

COVID-19 Testing Proposal

Learning and Operational Plan for the 2020-21 School Year

Monday, October 26, 2020

Parent Survey

#	Question	Consistently Attending In-Person Learning	Not Attending In-Person Learning	Occasionally Attending In-Person Learning
1	Describe how your student is currently learning	400	336	339
2	Moving forward, describe how your student intends to learn	475	240	360

#	Question	Yes	No	NA
3	Would you support your student participating in routine COVID-19 testing	890	106	79
4	Would you support the school district implementing mandatory testing	835	189	51
5	Does your student participate in non-school sponsored	364	711	
6	Would you support your student participating in routine COVID-19 testing for school-sponsored programs	961	114	
7	Would you support your student participating in routine COVID-19 testing for non school-sponsored programs	941	134	

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

Provider	Test Type	Unit Cost	Considerations
Safeguard Screening	RT-LAMP Saliva External Lab-Based	\$11	<ul style="list-style-type: none"> Includes all costs of supplies, personnel to analyze the sample, and disposal of all medical waste. School solely responsible for issuing/collecting sample tubes and transporting to the lab.
Elysian Medical Distribution (Megna Health)	RT-PCR Nasal Swab On-site Lab	\$21.95 + Personnel* + Waste Disposal	<ul style="list-style-type: none"> Includes costs of supplies. School district responsible for issuing/collecting sample tubes, and performing the test onsite in a lab environment using its own personnel. School district responsible for training personnel, performing the test, recording the results, and disposal of all medical waste.
University of Illinois	RT-qPCR Saliva External Lab-Based	\$20	<ul style="list-style-type: none"> Includes all costs of supplies, personnel to analyze the sample, and disposal of all medical waste. School solely responsible for issuing/collecting sample tubes and transporting to the lab. School only has access to aggregate data results.

* Per-test personnel expense is estimated at \$2-3 per test (note: nurse to administer nasal swab and lab technician).

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)

If the school district implemented mandatory COVID-19 testing as a condition to attending school in-person, would your student participate in the testing process? *

Yes

No

Please share any thoughts in SUPPORT of routine COVID-19 testing on-

Long answer text

Please share any thoughts in OPPOSITION to routine COVID-19 testing on-site.

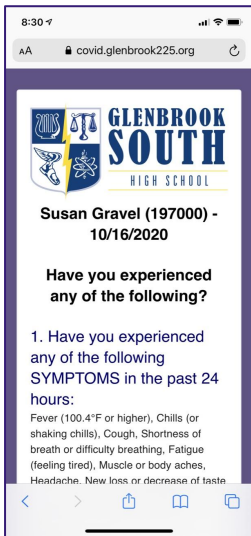
Long answer text

An Additional In-Person Learning Strategy to Reduce the Spread of COVID-19

Additional Step

Routine COVID-19 Testing

Participating students and staff would take a test that would be valid for “x” amount of days. The check in system will validate that the individual has a current, negative test on record before granting entry.



Daily Health Questionnaires



On-Site Check In and Temperature Check



Social Distancing (and Reminders)



Face Coverings, Assigned Seating and Social Distancing to Support Contact Tracing



Local Contact Tracing and Engagement with the CCDPH to Reduce the Spread of COVID-19

