MTT Test Event Request Form Links

These are the recommended forms:

Long Term Care Facilities (facilities not assigned to an HAI investigator):
https://forms.gle/TGtYZgALyxb867D6A

Other requests for special events, special populations or critical infrastructure (events not open to the community at large, but to specific groups/populations):
https://forms.gle/oSojsyvduKo5BV4YA

Community (HotSpot) Testing Event requests: https://forms.gle/MTaxovraiiVJLbwk7

School Testing event requests: https://forms.gle/rGFJLwYTWW4WVCgf6

Current COVID-19 Testing Considerations, Plans, and Resource Needs

Prepared by the Utah Department of Health,
COVID-19 Incident Command: Testing Branch
9/13/2021

Current testing environment

UDOH provides testing and oversees contracted testing for the following groups:

- **Community -** Currently NOMI runs all community locations until Oct 2nd with the exception of UPHL which is run by MTT. NOMI coverage will be revisited on 9/16 and weekly to see if extension is needed. UDOH MTT Teams covered 15 community sites prior to Aug 30th. NICUSA will also add community sites when SLA is completed. Community sites are determined by hotspot data - past 14 day case rate, past 7 day percent positivity, wastewater surveillance data, willing partners to host and help promote community site.
- **K-12 Test To Stay -** LHDs respond if available, then UDOH MTT Teams, Nomi and NICUSA are available to help with staffing or running entire event
- **Long Term Care Facilities -** UDOH MTT Teams
- **Prisons -** Currently MTT, to be taken over by NICUSA. Testing will occur twice weekly at two prisons. This may increase or decrease as needs arise. This SLA is being negotiated presently.
- **Tribes -** UDOH MTT Teams provide testing on request
- **State Hospital and State Developmental Center** - UDOH MTT provides testing weekly

*UDOH MTT has provided testing for other groups as demand and capacity changes. Groups UDOH has provided testing for previously, but does not currently provide for, include: universities/colleges, state and federal courts, professional sports teams (Utah Jazz and Real Salt Lake), amateur and professional sporting events, JJS facilities, military, and political events.

Community Testing

- To determine where we stand up community testing locations (both fixed and mobile), we look at:
    - Past 14-day case rates, past 7-day percent positivity, wastewater data, and willingness from community partners to host and promote the site.
    - The testing branch (leadership, MTT, contracted testing) meets weekly with the hotspot team, epi reps, wastewater reps, and SLCoHD testing team to go over this data and make recommendations and adjustments to testing locations.
- Sites are advertised currently through:
    - A news release that goes out weekly to state and local partners
    - Updates to the testing locations webpage as changes are made
    - Posting weekly testing locations and hours of operation on the blog post page of our website
    - We are open to ideas for improving advertising and awareness of testing sites

- While it is fairly easy and quick (1-2 days to pack up a fixed site, 0 days for mobile) to move the location for both fixed and mobile sites, our evaluation of these sites has shown that it takes an about 60 days for a new site to become known in the community and for that site to have an effect on percent positivity. For this reason, we try to add additional sites where needed and not move them around.
- Currently, there are 42 state-managed testing sites, 12 of those are fixed sites. The mobile vans address statewide needs and typically a mobile van will visit 2-3 locations per day. Hours vary depending on size of community, response from community, and logistics, such as site agreements.
    - In the past 2 weeks 75 additional testing hours have been added to these sites. Cannon has increased hours to Mon - Sat, 7 a.m. - 7 p.m. effective 9/7. Freeport Center and the Maverick Center hours will be increased to 7 a.m. - 7 p.m. the days they are currently open, effective the week of 9/13. The following fixed sites added additional hours: Bountiful, Draper, Logan Mt. Olympus, St. George all added additional hours, and plans are in place to increase St. George hours to 7 a.m. - 7 p.m. M-Sa as soon as possible (Goal is week of Sept 20th). Many of the mobile sites have also added hours including Elk Ridge High School (South Jordan) West Valley, Payson, Park City on Wednesday's, and Cedar City.
- Local health departments (LHDs) are not required to report their testing capacity/strategy to us, and have only provided us this information for K-12 testing for grant reporting purposes. In the past, they have reached out to us when their capacity is close to being met and we have arranged an event and/or stood up additional sites for them. It may be difficult to get all LHD testing resources/strategies/capacity reported to us.
- Self-administered testing sites:
    - The University of Utah (U of U) campus has saliva self-collection available to asymptomatic students, faculty, and staff and immediate family members of students, faculty, and staff on their campus in two locations. Both their symptomatic and asymptomatic testing is only open for these specified groups, so it is not promoted publicly or on our website.
    - https://alert.utah.edu/covid/testing/. U of U Health offers appointment-based saliva self-collection for their patients and the public. The patient must register, pick up the collection kit at a specified location, and return the sample to the same location. These sites are open to the public and are listed on our website. https://healthcare.utah.edu/coronavirus/testing/
    - Intermountain Healthcare launched a similar self-collection saliva model on August 30. Test kits can be picked up and returned to a locked drop box in a vestibule at 62 Intermountain clinic locations. Anyone that can access their website can sign up; this is not limited to Intermountain patients. Intermountain launched this service because their emergency departments and clinics were getting overrun with patients seeking testing. They are not advertising this service publicly and have opted not to have the state put a link to testing locations on the testing website because they do not want to overload their system. Intermountain is billing insurance for the testing, or charges a flat rate of $100 for those without insurance. More information can be found here:

https://intermountainhealthcare.org/health-wellness-promotion/pandemics/covid/get-testing

- Because both the U of U and IHC have run successful self-collection testing models for their own populations, and in some cases, the broader community, it would be worth asking their leadership what it would take to get them to expand their scope. Dr. Hofmann has offered to convene their leadership to make this request and see how we could support it if needed. She mentioned a potential leverage point would be to prevent further strain on their hospitals by expanding access to testing.
- Community organizations can requests testing events by filling out this form: https://docs.google.com/forms/d/e/1FAIpQLSdBno0uytX2fcxzOIrjHtN4c0EbEb0FFHBzSw_JAqinwMZ9yw/viewform

K-12 Test to Stay (TTS)

- Proactive Outreach: Maggie Graul and Kendra Babitz closely monitor the Daily School Outbreak Reports. When a school is approaching a 1% threshold, Maggie contacts the LHD to see if they would like to do preemptive testing for the school. If yes, UDOH works with the LHD to determine if the LHD or UDOH will be 1) contacting the school and 2) conducting the testing event.
  - A preemptive school/community testing event occurred on 9/2 and 9/3 in Eagle Mountain for two schools that reached a 1% threshold. MTT conducted the test event. 9/2: 371 tested, 9/3: 257 tested; 57 positives identified (9.08% positivity).
  - For the week beginning 9/12: As of 9/10, there are 13 schools that could potentially do school testing for the week of 9/12 - either preemptively (approaching 1%, met 1%) or required (met 2%). These schools fall within 4 LHDs - Bear River, Davis, Salt Lake, and Utah County health departments. Maggie has been in communication with each of these LHDs to determine their plan for testing in these schools. Bear River, Davis, TriCounty, and Salt Lake counties have their own K-12 testing teams and are planning to conduct their own testing. They do not anticipate needing UDOH support at this time. Utah County does not have its own testing team, and is working closely with the schools and UDOH to schedule preemptive testing events as schools and communities are willing. The Eagle Mountain test event mentioned above is an example of this.

- Process for fulfilling school TTS event requests:
  1) LHD conducts TTS event if a local testing team is available (Bear River, Central, Davis, Salt Lake, Tricounty, and Wasatch have their own teams),
  2) UDOH MTT conducts TTS event with assistance from UTNG,
  3) UDOH MTT conducts TTS event with additional staff support from Nomi or NICUSA,
  4) Nomi or NICUSA conducts TTS event (Nomi and NICUSA is also available to contract directly with LEA and/or LHD to support capacity outside UDOH)

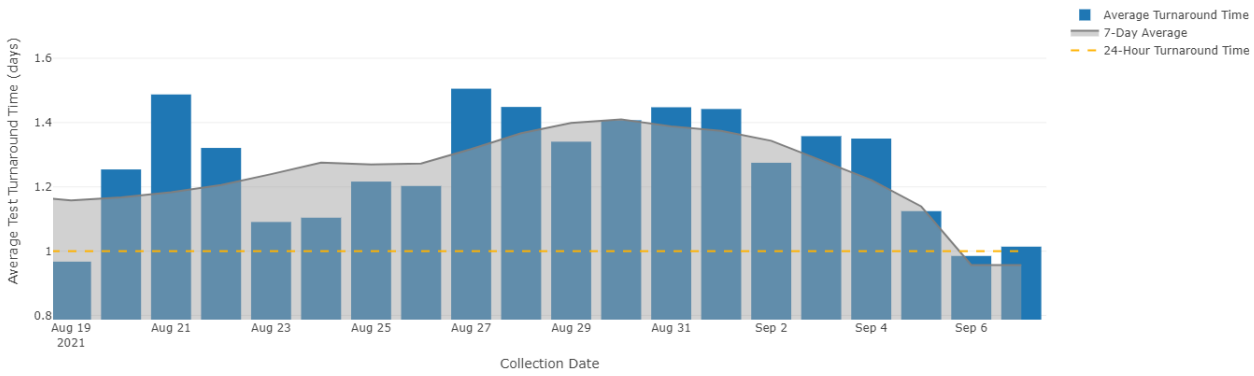
- Standard Operating Procedure (SOP) for TTS events conducted by UDOH MTT:

1) All students tested will receive a BinaxNOW rapid antigen test, regardless of previous infection or vaccination status,
2) parents will have the option to register a student for both rapid antigen and anterior nasal PCR tests. PCR will be encouraged for asymptomatic students and vaccinated students during registration,
3) UDOH MTT will conduct the testing event at the school site,
4) if demand for PCR exceeds UPHL processing capacity, PCR collection will stop once capacity is met,
5) If student needs a confirmatory PCR test and capacity has been met, student will be referred to community testing location or healthcare provider for PCR sample collection.

Testing goals and measures

The goals as outlined in the Utah Response Plan are 1) to stand up community testing within 10 days in the 10 small areas with the highest testing scores*. And 2) to respond to "A and B" priority testing requests within 48 hours of request. Please see the Testing Priority Matrix here for how testing requests are prioritized. *Testing scores are calculated based on percent positivity, elevated sewersheds, and 14 day case rates on the Aberration Detection Dashboard.

- **Lead Measure 1** [Testing]: 100% of high priority (A & B from Testing Priority Matrix) testing event requests are fulfilled within 48 hours.
    - **Measure** [Outbreak Response Testing]: Average turnaround time of response time to sample collection of high priority (A & B from Testing Priority Matrix) testing event requests.
    - **Measure** [Community Testing]**:** The 10 small areas with the highest testing scores from the Aberration Detection Matrix each week have mobile testing events offered within 10 days.
    - **Strategy** [Community Testing]: Ensure that at least the 10 small areas with the highest testing scores from the Aberration Detection Matrix each week have mobile testing events offered within 10 days
    - **Strategy** [Outbreak Response Testing]: MTT wll ensure priority testing event requests, including outbreaks in LTCF, correctional facilities, and K-12 schools are fulfilled within 48 hours.
- Test turnaround time goal
    - The goal for all major labs in Utah is to have PCR results to the patient within 24 hours of receipt of the sample. Most labs have been between 1.2 and 1.5 days since August 20th. Please see the chart below. This is also available on the public dashboard.



