection Table Checklist

Test Overview
RT-LAMP Surveillance Testing

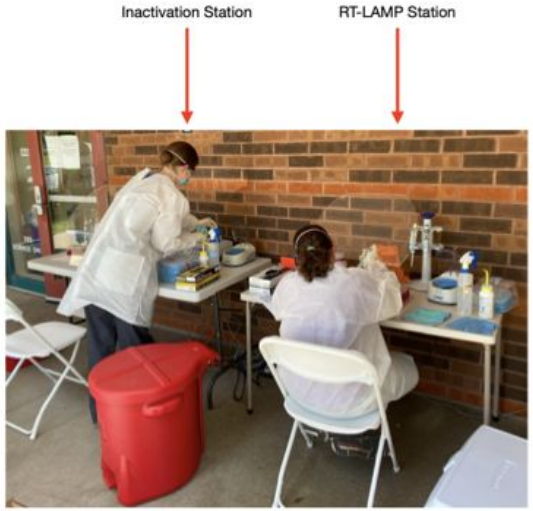
Consenting and Collection table workflows





Test Overview
RT-LAMP Surveillance Testing

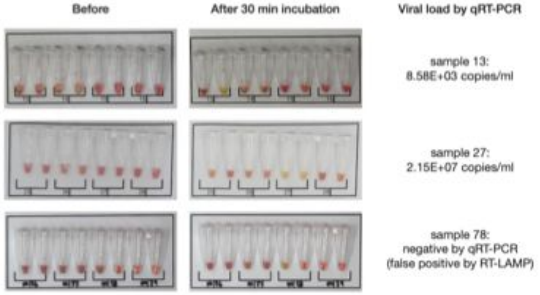
Inactivation and RT-LAMP stations

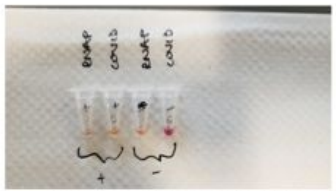


Test Overview
RT-LAMP Surveillance Testing

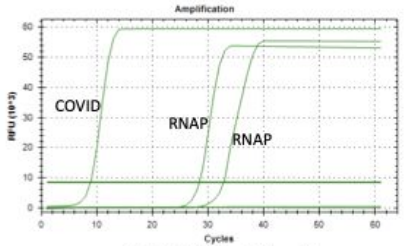
Establishing and Validating RT-LAMP assay

Colorimetric Assay

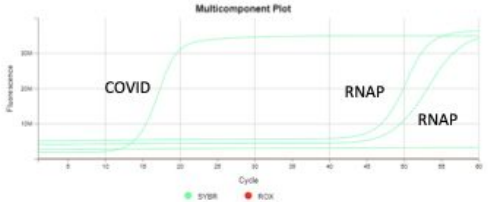




In validation, HUMAN RNA (RNAP) and COVID RNA in a "spiked" or control sample measured in both assays



RT-PCR Machine 1



RT-PCR Machine 2

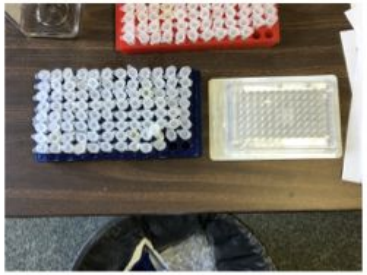
Adarsh Dharan, Sevnur Komurlu, Drew Lichon, Rasa Viliauga

Test Overview
RT-LAMP Surveillance Testing

Workflow of the Assay

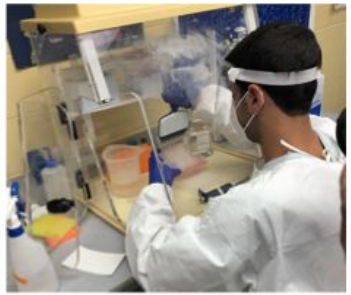
Barcoded Samples scanned in
Assigned daily sample number