Proposed Testing Framework

Voluntary Participation

Self-Administered,
Saliva-Based Test at Home

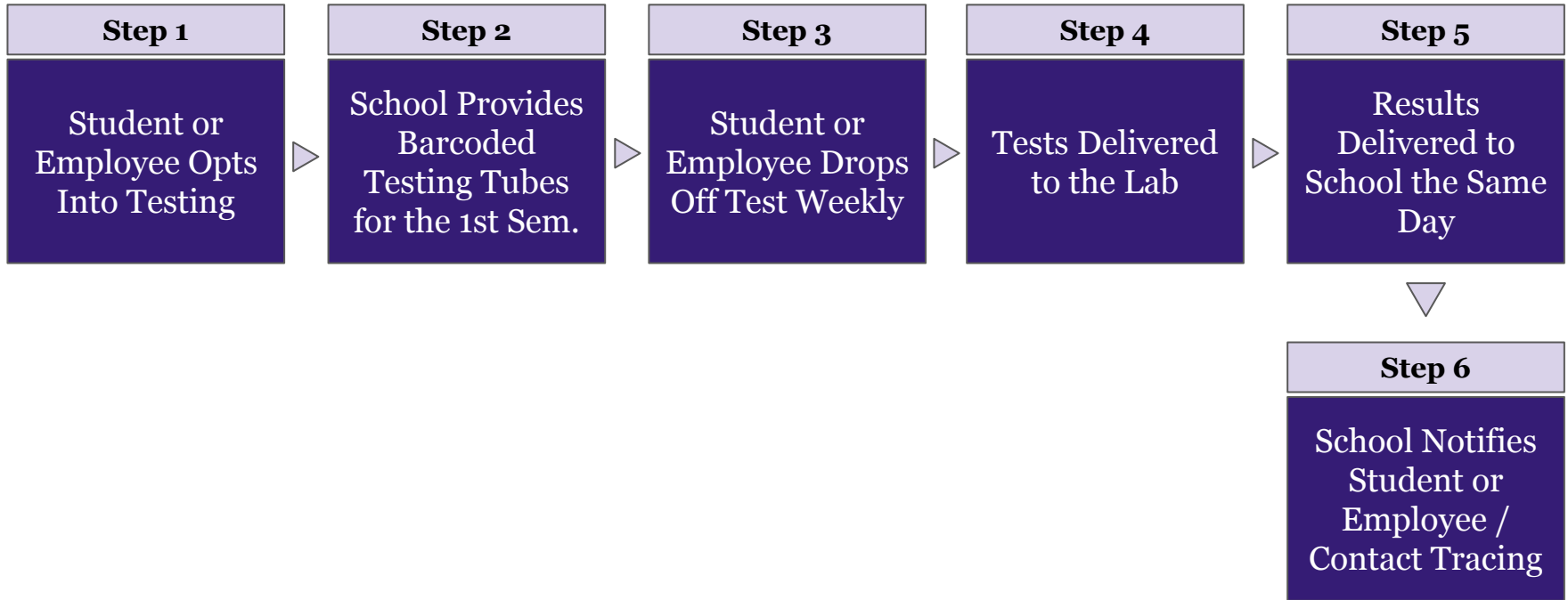
Weekly Testing

Confidential

Other Options for Consideration

- Mandatory Participation for Students for In-Person Instruction
- Administered at School
- Once or Twice a Week
- All That Opt-In or Random Sampling
- Limited Group Participation (e.g., Athletics)

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 + 3,194 Students = 4,044 Total Tests = \$44,484 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:

\$44,484 per Weekly Test x 27 Weeks = \$1,201,068

Testing Cost Projections

First Semester (Start Testing the Week of November 9th)

All Students and Staff Present and Participating:

\$66,550 per Weekly Test x 8 Weeks = \$532,400

Or

\$133,100 per Twice Weekly Test x 8 Weeks = \$1,064,800

All Students Currently Opting-Into In-Person and All Staff Present Participating:

\$44,484 per Weekly Test x 8 Weeks = \$355,872

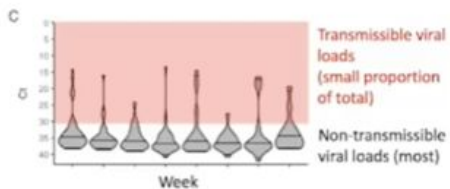
Or

\$88,968 per Twice Weekly Test x 8 Weeks = \$711,744

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/Abbott 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](#)

[Science 09-30-20](#)

America's Approach

Sensitivity

Cost

Speed

What the data say

Cost

Speed

Sensitivity

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

Your Coronavirus Test Is Positive. Maybe It Shouldn't Be.

The usual diagnostic tests may simply be too sensitive and too slow to contain the spread of the virus.



STUDIES SHOW

What if We Worried Less About the Accuracy of Coronavirus Tests?