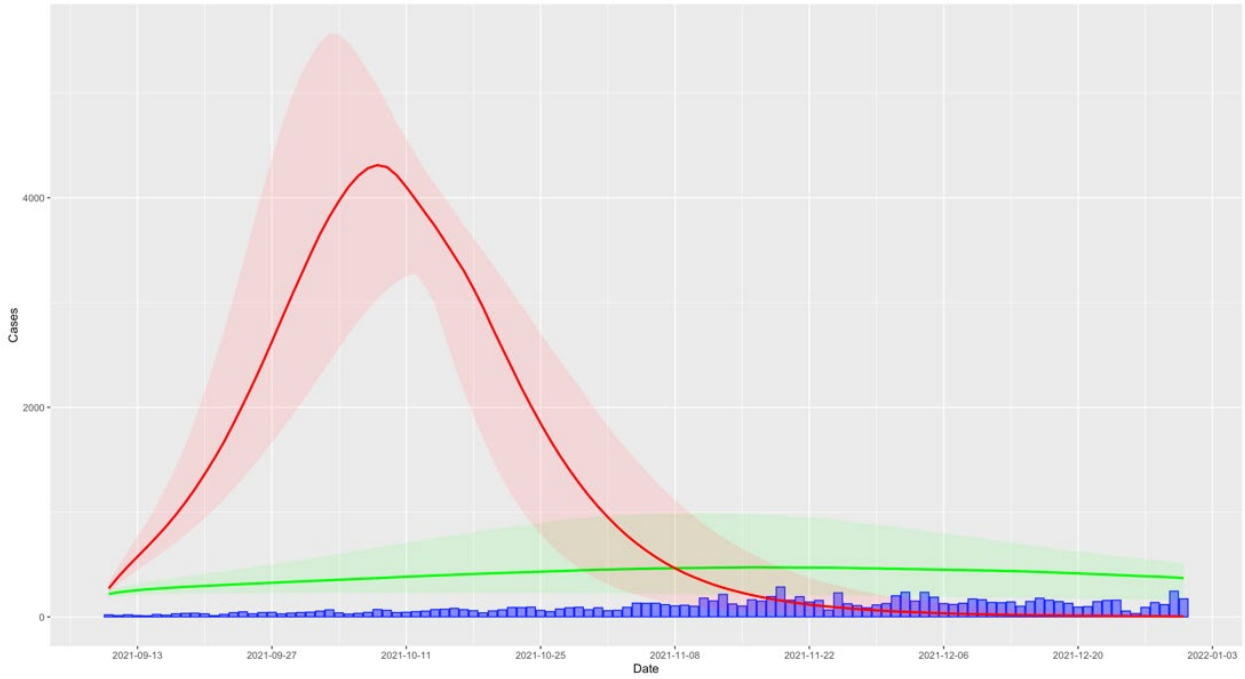
- Wait time goal
    - Nationally, Nomi's wait time goal is 20 minutes.
        (i) Currently our average wait time is 15-30 minutes across all sites.
        (ii) Wait times are tracked when a patient's QR code is scanned from when they are swabbed (check-in/check-out system). These results are monitored daily.
    - MTT tries to keep wait times less than 40 min, but wait times over 20 min have rarely been an issue.
- Tracking of Wait Times--I think we need to track this daily/hourly
    - Wait times are not regularly tracked by MTT. As lines begin to increase, MTT will add staff and/or additional lanes to help meet volume demand. MTT currently does not have enough staff to dedicate someone to tracking wait times daily/hourly. Additional state agency staff could help support this role. Concerning Nomi, they would not need additional staff to report on wait times.
    - How do we keep track of wait times and balance staff when the wait times are increasing? Dedicated staff from additional state agencies to track wait times would solve this issue.
    - If we do not want people waiting more than 15 minutes, do we have the staff capacity statewide to ensure people will not wait longer than 15 minutes? For MTT, no, hiring has been the biggest choke point. For Nomi, staffing would also be the issue. However, Nomi is hiring an additional 120 additional staff by the end of September to be able to keep wait times closer to 15 minutes.
        (i) If not, how many more staff are needed? To monitor wait times at each testing location, we would need either one person per team or one person per site depending on the number of hours staff are able to work and their willingness to travel.
        (ii) Do we want to ask for staff across our two departments to take testing shifts statewide? Staff from our agencies would be helpful to 1) track wait times and 2) fill in as the data/test result entry position for MTT until additional recorders can be hired. This position requires a utah.gov account and access to a laptop. 12 full time staff or 24 part time for 2 months would be helpful for this role.
        (iii) If not, who will staff? State agency staff would be the fastest resource to mobilize to help with this issue.

Projections for capacity needs

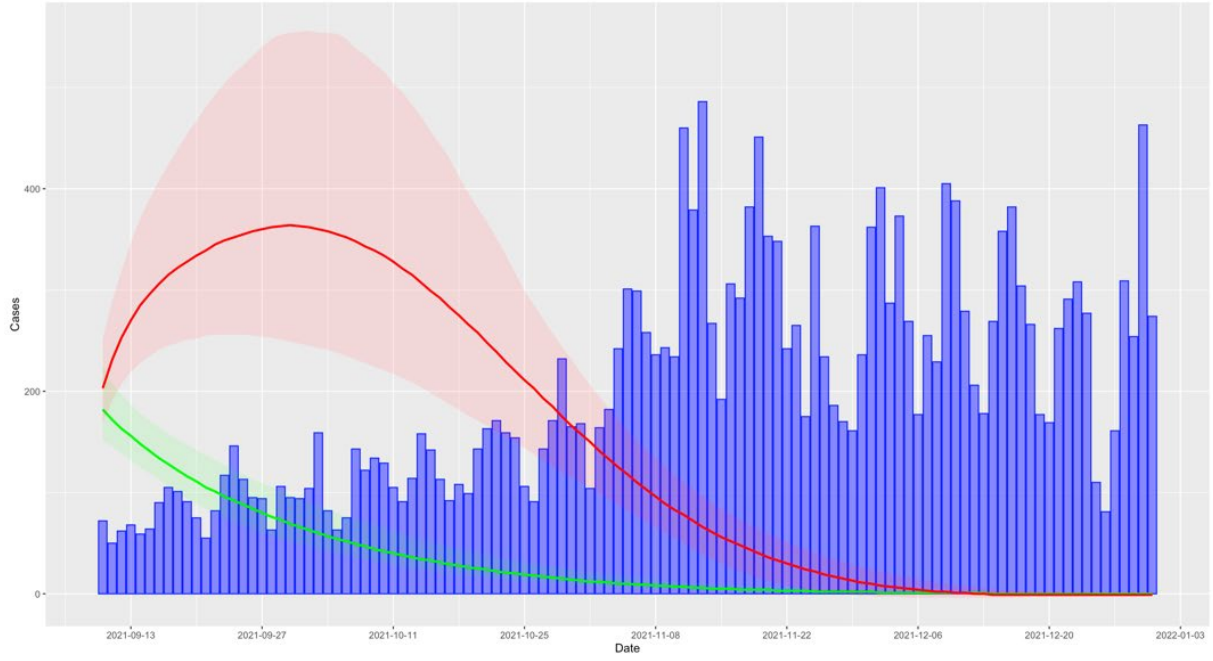
Sam LeFevre developed models this week to anticipate incidence; the team is currently working to interpret those projections and determine testing capacity needs. Below are the models. The blue bars are from last year's cases. Each age group has two scenarios. The green line scenario is based on the modeled Rt, where the current case patterns inform the model. The red line scenario is based on Imperial College's low estimate of Rt for the Delta variant. Sam believes the truth is somewhere in the middle of these two extremes. In summary, these models indicate school age groups and those ineligible for vaccination peaking much higher than the rest of the population. The anticipated peaks are projected late September through mid October for 5-11year olds, similar for 12-17 year olds, and the modeling shows that we are likely at the peak now for the rest of the population.

Age Group	Population	Past Cases	Vaccinated	Estimated Immunity	Green Line Rt	Red Line Rt
5-11 years	365,898	27,921	200	8%	1.3358	5.5
12-17	317,483	48,003	135,216	58%	1.3822	5.5
0-4 & 18+	2,522,577	404,112	1,479,393	75%	1.1644	5.5