Samples heat inactivated



Samples Aliquoted into 96 well plate
preloaded with buffer

Reaction performed
in RT-PCR Machine

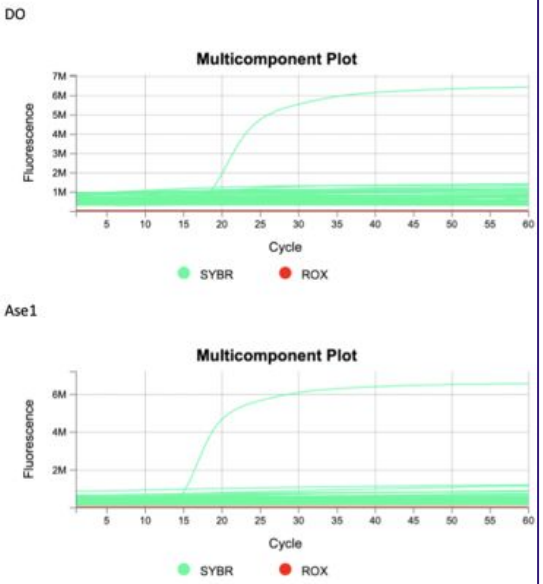


Samples added to
96 well plate containing
Reaction mixture

Test Overview
RT-LAMP Surveillance Testing

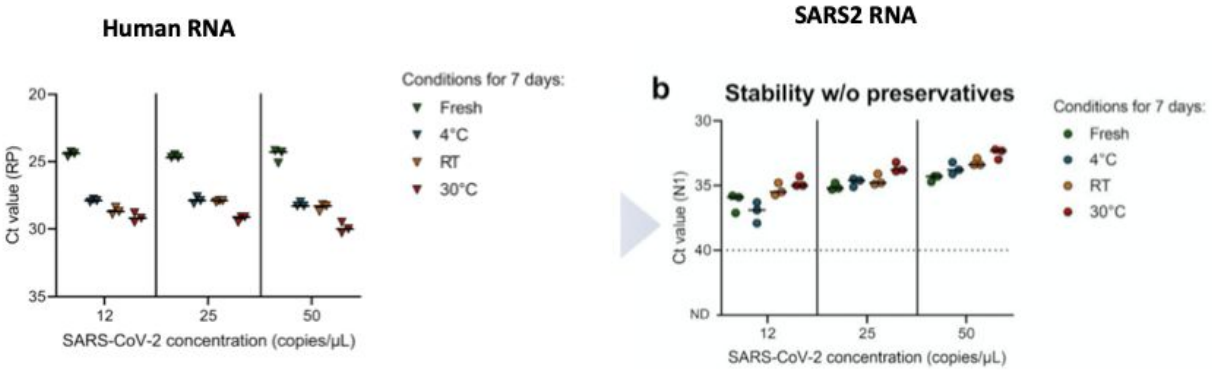
Typical Outcome of Assay

- Every Sample run with 2 primer sets
- Positive control indicates effective reaction
  - No failed batches to date
- 2 positive results lead to Kelli K contact
- 1 positive result -> Rerun with 4 primer sets
  - Any 2 positives lead to Kelli K Contact
- No False positives to date



Test Overview
RT-LAMP Surveillance Testing

The stability of SARS2 RNA in saliva samples facilitates home collections



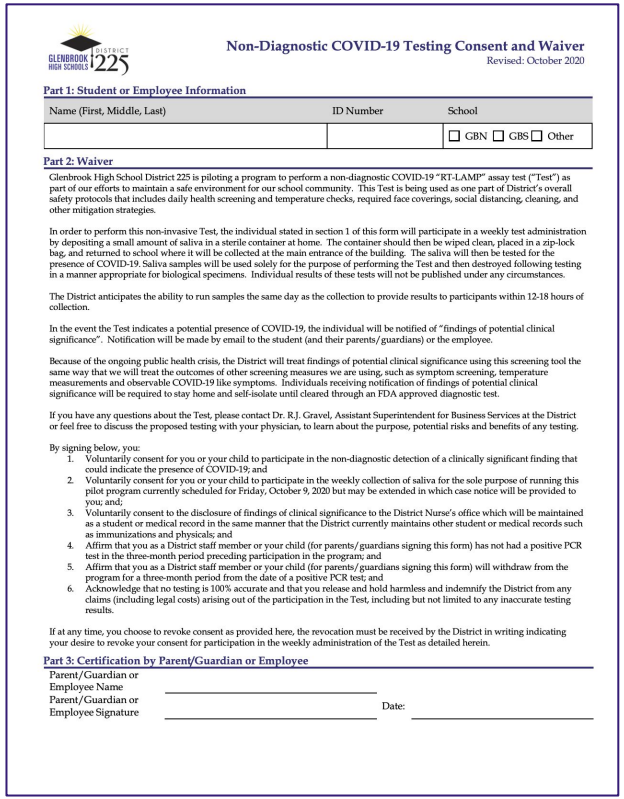
Vogels et al, 2020 MedRXIV
Yale "Saliva Direct" paper