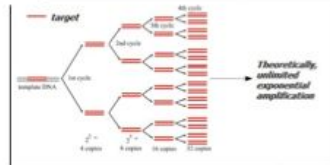
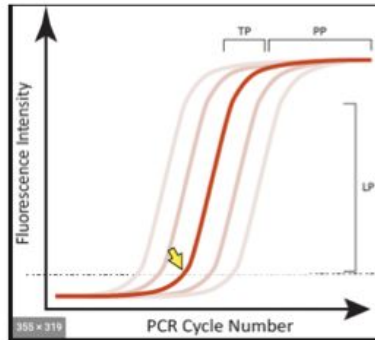
[nytimes.com/2020/08/29](https://www.nytimes.com/2020/08/29)
[New York Times/2020/08/20](https://www.nytimes.com/2020/08/20)

Test Overview

RT-LAMP Surveillance Testing

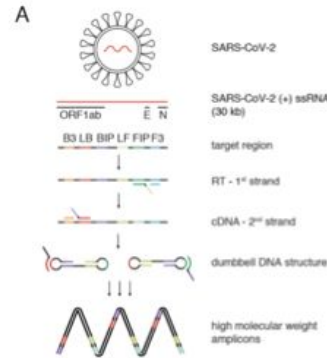
How does RT-LAMP compare to other comparable assays

• 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

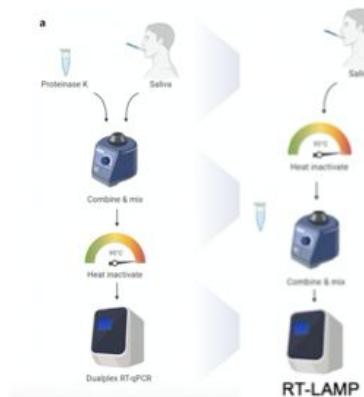
Saliva Direct

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

vs

RT-LAMP

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

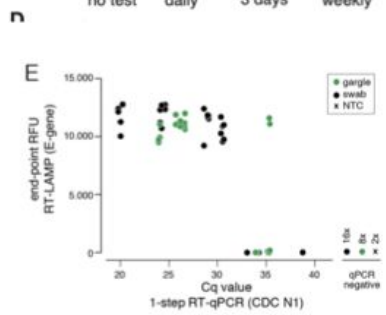
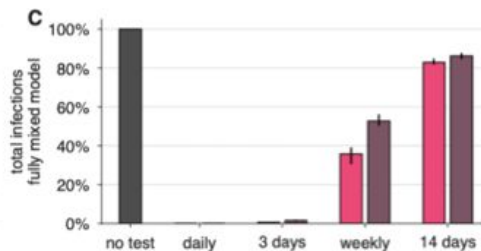
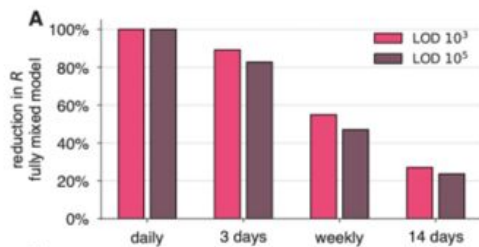


Vogels [et al, MedRXIV 2020](#)

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

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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.

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

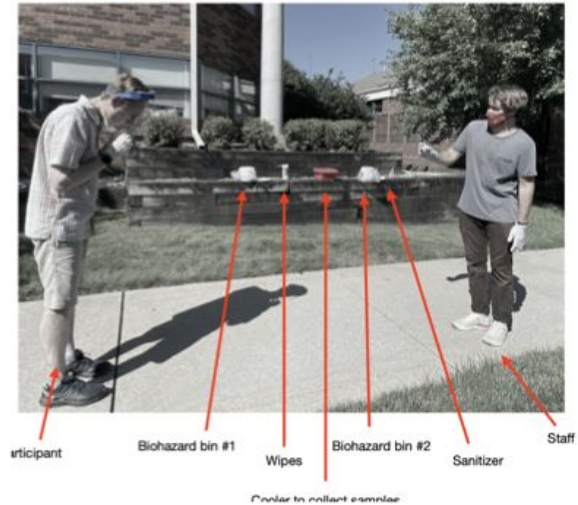
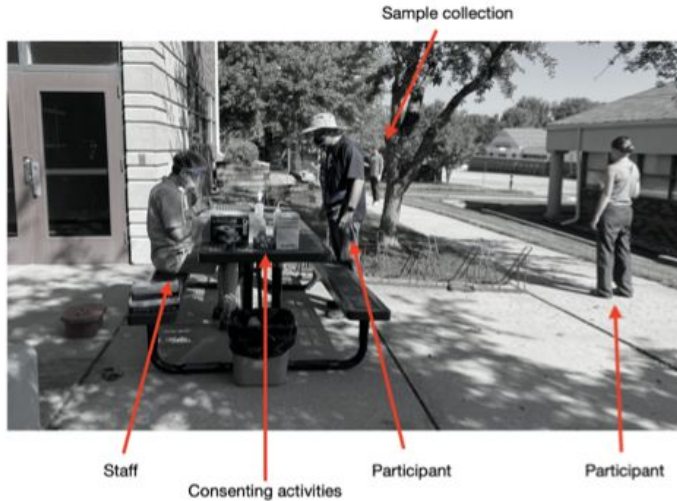
Item	Number
µ1000 Pipet tips for spitting (boxes)	3
Eppendorf racks for each batch	2-4
Spout tubes for spitting	100-200 (1 per spit sample)
Consent forms	stack
Labels	stack
Clipboards	2
pens	1 box
Sharpie marker	4
Something to clean pens between use	
hand sanitizer	
Lysol/bleach handwipes	
Insulated 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
Tables	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