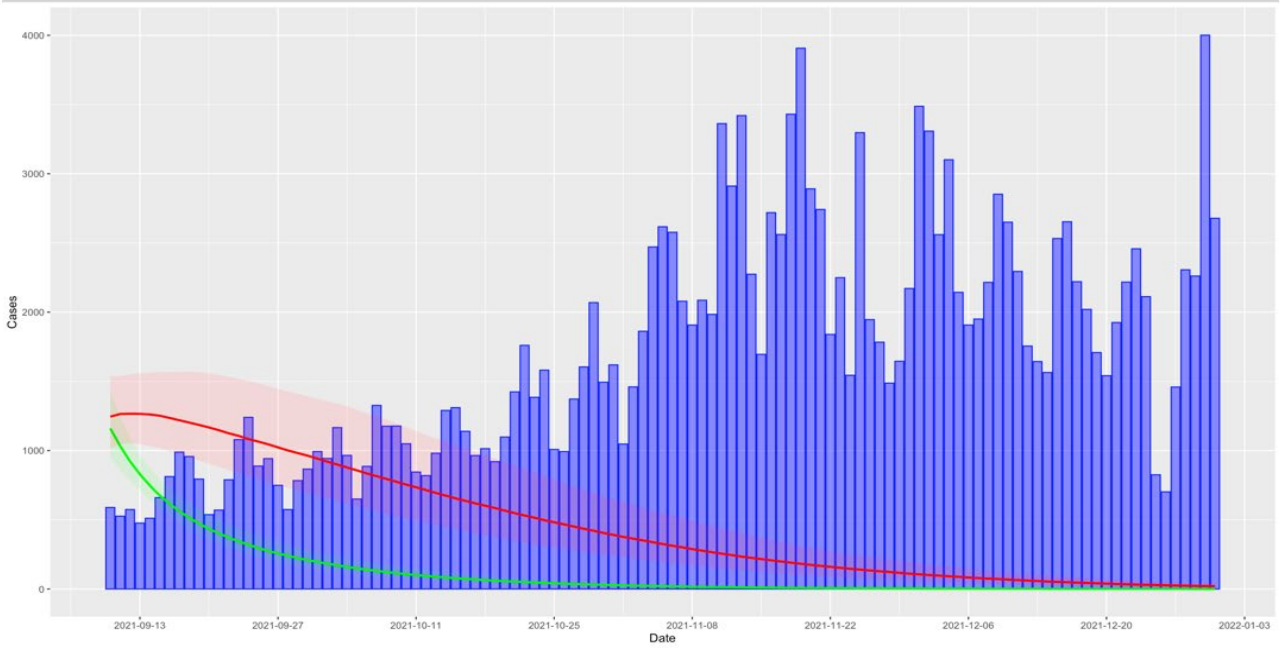
Age = 5-11



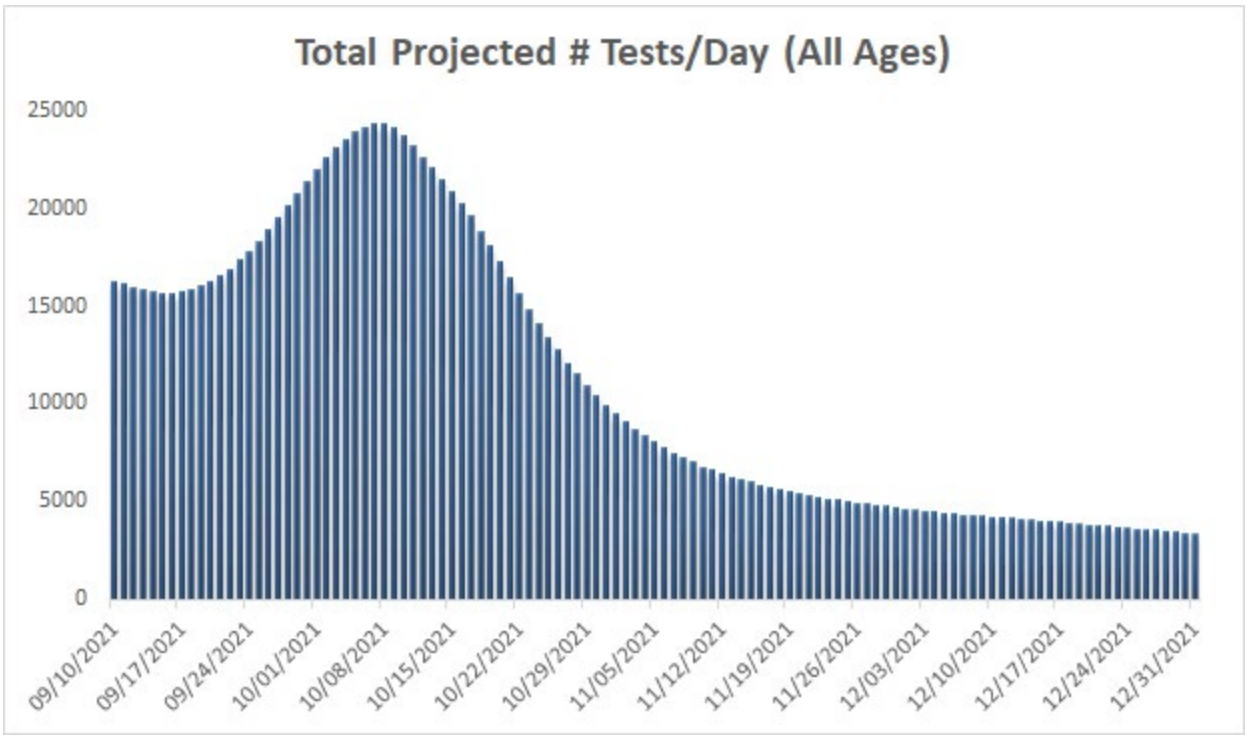
Age = 12-17



Age = 0-4; 18+



Modeling was done for anticipated case numbers of three different groups of the population: 1) school aged children that are not yet eligible for the vaccine (5-11 years), 2) school aged children that are eligible for the vaccine (12-17), and 2) the rest of population excluding school aged children (0-4 years and 18+). A percent positivity of 8% was applied to the projected case numbers for school-aged children in order to estimate a projected number of tests completed per day. This is a conservative estimate for percent positivity based on test to stay events conducted in May 2021 and testing done thus far in the school year. This percentage can be updated once test to stay events have occurred in order to establish a baseline. A percent positivity of 10% was applied to the projected case numbers for the rest of the population in order to estimate a projected number of tests completed per day. The charts below demonstrate the projected number of tests to be completed each day through December 2021 for the combined age groups, as well as each of the three age groups separately. It is important to note that these projections were based off modeling, and the number of tests will likely vary.


Total Projected # Tests/Day (All Ages)
25000
20000
15000
10000
5000
0
09/10/2021
09/17/2021
09/24/2021
10/01/2021
10/08/2021
10/15/2021
10/22/2021
10/29/2021
11/05/2021
11/12/2021
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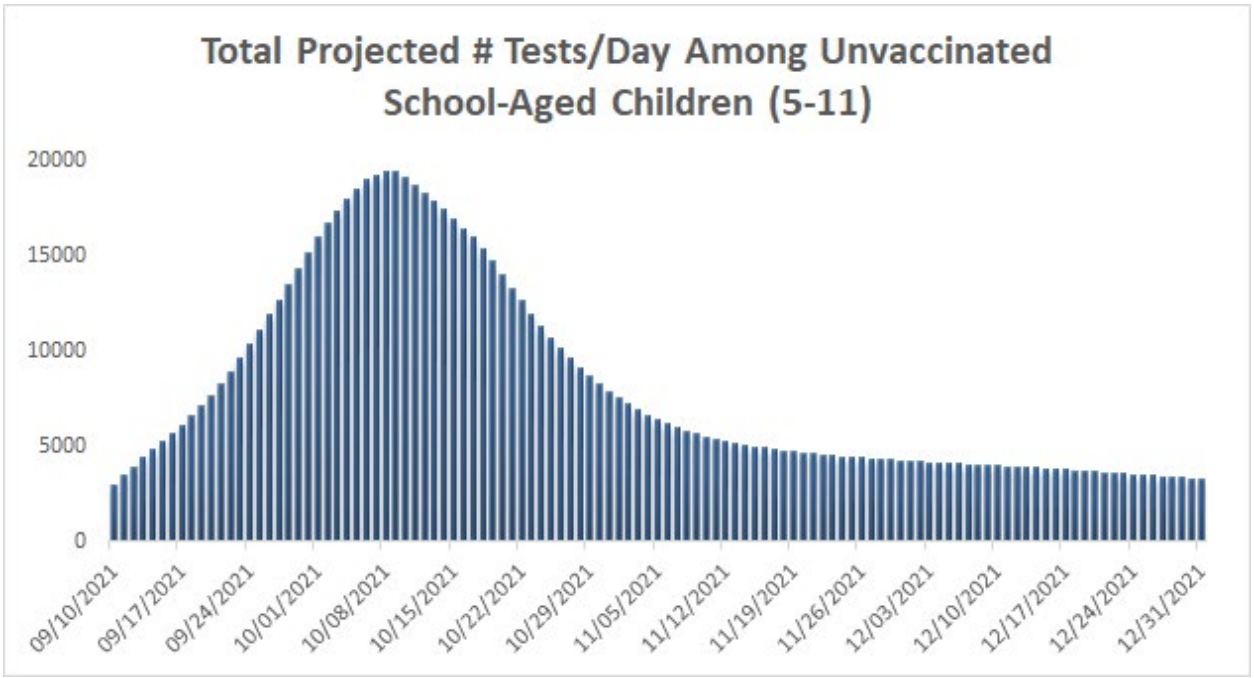
12/03/2021
12/10/2021
12/17/2021
12/24/2021
12/31/2021


Total Projected # Tests/Day Among Unvaccinated School-Aged Children (5-11)
20000
15000
10000
5000
0
09/10/2021
09/17/2021
09/24/2021
10/01/2021
10/08/2021
10/15/2021
10/22/2021
10/29/2021
11/05/2021
11/12/2021
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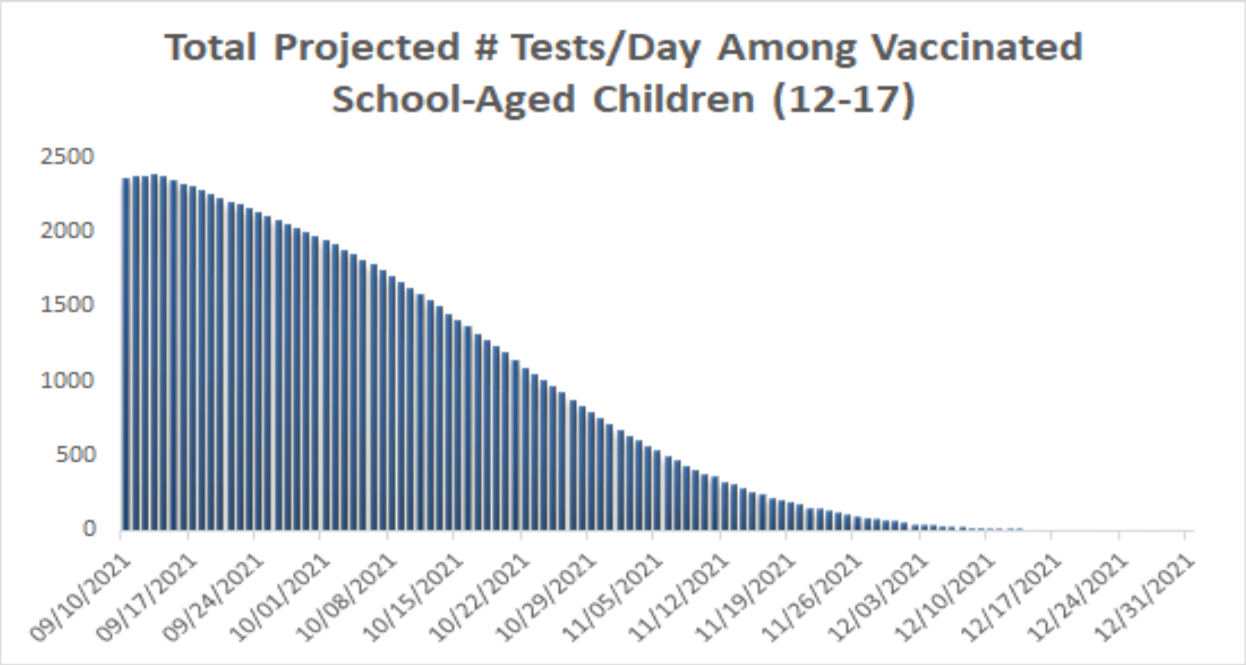
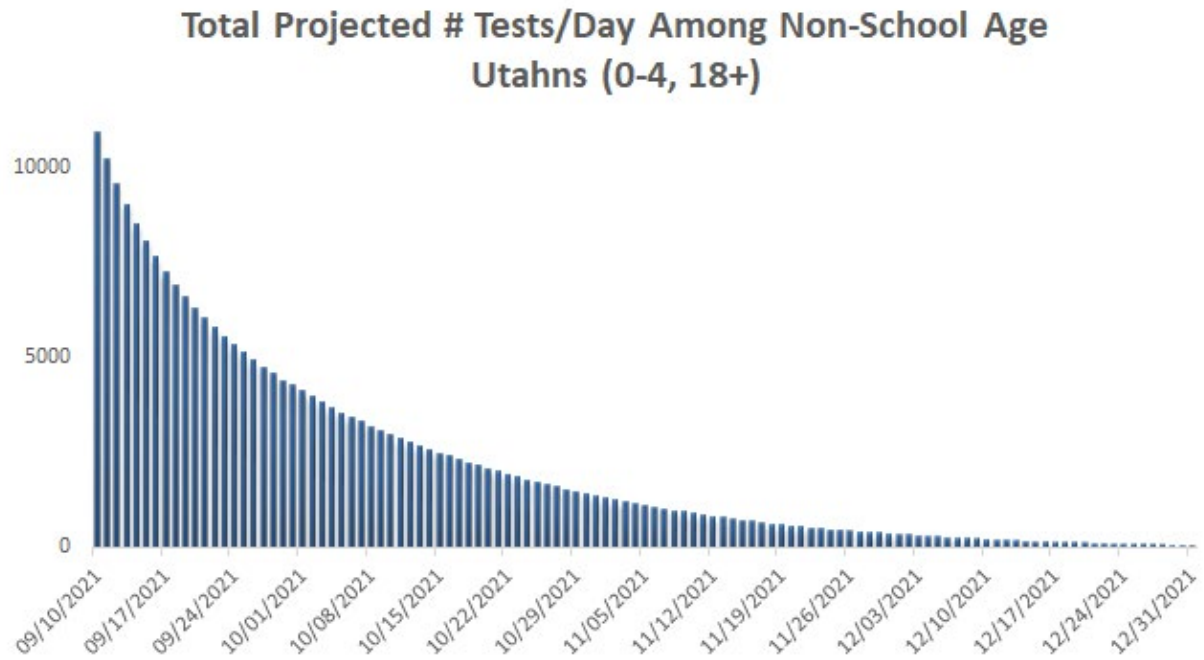
12/24/2021
12/31/2021





- How is the current surge in comparison to previous surges?
  The winter wave (2nd wave) starting about September 9, 2020, started with approximately 1.75% of the State population having already acquired natural immunity following recovery from infections. This wave started with a 7-day average case incidence of 389 cases per day. It peaked in approximately 74 days around November 22, 2020, with a 7-day average case incidence of 3,393 cases per day or an 8.7 fold increase in the case incidence. By this time approximately 4.32% of the population had

some level of natural immunity due to recovery from infection. However, during this wave period, a number of public health non-pharmaceutical interventions (NPI) were in effect including masking, social distancing and mass gathering restrictions. The winter wave plateaued for about 48 days until January 9, 2021, before declining through March 2021. In December, vaccination became available and the level of immunity in the population started to increase rapidly.

The current wave (3rd wave) started about June 1, 2021, with a 7-day average case incidence of 201 cases per day. At this time approximately 57% of the population had either natural or acquired (from vaccination) immunity. About 43.9% of the population were considered fully vaccinated. During this wave, there are no public health NPI interventions in effect. As of September 12, 2021, the 7-day case rate had reached 1,545 or about a 7.7-fold increase in the last 112 days.