Test Overview
RT-LAMP Surveillance Testing

Ensuring HIPPA and privacy compliance

- The district should maintain a record linking all participants to barcoded sample number (D102 uses ”powerschool”)
  - Safeguard Screening should never have this list
- The district should establish a district contact such as a nurse or other appropriate individual to receive information regarding findings of potential clinical significance to participants
- District should obtain consent from all participants or their guardians
  - D102 consent form provided to Hector 10/5 or prior

Potential Next Steps



GLENBROOK HIGH SCHOOLS DISTRICT 225

Non-Diagnostic COVID-19 Testing Consent and Waiver
Revised: October 2020

Part 1: Student or Employee Information

Name (First, Middle, Last)	ID Number	School
		☐ GBN ☐ GBS ☐ Other

Part 2: Waiver

Glenbrook High School District 225 is piloting a program to perform a non-diagnostic COVID-19 "RT-LAMP" assay test ("Test") as part of our efforts to maintain a safe environment for our school community. This Test is being used as one part of District's overall safety protocols that includes daily health screening and temperature checks, required face coverings, social distancing, cleaning, and other mitigation strategies.

In order to perform this non-invasive Test, the individual stated in section 1 of this form will participate in a weekly test administration by depositing a small amount of saliva in a sterile container at home. The container should then be wiped clean, placed in a zip-lock bag, and returned to school where it will be collected at the main entrance of the building. The saliva will then be tested for the presence of COVID-19. Saliva samples will be used solely for the purpose of performing the Test and then destroyed following testing in a manner appropriate for biological specimens. Individual results of these tests will not be published under any circumstances.

The District anticipates the ability to run samples the same day as the collection to provide results to participants within 12-18 hours of collection.

In the event the Test indicates a potential presence of COVID-19, the individual will be notified of "findings of potential clinical significance". Notification will be made by email to the student (and their parents/guardians) or the employee.

Because of the ongoing public health crisis, the District will treat findings of potential clinical significance using this screening tool the same way that we will treat the outcomes of other screening measures we are using, such as symptom screening, temperature measurements and observable COVID-19 like symptoms. Individuals receiving notification of findings of potential clinical significance will be required to stay home and self-isolate until cleared through an FDA approved diagnostic test.

If you have any questions about the Test, please contact Dr. R.J. Gravel, Assistant Superintendent for Business Services at the District or feel free to discuss the proposed testing with your physician, to learn about the purpose, potential risks and benefits of any testing.

By signing below, you:

1. Voluntarily consent for you or your child to participate in the non-diagnostic detection of a clinically significant finding that could indicate the presence of COVID-19; and
2. Voluntarily consent for you or your child to participate in the weekly collection of saliva for the sole purpose of running this pilot program currently scheduled for Friday, October 9, 2020 but may be extended in which case notice will be provided to you; and;
3. Voluntarily consent to the disclosure of findings of clinical significance to the District Nurse's office which will be maintained as a student or medical record in the same manner that the District currently maintains other student or medical records such as immunizations and physicals; and
4. Affirm that you as a District staff member or your child (for parents/guardians signing this form) has not had a positive PCR test in the three-month period preceding participation in the program; and
5. Affirm that you as a District staff member or your child (for parents/guardians signing this form) will withdraw from the program for a three-month period from the date of a positive PCR test; and
6. Acknowledge that no testing is 100% accurate and that you release and hold harmless and indemnify the District from any claims (including legal costs) arising out of the participation in the Test, including but not limited to any inaccurate testing results.