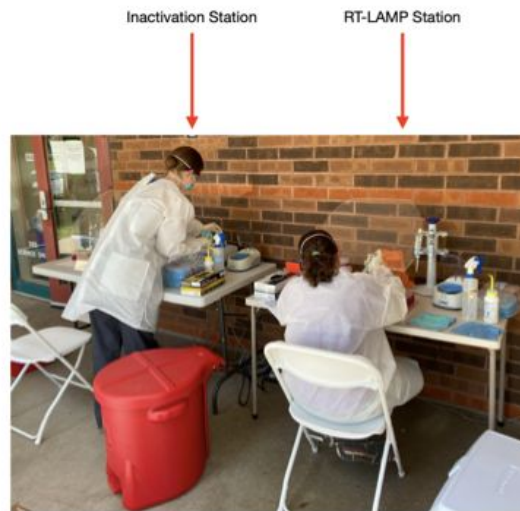
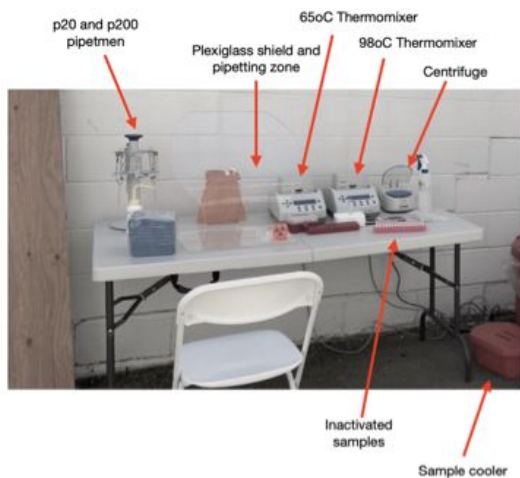
Consenting and Collection table workflows



Test Overview

RT-LAMP Surveillance Testing

Inactivation and RT-LAMP stations

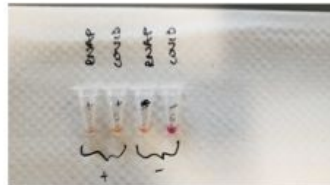
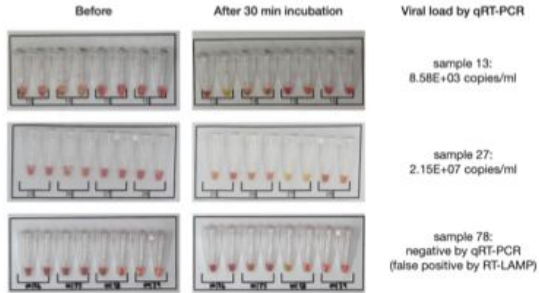