Of note is a difference in the age groups driving the two surges. In the winter wave, 35% of cases were in the 25-44-year age group, and 66% were 25-years and older. In the current wave, 37% of the cases are in the 18-24-year age group, and 63% are 0-24-years old. For our school children, in the winter wave, 5% were in the 5-11-year age group, and 10% were in the 12-17-year age group. In the current wave, 9% are in the 5-11-year age group, and 14% in the 12-17-year age group.

- Do we expect testing numbers to increase, and over what time period?
  Based on the modeling, it is anticipated that testing numbers will continue to increase through mid mid-October and then slowly begin to decrease through the end of the year. It is anticipated that school aged children that are not yet eligible for vaccination (5-11 years) will drive the case counts and testing through mid-October.

- What is the appropriate estimated number of daily tests we should plan for given this surge? Is it 20,000?
  Modeling projects that the number of tests estimated per day will gradually increase through the beginning to mid-October, with a maximum number of daily tests reaching around 24,300 before slowly decreasing to about 3,400 daily tests by the end of the year.
    - If we assume an estimated 20,000 tests per day, how many more sites do we need? (or - how would this be covered across the system)?
      Over the past five weeks, the UDOH Mobile Testing Team and contracted testing through NOMI have done between 25-30% of the total number of tests collected in the state. To get through the projected surge of up to 24,300 tests per day, UDOH Mobile Testing Team and contracted testing would need to conduct an average of 7,290 tests per day assuming they continue to conduct 30% of the state's testing. Over the past two weeks (8/21-9/4), the UDOH Mobile Testing Team and NOMI have averaged a combined number of 5,274 tests per day. The Testing Branch will be meeting this upcoming week to determine the total number of testing teams needed to meet the testing capacity.

How we plan to meet testing demands

K-12 Test to Stay

Plans to address TTS requests are summarized above in the *Current Testing Environment* section. Summary is below.

1. LHD does testing if its own team is available
2. LHD or LEA reaches out to UDOH MTT to do the testing
3. MTT does the testing with additional swabbers from Nomi or from NICUSA
4. Nomi or NICUSA does all of the testing at selected sites

- We are working to get an SLA in place for NICUSA and then they will be ready for deployment. This SLA is with NICUSA for review, and then will be routed for Department approval. UDOH staff are in daily contact with NICUSA to get this in place.
- As of September 10, MTT has 12.5 mobile teams to address Test to Stay, in addition to Nomi capacity. For MTT and Nomi capacity to respond to K-12 testing needs, please reference here for the latest numbers: https://docs.google.com/spreadsheets/d/1m11vY7haeOdnQObJEkKaZhmM1HoAFfE24vuXDoe1c_A/edit?usp=sharing

Surge Management

- Community Testing has 39 TestUtah locations, and 3 MTT locations throughout the state
- Combined - they tested 30,741 total individuals, that excludes 1 testing day for the holiday (Labor Day). If we add in the average from the previous week, that would be a 13% increase in Testing from the previous week (35,476 compared to 31,495). 31,495 people the week of Aug 30th, a 9% increase in testing from the previous week of Aug. 23rd. The previous week's testing totals were 29,009.
- Most TestUtah locations offer between 7-12 hours of testing each day. Most MTT locations offer 3-5 hours.

Drive-up only model

- Starting Saturday, September 11th, there will be no appointments, just walk-ups to better handle the surge volumes and appointment concerns with waiting in lines. This is the model the state mobile test team (MTT) follows. Switching to the walk up model is a clearer indication of first come first serve.
- Due to the recent surge in testing needs across the state, we are transitioning to a walk-up model to ensure access and equity by servicing patients with a first come, first serve process. Typically the testing sites offer both appointments and walk-ups at all locations across the state. Under normal circumstances this model works fine. But, in times of a significant surge like what we are experiencing now, the shift to a walk-up only model has proven to be more efficient. Under the walk-up only approach, patients are distributed more evenly across the sites and better balance is achieved as patients

are more likely to go to sites near them vs. driving long distances for a guaranteed appointment.
- We do not recommend people arrive any earlier than 10 minutes prior to the opening of any testing site. We have enough tests and are prepared and ready for a steady flow of patients every day at every location. We encourage people to arrive at the testing site during operating hours when it's most convenient for them.
- We currently have the supply, staff, and capacity to conduct thousands of tests per day at each testing site. We are constantly evaluating supply based on demand across the state. Currently our average wait time is 15-30 minutes across all sites, and we expect that time to remain consistent. This improved wait time is a direct result of the transition to the walk-up model. Wait times are tracked when a patient's QR code is scanned from when they are swabbed (check-in/check-out system). These results are monitored daily.
- Nomi's team leads do an hourly wait time check-in. They will measure this week's wait times compared to the previous. This will be an on-going process done daily/weekly.

Nomi adding additional staff

- On 9/9 TestUtah added 9 additional staff
- Since the surge began, they have added 60 additional staff
- By the end of September, they will hire an additional 120 staff (40/week) which will allow the teams size at each site to be between 7-12

Adding additional sites, hours, days

- Nomi has plans to add 15 additional sites by the end of September to meet the current testing demand
    - West Jordan, West Valley and Ogden will become fixed sites as soon as the shipping containers arrive (fixed sites offer additional testing days and hours). The biggest constraint is getting the shipping containers delivered, as the companies who do so are on a backorder. They will be delivered by the end of September, or early October. These sites were identified by UDOH and Nomi based on the increased testing demand over the last 30 days, 7-day positivity rate, and sewer water detection levels. The additional sites that will be added are still to be determined, and will be evaluated with the same data.
    - Until then, Nomi is continuing to add additional staff to expand hours and days at the existing 39 locations.
    - We are currently developing a contingency plan to implement home test kits and kits at the sites with Nomi. Please refer to the section regarding home testing.
- The Cannon site increased hours this week to 7-7pm, M-Sa. We are planning on extending hours at Freeport, Maverick, St. George as soon as next week, and at other sites as soon as possible.
- In the last 2 weeks, 75+ additional testing hours have been added to meet demand.

Addressing scheduling and site issues

- Nomi will be personally confirming each night with staff that they will be able to work at their designated site the next day.
- Nomi, MTT and Nicole B will be working closely to ensure that any site issues are handled immediately. We have designated certain team members to ensure that if any problems arise, they are immediately addressed.

Current demand

- Where are we seeing the largest increase in testing demand? Where are we anticipating the largest increases in testing demand? Are we throwing more people in those locations? If not, how can we?
    - The largest increases in testing demand are always seen in more populated areas simply because there are more people.
    - When we look at the hotspot data, we know where more testing should be happening in the state. But, we also know that sending testing resources to these locations and promoting them does not always return higher testing numbers. Tricounty is a great example of this. They have had the highest case rate and percent positivity for months during the summer. But, when we increase testing availability in already established locations and increase promotion, turnout remains the same.
    - In areas where long lines are reported, Nomi has been adding staff, increasing lanes, increasing days and hours at locations. Long lines have by in large been mitigated.
    - Data from the past seven days on the Internal Dashboard show that 11 of the 13 LHDs have testing rates consistent with the rest of the state. Two LHDs (Southwest and San Juan) have lower testing rates compared to the rest of the state. This indicates testing demand is increasing across the entire state.

Table 1: Local Health District Testing Rates Compared to the Rest of the State (Total Tests)

LHD	RR	95% CI	Compared To State
Bear River	0.98	(0.56-1.4)	No difference
Central Utah	0.81	(0.43-1.19)	No difference
Davis County	1.02	(0.61-1.43)	No difference
Salt Lake County	0.94	(0.58-1.29)	No difference
San Juan	0.49	(0.25-0.73)	Lower
Southeast Utah	1.01	(0.5-1.53)	No difference
Southwest Utah	0.7	(0.46-0.94)	Lower
Summit County	0.99	(0.74-1.23)	No difference
Tooele County	1.1	(0.54-1.65)	No difference
TriCounty	0.97	(0.48-1.45)	No difference
Utah County	0.93	(0.55-1.31)	No difference
Wasatch County	0.87	(0.61-1.14)	No difference
Weber-Morgan	0.8	(0.46-1.14)	No difference

Limitations

There is also some information that we do not have access to and cannot address:

- LHD Testing Capacity:
  As mentioned above, LHDs are not required to report their testing capacity/strategy to UDOH, and have only provided us this information for K-12 testing for grant reporting purposes. In the past, they have reached out when their capacity is close to being met and additional sites are stood up for them. Getting this information will be a big ask of them and seen as undue burden. It took a couple months to get this information for K-12. But, if the ask comes from UDOH leadership, it may be prioritized.
- Staffing Availability Outside UDOH:
  We do not have insight into staffing at other state agencies. However, if we know there are state employees that are able and willing to assist (DEM or DHS for example) who already have utah.gov accounts and access to their own laptops, we would gladly take some assistance over the next couple months until we get more people hired into the

recorder position for MTT. We could use 12 full time staff or 24 part time staff. Nicole also reached out to the recommended temp agencies from finance, and it seemed like they would not be able to provide their own tech equipment (which is where we have a deficit) so this would not be feasible at the moment. Volunteer agencies take a really long time to get set up with utah.gov accounts and through our security hoops. That has made volunteer groups not worth our lift. We also have no visibility or control over getting healthcare workers back into healthcare work. We know there is a lot of burnout and people are leaving the healthcare field, but also a nationwide staffing shortage in this area that contributes to our slow hiring for some positions. However, Dr. Hofmann has offered to bring together healthcare leadership from across the state to see how we might persuade them to get their feet wet again with community testing, even if it's only expanding an existing self-collection model.

At-Home Testing Models

Goals: Ensure everyone has access to testing and address current gaps in testing

https://docs.google.com/document/d/1RmXIBQ3MKDIrNhOb1rEWneIgxqg6dtfDsZQsuRnPZ7M/edit?usp=sharing

Recommendation:

1. Begin by utilizing a Turn Key Model (Model III) while investigating a long-term approach. This would be the fastest way to begin implementation given current testing supplies and capacity.
2. Explore options to partner with U of U and/or Intermountain to expand home testing models.

Next Steps for the Turn Key Model (many can be done simultaneously)

- Talk to U of U and Intermountain
- Talk to finance regarding funding source
- Determine procurement process with State Purchasing.
    - Can a current vendor supply?
        - Reach out to current Vendors and see if they offer
    - If not, then work through the procurement process.
        - Is it a sole source or RFP?
- Identify vendor and begin negotiations
    - Determine eligibility for at home testing (rural, Consult LHDs)
        - Identify our needs
            - Rural, urban, homebound, statewide, etc
        - Determine if vendors provide options for both rapid antigen and PCR testing.
        - Determining limitations, such as weekend/holiday shipping/processing; shipping to PO boxes in rural areas, etc.

Next Steps for Long Term Approach

While a turn key model is being implemented with a contracted lab, this would buy time for UDOH to determine additional gaps in existing testing models, solicit community and stakeholder input, and build capacity to implement another more sustainable model such as Model II.

- Determine gaps in current testing models and future testing needs
- Solicit community and stakeholder input about what at-home testing model would be most widely utilized and accepted. Feedback could be solicited from LHDs, CHWs, clinics, etc.
- Work through logistics to implement an alternative at-home testing model, such as determining staff time needed, materials (testing kits, locked drop boxes, temperature controlled kiosks, transportation of specimens from dropbox to lab, etc.), lab capacity.
- Build staff capacity to design and implement the model. This would likely require hiring additional staff to oversee at-home testing.
- Evaluate current testing and develop a plan to evaluate at-home testing.

Current testing gaps that would be addressed with the turn-key testing (Model III):

- Weekend testing
- After hours testing
- Access in rural locations
- Long wait times
- Holiday testing
- Access for homebound, very ill, elderly

Reasons UDOH is not allowed to dispense rapid test kits:

- Not allowed legally to distribute for at-home testing due to CLIA waiver and FDA approval
- Come in large packs that can't be broken out
- Supply shortage so can't order home-test kits quickly

Concerns and gaps for testing

Staffing is a significant concern for UDOH MTT and Nomi. Both teams are working to hire, and are increasing advertising as well. An additional contractor should help with this concern to some extent. The Team will communicate any other identified gaps and needs to Leadership as they are identified.