If at any time, you choose to revoke consent as provided here, the revocation must be received by the District in writing indicating your desire to revoke your consent for participation in the weekly administration of the Test as detailed herein.

Part 3: Certification by Parent/Guardian or Employee

Parent/Guardian or Employee Name _____

Parent/Guardian or Employee Signature _____ Date: _____

Draft Email for Families and Staff
Subject: Non-Diagnostic COVID-19 Testing Pilot Program

Dear Glenbrook Families and Staff,

As part of Glenbrook High School District's return to in-person learning, the Board of Education has explored the possibility of implementing routine COVID-19 testing for students and staff. During the week of September 21st, we asked parents and staff to share their thoughts through a brief survey regarding whether the school district should implement mandatory, routine COVID-19 testing on-site at no cost to students and staff. Over 3,500 responses were received, indicating strong support among parents (89%) and staff (92%) to implement COVID-19 testing. With this feedback, we have engaged multiple testing providers to identify a test to be implemented in our schools. Through a partnership with our colleagues at the New Trier High School District, we are pleased to share that we have identified a provider to facilitate an initial testing pilot program at a reasonable cost ($11.00 per test) for both school district 203 and 225.

Beginning November 9, 2020, the school district will pilot a voluntary COVID-19 screening program for students and staff members. The screener test the District is using is a non-diagnostic "RT-LAMP" assay test. This COVID-19 screening program has been developed by scientists at the University of Wisconsin Madison and adapted for use in Illinois schools by Safe Guard Screening, LLC.

Participants will provide a saliva sample at home in a sterile container provided by the school, which will be analyzed to indicate the potential presence of COVID-19. The container will be placed in a provided zip-lock bag and returned to the school. Staff will collect containers at the main entrance of each school. The District anticipates that it will receive results within 12 to 18 hours.

If the screener indicates a potential presence of COVID-19, the individual will be notified and asked to contact their doctor to obtain a test to make a formal diagnosis. As with other screening measures, individuals are not permitted to return to school until cleared through an FDA approved diagnostic test or have otherwise complied with IDPH guidance on required quarantine and return to work/school protocols.

The use of this screening tool provides supplemental infection control. It will not replace any safety plans implemented by the District, including wearing masks and social distancing, and it should not change any behavior by the student or staff member. All school community members should continue to follow the guidelines developed by the district and local public health officials.

Students or staff members that have previously tested positive for COVID-19 should not enroll in the trial, as a previous diagnosis may lead to erroneously positive results.

Participation in this program is voluntary, and staff/parents must sign and return the attached form to covid19testing@glenbrook225.org by Monday, October 26th, at noon to participate. Additional information will be shared with participants during the week of October 26th.

Thank you in advance for your ongoing support,

Dr. R.J. Gravel
Assistant Superintendent for Business Services

Non-Diagnostic COVID-19 Testing Consent and Waiver

Revised: October 2020

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If the screener indicates a potential presence of COVID-19, the individual will be notified and asked to contact their doctor to obtain a test to make a formal diagnosis. As with other screening measures, individuals are not permitted to return to school until cleared through an FDA approved diagnostic test or have otherwise complied with IDPH guidance on required quarantine and return to work/school protocols.

The use of this screening tool provides supplemental infection control. It will not replace any safety plans implemented by the District, including wearing masks and social distancing, and it should not change any behavior by the student or staff member. All school community members should continue to follow the guidelines developed by the district and local public health officials.

Students or staff members that have previously tested positive for COVID-19 should not enroll in the trial, as a previous diagnosis may lead to erroneously positive results.

Participation in this program is voluntary, and staff/parents must sign and return the attached form to **covid19testing@glenbrook225.org** by Monday, October 26th, at noon to participate. Additional information will be shared with participants during the week of October 26th.

Thank you in advance for your ongoing support,

Dr. R.J. Gravel
Assistant Superintendent for Business Services