Test Overview

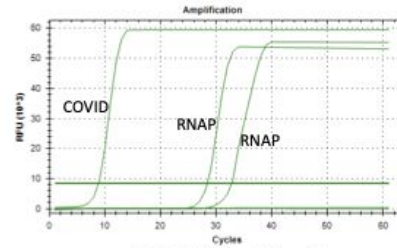
RT-LAMP Surveillance Testing

Establishing and Validating RT-LAMP assay

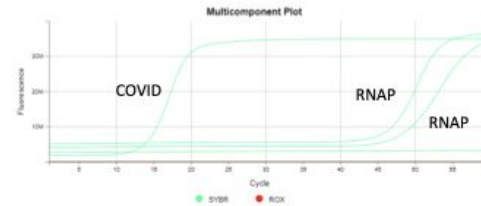
Colorimetric Assay



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



RT-PCR Machine 1



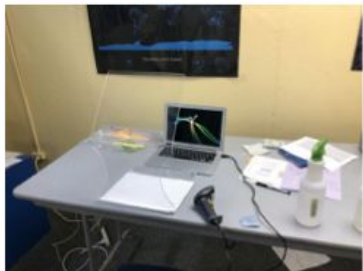
RT-PCR Machine 2

Adarsh Dharan, Sevnur Komurlu, Drew Lichon, Rasa Viliauga

Test Overview

RT-LAMP Surveillance Testing

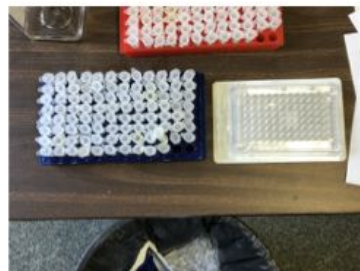
Workflow of the Assay



Barcoded Samples scanned in
Assigned daily sample number



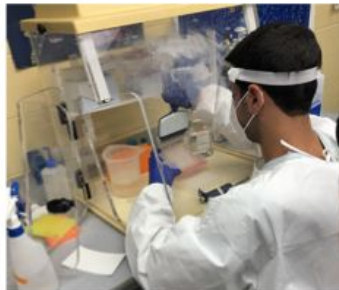
Samples heat inactivated



Samples Aliquoted into 96 well plate
preloaded with buffer



Reaction performed
in RT-PCR Machine



Samples added to
96 well plate containing
Reaction mixture

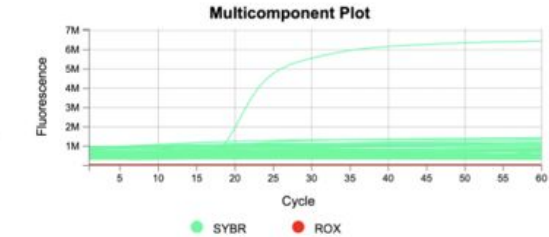
Test Overview

RT-LAMP Surveillance Testing

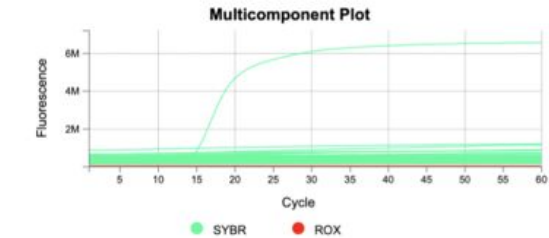
Typical Outcome of Assay

- 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

DO



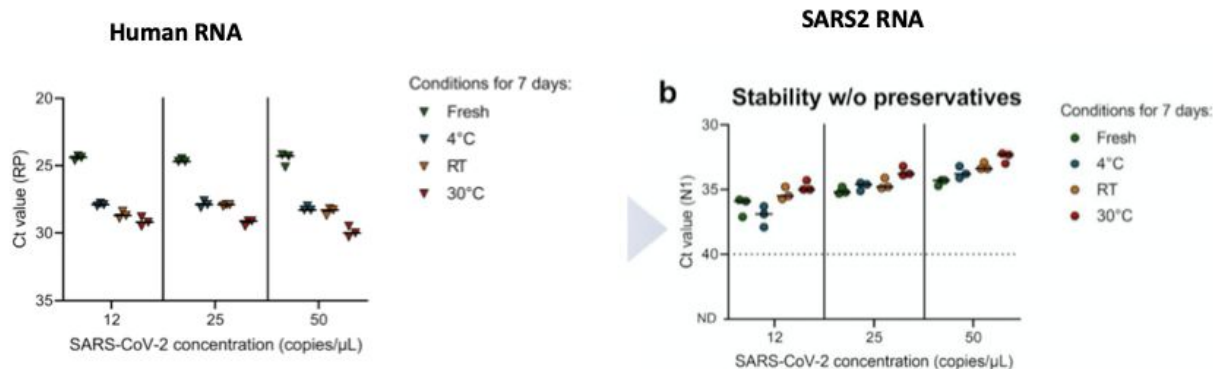
Ase1



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