Specific Q&A not covered in prior sections

1. **I wanted to restate the request to have a plan on Monday regarding testing that includes needs throughout the state that will both ensure that (1) wait times are reduced and (2) test results are delivered within 24 hours.**

Generally, the wait times are not a concern. There are times we can anticipate that there will be increased volumes such as Monday, Saturday, or after a holiday. We do add staff to those days. There is no way to measure wait times other than anecdotally. Nomi does track wait times. The process is when a patient's QR code is scanned from when they are swabbed (check-in/check-out system). These results are monitored daily. Nomi also stated that last week test time averaged one car per minute per tester on average. The busier times are usually at the beginning of the testing shift and at the end.

TestUtah - 90% of Antigen test results are delivered within 15 minutes, across the entire state it's roughly 24 minutes.

PCR average turnaround times
ARUP bulk of the tests 39 hours (at time of receipt) for ARUP due to current volume. Last week's test volume was 4,086.

UPHL average turnaround time for samples tested on September 08, 2021 is 0.77 days with a minimum of 0 days and a maximum of 7 days. UPHL capacity is 2,790 samples, current use 9/9/2021- 1,953 samples

1. **The team should identify the number of swabbers, traffic control, check in, etc needed at each site and the strategies to get these positions filled, including from other State agencies, volunteer organizations, UTNG, etc.**

Nomi and MTT each have a scope of practice document outlining procedures including staffing. Staffing needs are reviewed daily and accommodations made. Surge provides a unique environment that is very volatile, which makes projecting challenging. Additionally, since this is entirely a man power operation, no shows occur occasionally. These are dealt with as soon as possible.

Both MTT and Nomi are actively hiring and will continue to do so until the need is met. The limiting factor is interested people applying for positions. Extensive advertising has taken place. Additionally, UDOH is in the process of contract negotiation with a second testing vendor. Nomi is able to pull from employees located across the nation. Also, Nomi plans to contract with a security/traffic control company to help with traffic concerns if needed.

There are multiple options for TTS events, from minimal state support (1 person to help direct to multiple full state teams (5 people per team) to conduct events for large schools 2,000+. There are specific staffing needs identified for each type of TTS request.

2. **Additionally, we also discussed establishing the contingency plan and deep contingency plan that would need to be implemented if we do not have**

enough capacity to meet the demands of schools requiring TTS. We all hope we will never get there but we need to plan as if it will happen.

The testing team is working with surveillance who is providing modeling to assist in determining testing needs. This should provide us with a solid projection of what is needed related to testing.

Nomi feels they can take on additional testing and the testing team is negotiating a supplemental testing contract.

UTAH DEPARTMENT OF HEALTH

COVID-19 Operations Meeting

Tuesday, August 17, 2021 - 1:00pm - 2:00pm

Purpose: Internal coordination of Operations Section including branches and teams to discuss activities and strategies around leadership priorities and the COVID-19 Response Plan metrics; provide awareness of ongoing and planned activities; and to provide a forum to address any gaps or concerns to bring to leadership's attention.

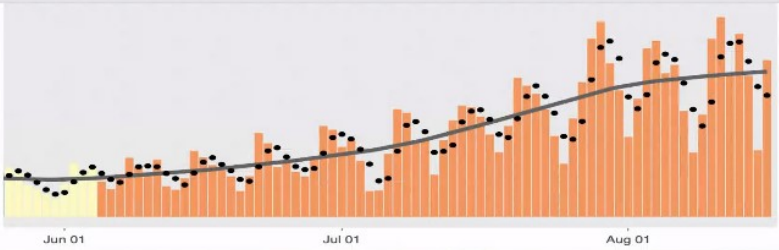
1. **Welcome & Announcements** (Sam LeFevre)

Activation of the UDOH ICS	January 21, 2020	574 days
Return to UDOH ICS	May 17, 2021	92 days

a.

UTAH RESPONSE PLAN (Old)					
	Goal	*Last Week*	*This Week*	*Source*	*As of Date*
Case Fatality Ratio	<1%	0.57%	0.57%	Public Dash	August 17
14-day Case Incidence / 100 K (by July 4th)	<20	369	385	Public Dash	August 17
• Mask Usage		18%	21%	BRFSS	August 14
• Percent Wrap Around Services Connected	>50%	67%	67%	VP Team	July 20
• Percent of Ut SASHU 7-day w/ Percent Positivity (T/T) <10%	>95%	15%	22%	HS Team	August 16
• Percent of Contacts that are Unknown/Pending	<15%	42.4%	42.5%	Public Dash	August 17
7-day COVID-19 ICU Utilization Rate	<15%	30.9%	28.8%	DOMO	August 15
Rapid Response for Long Term Care Facilities	>90%	95%	100%	DOMO	July 18
Rapid Response for non-LTC Facilities	>90%	96%	93%	DOMO	July 18
Percent 16+ Population Vaccinated (1 Dose)	>70%	68.5%	69.7%	Public Dash	August 17
Percent 12-15 Population Vaccinated (1 Dose)	>25%	39.7%	43.5%	Public Dash	August 17

b.



UTAH RESPONSE PLAN (New)					
	Goal	*Last Week*	*This Week*	*Source*	*As of Date*
MG 1 Sustained Incidence Plateau/Decline	45 days	6	0	Internal	August 17
• Case Growth Rate	< 1.0	0.93	1.17	Internal	August 17
SG 1.1 Weekly Administration of Prime Doses	> 18,775	31,857	35,860	Public Dash	August 17
SG 1.2 Hotspot Response and Management					
• Percent of Ut SASHU 7-day w/ Percent Positivity (T/T) <10%	>95%	15%	22%	HS Team	August 16
SG 1.3 COVID-19 ICU Utilization	< 15%	30.9%	28.8%	DOMO	August 15

c. Reminder of 204s

d. One Utah Road Map assignments to be filled out for the matrix on August 20th

2. **Review of Priorities** (Melissa)
    a. Command and General Meeting
        i. Key priorities this week
            1. Continue to get vaccines out
            2. Prepare for school and potential surge
            3. Supporting hospital decompression

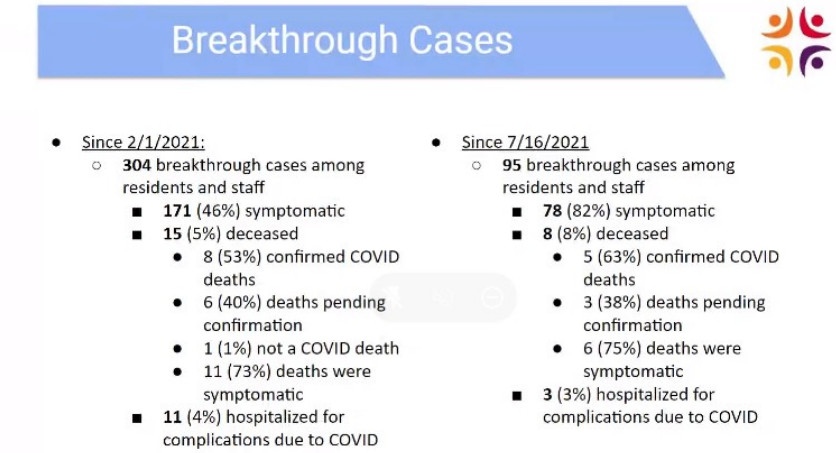
3. **UTNG Status** (Melissa)
    a. One LHD requesting extension need
    b. Short staffing in Lab (Alessandro)
    c. Request to finance for temporary hires (Kevin)
    d. Specific nurse IP to pull back in again? (April)
    e. Contact tracing needs, Call center with mobile testing teams and increase of calls (Nicole)
    f. Juli - Call center only open 9a-5p, need open during community test event times
        i. Starting testing at 7am with events going through 7:30 pm
        ii. Propose
    g. Dr. Hofmann: Mobile testing capacity
        i. Conversations to divert away from LTCFs due to anticipated school surge
    h. Juli: Need to create a new prioritization list to provide direction
    i. Melissa: Title 32 has been extended to the end of December 2021
    j. Dr. Hofman: Look at where all resources are provided across the system and identify prioritization

4. **Test to Stay** (Nate/Tracy/Testing Team)
    a. Will take place when school hits 2%
        i. Envision that this may take place soon and happen frequently
        ii. Need to have the ability to handle the requests
    b. Resources available/Plans to expand
        i. Antificape testing team 33% of schools within a one week time frame
        ii. Staffing shortage : NOMI to take over mobile testing sites August 30 through end of October
        iii. Anticipate 10-15 mobile testing teams available August 30th
        iv. Funding requests for LHD mobile testing teams: Davis, Tri County, Salt Lake and Bear River
        v. Maggie: To receive K-12 strategic response plans from LHDs by the end of the week
        vi. Melissa Zito: Do we have a process in the last surge with the schools and how they will connect with tribal public health
            1. San Juan conversations to coordinate support
            2. Need Paiute, Ute and Ute Mountain tribal support

5. **Mass Vaccination** (Nate/Tracy/Vaccine Team)

a. Need for vaccine surge environment for clinics and high volume
b. Need for boost vaccinations
c. Sam: Risk when we jump ahead of the EUA process in terms of liability
d. Cindy: Concerns for mass vaccination site availability
    i. Timing with flu, testing, and outreach to schools the message from LHDs is that we truly need to rely on pharmacies and providers
    ii. Met with Pharmacy partners in regards to LTCFs
    iii. CDC has Walgreens and CVS back on board: working on planning process for LTCFs
    iv. Ability to reinstate the mass vaccination sites
        1. CNS can ramp up at whatever level if needed

6. **LTC Facility Discussion** (April)
    a. Outbreaks
        i. Exposure only: 4
        ii. >20: 0
        iii. 11-20: 2
        iv. 5-10: 4
        v. 1-4: 16
        vi. HCW only: 33
        vii. Total facilities: 59
        viii. With Positive Residents: 26
    b. Seeing a large number of vaccine breakthrough cases



    c.
    d. Kevin working with facilities on contracts to coordinate funding
    e. LTCFs have critical staff shortages
    f. Important to allow testing in LTCFs
    g. Keegan: Will contact with Scarlett to get vaccination rates
    h. Dr. Nolen: Staff not vaccinated: Can we show that deaths due to unvaccinated staff?

7. **Hotspots Pilot Update/Discussion** (Nicole B/Willie)
    a. **Hotspots Dashboard** (Nate/MP)

i. Sections: Current snapshot, Goals, HII Equity
ii. Keegan: Nervous about having similar dashboards with different numbers and calculation methods. Would be helpful to know the development channels and reduce duplication.

2/24/2021 K-12 Testing

Agenda:
- Public Health Order update on new changes
- Test to Stay virtual training planning

Kenda Babitz:

- Thanks to Jenny's team for getting this done. (**Jenny**: this will updated again)
- Public Health Order Link
    - https://coronavirus-download.utah.gov/Health/UPHO_2021-6_Updated_Statewide_COVID19_Restrictions.pdf
- Major Changes That Pertain to Schools:
    - Test to Play Section - Section 6.II (Page 8)
        - Added single events schools want to hold
            - Have to have proof of test 48 hours before the event
                - Determined by LEA
                    - Test themselves or at a community test event?
        - In Section 10 (page 10) added Test to Stay protocols
            - Added bridge between Test to Stay and Test to Play
            - Requested that positive cases found during Test to Play do not count towards threshold
            - Covers all extra curricular events
                - Ongoing events (sports)
                - Singular events
            - Also included the recommendation requiring parental permission once per school year, and/or once per term
                - So as not to seek permission for every testing event
            - Threshold for triggering Test to Stay remained the same at 1% population
                - for schools over 1500 students
                - 15 cases for schools with fewer than 1500 students
            - When the threshold is triggered, the LEA gets to determine if a testing even is appropriate or if there are other mitigations strategies should be implemented
            - No longer is the option to go virtual an option at that point
        - Roman numeral 4 in the same section: when a student can participate in remote learning.
            - Unable to participate in testing of any kind
            - If they do not participate in the testing event
            - Or if less than 60% of the students participate in the testing event
            - Or if the positivity testing from the event is equal to, or greater than. 2.5%
    - Those are the latest High Level/Major Updates in the Public Health Order
    - Latest updates were 10PM last night

- **Jenny:** Created a 5 Page Summary/High Level Guidelines of the Test to Stay / Test to Play (A couple of changes to be completed in the next 45 minutes)
- For Quarantine Guidelines refer to the protocols that are outlined in the manual
    - For Test to Play/Stay
        - The date of isolation begins the date of test was done, for anyone who tests positive
        - For close contacts the Health Department will work on a one-on-one basis to determine when the quarantine starts
        - Err on the side of caution for close exposures
        - Trace Contact 2 days before symptoms
    - Change in Document: Local Health Department will be able to make the determination when quarantine begins

- **Sidney**: Put in a pin in masks - we can come back to that.

- **Kendra**: Start planning for a virtual training for Test to Stay, as it will be pushed as a priority to keep kids in in-person learning.
    - Need feedback from LEA's on:
        - Days
        - Times
        - Length of training
        - What would work best
        - Capture from as many people as possible
    - We will be recording the training
    - Have Mobile Testing Team lead out on the training
        - Peer to peer learning
- **Lexi:** Would be greatly appreciated if this could be made online training.
    - 45 minutes to an hour. Whatever amount of time is needed
    - On demand would be helpful
- **Pete:** That is our intent. To create a training video at the first opportunity. Similar to a YouTube type video that people can log into at their leisure
    - It would be nice to track who has seen the video
        - Sign up sheet?
    - Know who has view it
    - Create a sense who has received the training.
        - And who we need to follow up with
    - Lisa has created a great program
    - The training will reflect the basic standards
- **Lisa:** Some Districts have a "Teacher Only" day at the end of the term. That might be a good time to get a mass amount in a given school trained.

- **Kendra**: Recap and clarify:
    - It would be best to have a recorded training online, on demand, from the get go?
        - There is no desire to have the in-person, back and forth interaction?

        - If they have questions they can contact me
- **Sidney**: - Chat Comment: *That is great! Thanks so much for thinking digital. You can make the training available via digital sign up/RSVP then you can have a ready roster. You could use something like Sign Up Genius, EventBrite, etc.*
    - This is primarily for the Districts. Speaking for the Superintendents in the Districts. Charters may be a different situation.
    - May want to check with the Charters.
- **Lexi:** I have a Charter Focus Group and I think they would appreciate the same thing.
    - Minimize paper back and forth
    - Just sign them up and track them
    - Figure out who is missing
    - Encourage not to send things out to schools that go back and forth.
- **Lisa:** Think about creating a list of people who can be contacted if you're not available.
- **Kendra**: I will work with the Mobile Testing Team to put that together. The quicker the better.
- **Sidney:** Chat Comment: *And/or a FAQ link at the end of the training.*
  I have had a few texts about mandates until the end of the year. And it is a little confusing with the thresholds, the 8 weeks? Is that still in play?
- **Jenny**: Some of the reporting is not helping. Reported incorrectly.
    - When a County gets to “Low”, and when the State has administered the 1.366 million doses, eight weeks after that is when masks are no longer mandated
    - There are two Mask Orders. The School and the State. The Order that came out last night does not trump the School Mask Mandate
    - The School Mask Mandate stays in effect until the end of the school year
    - I don't think we will hit the 1.366 mark and then the 8 weeks after that, before the end of the school year

- **Kendra:** Any other questions or items of concern? (None)

Adjourn: 9:58

FREE COVID-19 TESTING

- Nasal PCR
- Saliva PCR
- Rapid Antigen

TESTING FOR AGE 3 AND ABOVE. CHILDREN YOUNGER THAN 3 MAY ALSO TEST IF THEY ARE ABLE TO PRODUCE SALIVA ON THEIR OWN!

WHEN:

Thursday, October 28th

4:00 pm - 6:00 pm

WHERE:

John Hancock School

125 North 100 East

Pleasant Grove, UT 84062

Testing located in the parking lot of John Hancock Charter School. Enter off 100 North.

PLEASE PREREGISTER AT

https://redcap.link/utah.gov-JHCS-PG

OR BY SCANNING

CORONAVIRUS UTAH.GOV

UTAH DEPARTMENT OF HEALTH

FREE COVID-19 TESTING

- Nasal PCR
- Saliva PCR
- Rapid Antigen

TESTING FOR AGE 3 AND ABOVE. CHILDREN YOUNGER THAN 3 MAY ALSO TEST IF THEY ARE ABLE TO PRODUCE SALIVA ON THEIR OWN!

WHEN:

Tuesday, October 26th

3:00 pm - 7:00 pm

WHERE:

Ignite Entrepreneurship Academy

1650 W Traverse Terrace Drive

Lehi, UT 84043

Testing located on the east side of Ignite Academy in the parking lot.

PLEASE PREREGISTER AT

https://redcap.link/utah.gov-IGNITE

OR BY SCANNING

CORONAVIRUS UTAH.GOV

UTAH DEPARTMENT OF HEALTH

FREE COVID-19 TESTING

- Nasal PCR
- Saliva PCR
- Rapid Antigen

TESTING FOR AGE 3 AND ABOVE. CHILDREN YOUNGER THAN 3 MAY ALSO TEST IF THEY CAN PRODUCE SALIVA ON THEIR OWN!

WHEN:

Saturday, October 22nd

11:00 am - 1:00 pm

WHERE:

Cedar Fort

185 East Center Street

Cedar Fort, UT 84013

Testing in the parking lot of the LDS church located at the corner of Hwy 73 and Center Street. Enter and exit from Center Street

PLEASE PREREGISTER AT

https://redcap.link/utah.gov-CEDARFORT

OR BY SCANNING

CORONAVIRUS UTAH.GOV

UTAH DEPARTMENT OF HEALTH

FREE COVID-19 TESTING

- Nasal PCR
- Saliva PCR
- Rapid Antigen

WHEN:

Monday, October 4th

4:30 - 6:30 pm

WHERE:

Edgemont Elementary School

566 East 3650 North

Provo, UT 84604

Mobile van testing in the parking lot of Edgemont Elementary. For questions about results please call (385) 273-7878

ANYONE OLDER THAN AGE 3 CAN BE TESTED!

PLEASE PREREGISTER AT

https://redcap.link/utah.gov-EDGEMONT

OR BY SCANNING

CORONAVIRUS UTAH.GOV

UTAH DEPARTMENT OF HEALTH

FREE COVID-19 TESTING

WHEN:

Monday, October 4th

4:30 - 6:30 pm

WHERE:

Edgemont Elementary School

566 East 3650 North

Provo, UT 84604

Mobile van testing in the parking lot of Edgemont Elementary. For questions about results please call (385) 273-7878

- Nasal PCR
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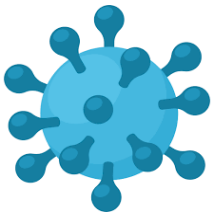
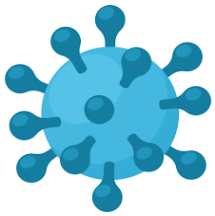
- Rapid Antigen



ANYONE OLDER THAN AGE 3 IS ABLE TO BE TESTED!



PLEASE PREREGISTER AT

https://redcap.link/utah.gov-EDGEMONT

CORONAVIRUS UTAH.GOV

UTAH DEPARTMENT OF HEALTH

For use under the Emergency Use Authorization (EUA) only

For in vitro diagnostic use

℞ ONLY

QUIDEL | Sofia 2 Flu+SARS Antigen FIA

INTENDED USE

The Sofia 2 Flu + SARS Antigen FIA employs immunofluorescence technology in a sandwich design that is used with Sofia 2. Sofia 2 Flu + SARS Antigen FIA is intended for the simultaneous qualitative detection and differentiation of the nucleocapsid protein antigens from SARS-CoV-2, influenza A and influenza B in direct nasopharyngeal (NP) and nasal (NS) swab specimens from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider within the first five days of the onset of symptoms. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The test is intended for use in the simultaneous rapid in vitro detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus nucleocapsid protein antigen , but does not differentiate, between SARS-CoV and SARS-CoV-2 viruses and is not intended to detect influenza C antigens. Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled “Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine.” Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, samples should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing.

SARS-CoV-2, influenza A and influenza B viral antigens are generally detectable in upper respiratory specimens 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 co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2results to the appropriate public health authorities.

Negative SARS-CoV-2 results, from patients with symptom onset beyond five days, 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 COVID-19 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 a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

A negative test is presumptive for influenza A and B and it is recommended these results be confirmed by an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions.

The Sofia 2 Flu + SARS Antigen FIA is intended for use on the Sofia 2 only and by medical professionals or trained operators who are proficient in performing tests using the Sofia 2 Instrument. The Sofia 2 Flu + SARS Antigen FIA test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

Influenza viruses are causative agents of highly contagious, acute, viral infections of the respiratory tract.

Influenza viruses are immunologically diverse, single-stranded RNA viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with most serious epidemics. Type B viruses produce a disease that is generally milder than that caused by type A. Type C viruses have never been associated with a large epidemic of human disease. Both Type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season.[i]

Every year in the United States, on average 5%-20% of the population contract influenza; more than 200,000 people are hospitalized from influenza complications; and, about 36,000 people die from influenza-related causes. Some people, such as adults 65 years of age and older, young children, and people with certain health conditions, are at high risk for serious influenza complications.[ii]

SARS-CoV-2, also known as the COVID-19 virus, was first identified in Wuhan, Hubei Province, China December 2019. This virus, as with the novel coronavirus SARS-1 and MERS, is thought to have originated in bats, however the SARS-CoV-2 may have had an intermediary host such as pangolins, pigs or civets.[iii] The WHO declared that COVID-19 was a pandemic on March 11, 2020, and human infection has spread globally, with hundreds of thousands of confirmed infections and deaths.[iv]

The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection.[v] The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough and shortness of breath.[vi]

PRINCIPLE OF THE TEST

The Sofia 2 Flu + SARS Antigen FIA employs immunofluorescence technology in a sandwich design that is used with Sofia 2 to detect nucleocapsid protein from influenza A, influenza B, and SARS-CoV-2. This test allows for the detection of SARS-CoV and SARS-CoV-2. The test detects, but does not differentiate, between the two viruses.

The patient sample is placed in the Reagent Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is dispensed into the Test Cassette sample well. From the sample well, the sample migrates through a test strip containing various unique chemical environments. If Influenza A, Influenza B, SARS-CoV or SARS-CoV-2 viral antigen is present, they will be trapped in a specific location.

Note: Depending upon the user's choice, the Test Cassette is placed inside Sofia 2 for automatically timed development (WALK AWAY Mode) or placed on the counter or bench top for a manually timed development and then placed into Sofia 2 to be scanned (READ NOW Mode).

Sofia 2 will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. Sofia 2 will display the test results (Positive, Negative, or Invalid) on the screen.

REAGENTS AND MATERIALS SUPPLIED

25-Test Kit:

- Individually Packaged Test Cassettes (25): Mouse monoclonal anti-influenza A and anti-influenza B antibodies; Monoclonal anti-SARS antibodies
- Reagent Tubes (25): Lyophilized buffer with detergents and reducing agents
- Reagent Solution (25): Ampoules with salt solution
- Sterile Nasal (SKU # 20377) or Nasopharyngeal Swabs (SKU # 20390) (25)
- Small, Clear 120 µL Fixed Volume Pipettes (25)
- Flu + SARS Positive Control Swab (1): Swab is coated with non-infectious recombinant influenza A, influenza B, and SARS antigens
- Negative Control Swab (1): Swab is coated with heat-inactivated, non-infectious Streptococcus C antigen
- Package Insert (1)
- Quick Reference Instructions (1)
- QC Card (located on kit box)

MATERIALS NOT SUPPLIED IN KIT

- Timer or watch
- Sofia 2
- Calibration Cassette (supplied with the Sofia 2)
- Dry transport tube (SKU # 20385) (25). Store at room temperature.
- Sofia 2 Flu + SARS Control Swab Set for additional QC (20391)

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For prescription use only.
- This test is for use with the Sofia 2 instrument only.
- This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the CLIA that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This test has been authorized only for the detection and differentiation of proteins from SARS-CoV-2, influenza, not for any other viruses or pathogens
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- The Sofia 2 Flu + SARS FIA is intended to be used with direct nasal or nasopharyngeal swabs and is not validated for use with viral transport media.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.

- Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
- Do not reuse the used Test Cassette, Fixed Volume Pipettes, Reagent Tubes, solutions, or Control Swabs.
- The user should never open the foil pouch of the Test Cassette exposing it to the ambient environment until the Test Cassette is ready for immediate use.
- Discard and do not use any damaged or dropped Test Cassette or material.
- The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.
- To obtain accurate results, the Package Insert instructions must be followed.
- The Calibration Cassette must be kept in the provided storage pouch between uses.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Sample collection and handling procedures require specific training and guidance.
- When collecting a nasal swab sample, use the Nasal Swab supplied in the kit.
- When collecting a nasopharyngeal swab sample, use the nylon flocked nasopharyngeal swab supplied in the kit.
- Use the appropriate Fixed Volume Pipette in accordance with test procedures.
- **Do not pour sample from the Reagent Tube into the Test Cassette sample well. Use the provided Small, Clear 120 µL Fixed Volume Pipette when adding the sample to the Test Cassette.**
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- Do not write on the barcode of the Test Cassette. This is used by Sofia 2 to identify the type of test being run and to identify the individual Test Cassette to prevent a second read of the Test Cassette by the same Sofia 2.
- If infection with a novel influenza A virus is suspected, based on current clinical and epidemiological screening criteria recommended by public health authorities, samples should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture samples.
- Although this test has been shown to detect cultured avian influenza viruses, including avian Influenza A subtype H5N1 virus, the performance characteristics of this test with samples from humans infected with H5N1 or other avian influenza viruses are unknown.
- As the detection reagent is a fluorescent compound, no visible results will form on the test strip. Sofia 2 must be used for result interpretation.
- To obtain accurate results, an opened and exposed Test Cassette should not be used inside a laminar flow hood or in a heavily ventilated area.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State, and Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

KIT STORAGE AND STABILITY

Store the kit at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

QUALITY CONTROL

There are three types of Quality Control for Sofia 2 and the Test Cassette: Sofia 2 Calibration Check procedure, built-in procedural control features, and External Controls.

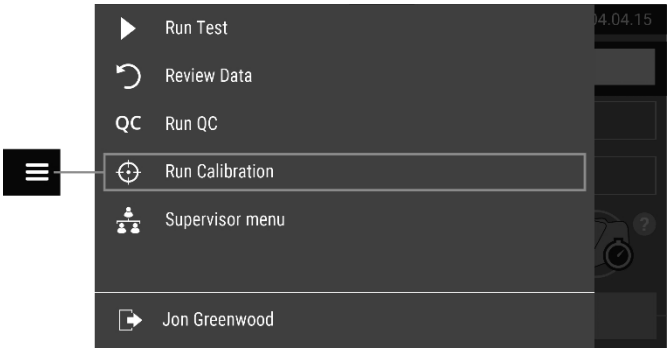
Sofia 2 Calibration Check Procedure

The Calibration Check Procedure should be performed every 30 days. Sofia 2 can be set to remind the user to complete the Calibration Check Procedure.

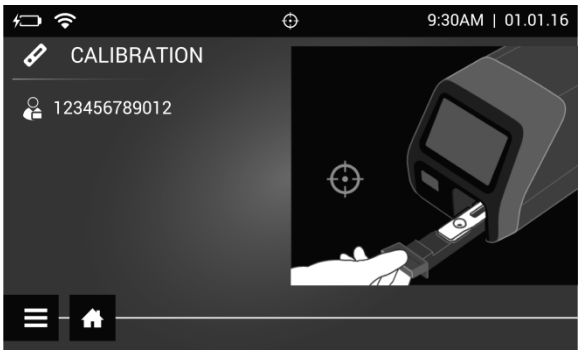
The Calibration Check is a required function that checks Sofia 2 optics and calculation systems using a specific Calibration Cassette. This Calibration Cassette is supplied with Sofia 2. Refer to the Sofia 2 User Manual for details regarding the Calibration Check Procedure.

Important: Ensure that the Calibration Cassette is stored in the provided storage pouch between uses to protect from exposure to light.

1. To check the calibration of Sofia 2, select "Run Calibration" from the Main Menu.



2. Following the prompts, insert the Calibration Cassette into Sofia 2 and close the drawer. Sofia 2 performs the Calibration Check automatically within one minute with no user input required.



Sofia 2 indicates when the Calibration Check is completed. Select ⌂ to return to the Run Test screen.

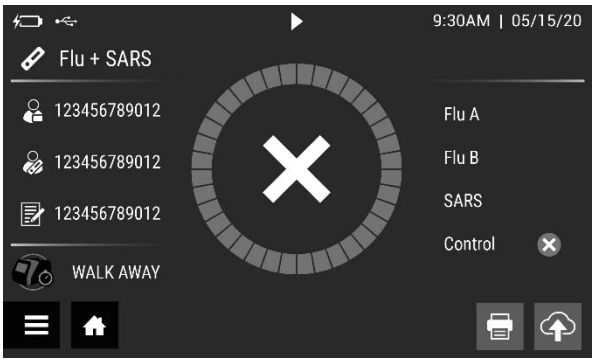
NOTE: If the Calibration Check does not pass, notify the on-site Supervisor or contact Quidel Technical Support for assistance Monday through Friday from 7:00 a.m. to 5:00 p.m. Pacific Time at 800.874.1517 (in the U.S.); 858.552.1100 (outside the U.S.); Fax: 858.455.4960; customerservice@quidel.com (Customer Service); technicalsupport@quidel.com (Technical Support); or contact your local distributor.

Built-in Procedural Controls

The Sofia 2 Flu + SARS Antigen FIA contains a built-in procedural control feature. Each time a test is run in Sofia 2, the procedural control zone is scanned by Sofia 2 and the result is displayed on the Sofia 2 screen.

The manufacturer's recommendation for daily control is to document the results of these built-in procedural controls for the first sample tested each day. This documentation is automatically logged into Sofia 2 with each test result.

A valid result obtained from the procedural control demonstrates that the test flowed correctly and the functional integrity of the Test Cassette was maintained. **The procedural control is interpreted by Sofia 2 after the Test Cassette has developed for 15 minutes. If the test does not flow correctly, Sofia 2 will indicate that the result is invalid.** Should this occur, review the procedure and repeat the test with a new patient sample and a new Test Cassette.



For example: This display shows an invalid result on Sofia 2.

External Quality Control

External Controls may also be used to demonstrate that the reagents and assay procedure perform properly.

Quidel recommends that Positive and Negative External Controls be run:

- once for each untrained operator
- once for each new shipment of kits – provided that each different lot received in the shipment is tested
- as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements.

The user must first select Run QC on the Main Menu of Sofia 2 and then, when prompted, scan the QC Card (located on kit box). This card provides information specific to the kit lot, including lot number and expiration date.

The user will select the desired mode (WALK AWAY or READ NOW) then run the External Control swabs.

External Positive and Negative Control swabs are supplied in the kit and should be tested using the Swab Test Procedure provided in this Package Insert or in the Quick Reference Instructions. The Flu + SARS Positive Control Swab contains influenza A, influenza B, and SARS antigen. **The Positive Control Swab must be run first, followed by the Negative Control Swab.**

When the QC run is complete, each result will be displayed as ✓ or ✗ on Sofia 2, for the Positive Control and the Negative Control.

Do not perform patient tests or report patient test results if either of the QC test results fail. Repeat the test or contact Quidel Technical Support before testing patient samples.

If both the Positive and Negative Controls fail, repeat testing with new Positive and Negative Controls a second time. If only a single Control fails, the user has the option of repeating both the Positive and Negative Controls OR to repeat only the Control that failed. The user may select » on the Sofia 2 display to skip the Control test that previously passed. The QC Results will show a skipped Control test as » on Sofia 2.

Additional External Control swabs may be obtained separately by contacting Quidel Customer Support Services at 800.874.1517 (in the U.S.) or 858.552.1100.

SAMPLE COLLECTION AND HANDLING

SAMPLE COLLECTION

Nasal Swab Sample

Use the nasal swab supplied in the kit.

Prior to collecting the nasal swab, the patient should be instructed to blow their nose. To collect a nasal swab sample, carefully insert the swab (provided in the kit) into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then remove it from the nostril.

Nasopharyngeal Swab Sample

Use the nasopharyngeal swab provided in the kit or an alternate nylon flocked nasopharyngeal swab.

To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx.

SAMPLE TRANSPORT AND STORAGE

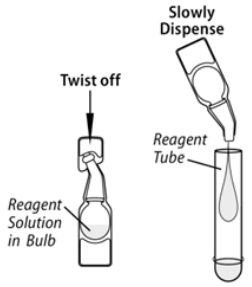
Samples should be tested as soon as possible after collection. Based on data generated with the SARS Antigen FIA, nasal or nasopharyngeal swabs are stable for up to 48-hours at room temperature or 2° to 8°C in a clean, dry transport tube.

TEST PROCEDURE

All clinical samples must be at room temperature before beginning the assay.

Expiration date: Check expiration date on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

Swab Test Procedure (Nasal/Nasopharyngeal)



1. Verify that Sofia 2 is set to the desired mode: **WALK AWAY** or **READ NOW**. See the "Using Sofia 2" section for more information.

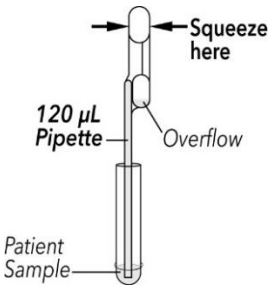
2. Dispense all of the Reagent Solution into the Reagent Tube. **Swirl the Reagent Tube to dissolve its contents.**

3. Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.

   Leave the swab in the Reagent Tube for 1 minute.

4. Roll the swab head against the inside of the Reagent Tube as you remove it. Dispose of the used swab in your biohazard waste.

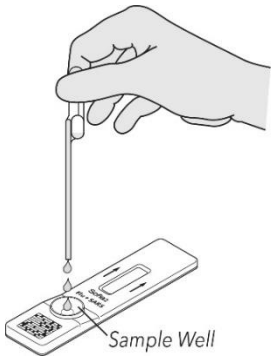
5. Fill the provided **Small, Clear 120 µL Fixed Volume Pipette** with the patient sample from the Reagent Tube.



To fill the Fixed Volume Pipette with the patient sample:

a) FIRMLY squeeze the top bulb.
b) Still squeezing, place the Pipette tip into the patient sample.
c) With the Pipette tip still in the patient sample, slowly release pressure on bulb to fill the Pipette.

6. Firmly squeeze the top bulb to empty the contents of the **Small, Clear 120 µL Fixed Volume Pipette** into the Test Cassette sample well. Extra liquid left over in the overflow bulb should be left behind.



NOTE: The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample. Discard the pipette in your biohazard waste.

NOTE: Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120 µL Fixed Volume Pipette.

7. Promptly proceed to the next section, "Using Sofia 2," to complete the test.

USING SOFIA 2

WALK AWAY/READ NOW Modes

Refer to the Sofia 2 User Manual for operating instructions.
Sofia 2 may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.

WALK AWAY Mode

In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia 2. Sofia 2 scans the Test Cassette periodically during the test development time. Positive and negative test results will be displayed in 15 minutes.

READ NOW Mode

Critically important: Allow the test to develop for the FULL 15 minutes BEFORE placing it into Sofia 2.

The user must first place the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia 2) and manually time this development step. Then, the user inserts the Test Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute

Warning: Results must not be interpreted past 30 minutes after inoculation. Using the Sofia 2 past this time may result in false results.

Critically important: The user should never open the foil pouch exposing the Test Cassette to ambient environment until ready for immediate use.

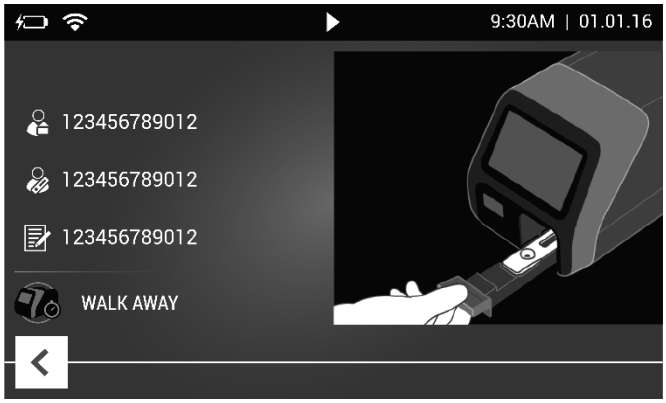
RUN TEST WITH SOFIA 2

1. Input the User ID using the integrated barcode scanner or manually enter the data using the on-screen key pad.

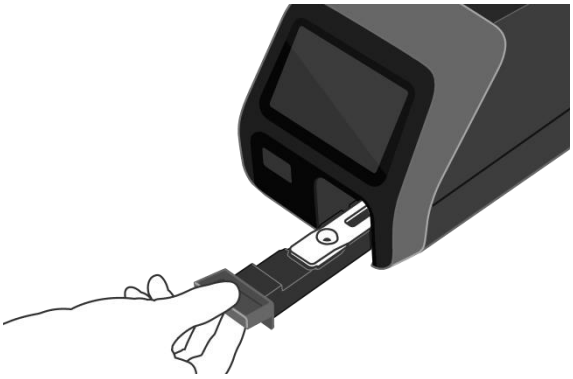
NOTE: *If you mistakenly scan the incorrect barcode, select the field again to re-highlight it. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.*

2. Input the Patient ID and Order #, if applicable, using the barcode scanner or manually enter the data using the on-screen key pad.

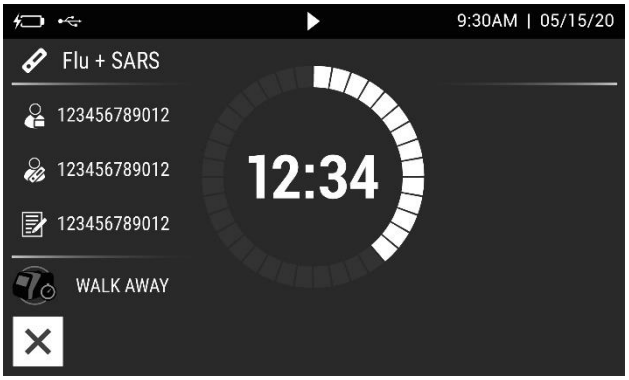
3. Verify that the correct development mode, WALK AWAY or READ NOW, has been selected. Press ▶ and open the Sofia 2 drawer.



4. Insert the prepared Test Cassette into the drawer of Sofia 2 and close the drawer.



5. Sofia 2 will start automatically and display the progress, as shown in the example below. In WALK AWAY Mode, the test results will be displayed on the screen in 15 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See Sofia 2 Interpretation of Results section.



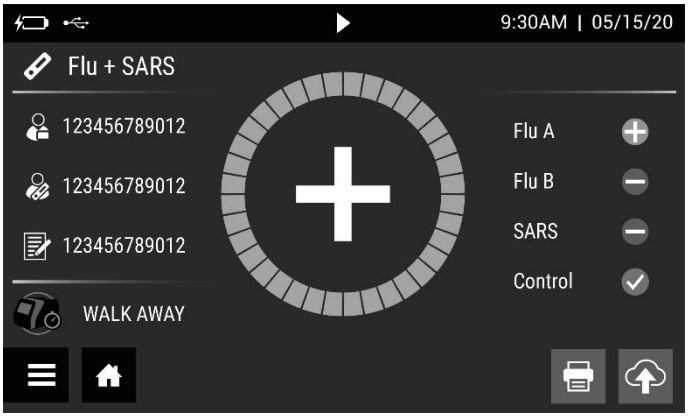
For example: This display shows that the test in WALK AWAY Mode has 12 minutes, 34 seconds remaining. Sofia 2 will read and display the results in 15 minutes.

INTERPRETATION OF RESULTS USING SOFIA 2

When the test is complete, the results will be displayed on the Sofia 2 screen. Test Lines, which are fluorescent, cannot be seen with the naked eye.

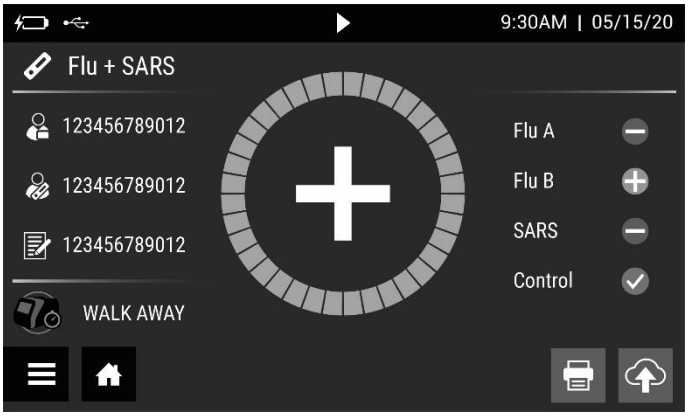
The Sofia 2 screen will display results for the procedural control as being ✓ or ✗, and will individually provide a ⊕ or ⊖ result for influenza A, influenza B, and SARS. If the procedural control is ✗ retest with a new patient sample and a new Test Cassette. If a printer is connected, the results can be printed manually by selecting the print icon while the test results are displayed on the screen.

Positive Results:



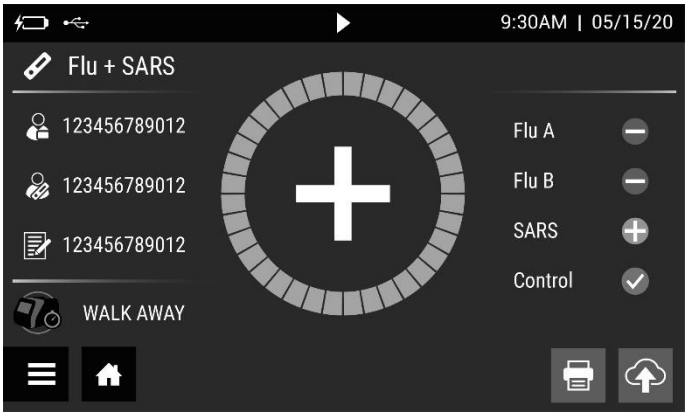
For example: This display shows a valid <u>positive result for influenza A</u>.

NOTE: A positive result does not rule out co-infections with other pathogens.



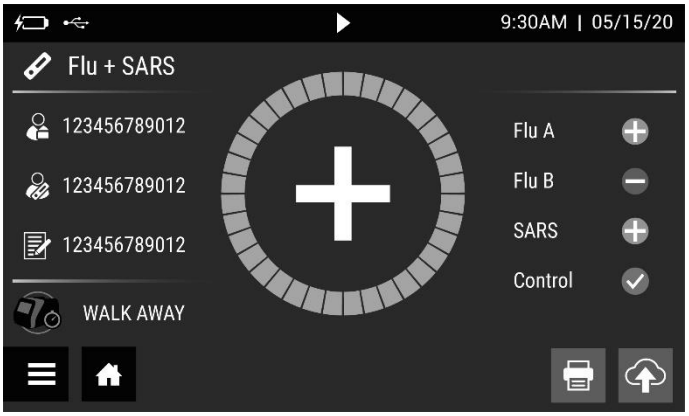
For example: This display shows a valid <u>positive result for influenza B</u>.

NOTE: A positive result does not rule out co-infections with other pathogens.



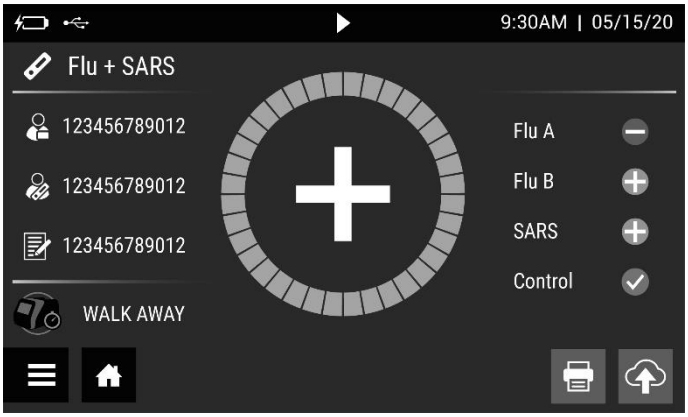
For example: This display shows a valid <u>positive result for SARS</u>.

NOTE: A positive result does not rule out co-infections with other pathogens.



For example: This display shows a valid <u>positive result for influenza A and SARS</u>.

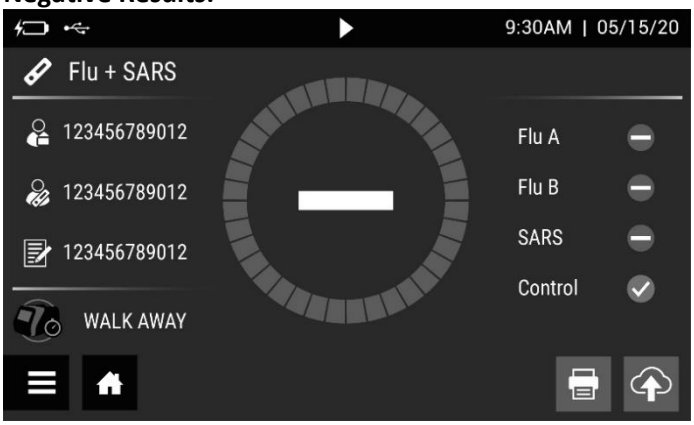
NOTE: A positive result does not rule out co-infections with other pathogens.



For example: This display shows a valid <u>positive result for influenza B and SARS</u>.

NOTE: A positive result does not rule out co-infections with other pathogens.

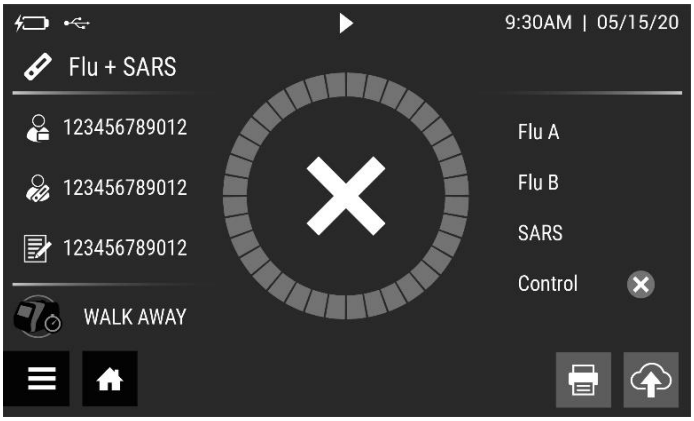
Negative Results:



For example: This display shows a valid <u>negative</u> result for influenza A, influenza B, and SARS.

NOTE: A negative result does not exclude infection.

Invalid Results:



For example: This display shows an invalid result.

Invalid Result: If the test is invalid, a new test should be performed with a new patient sample and a new Test Cassette.

LIMITATIONS

- The contents of this kit are to be used for the qualitative detection of influenza A, influenza B, and SARS antigens directly from nasal swab and nasopharyngeal swab.
- Viral Transport Media (VTM) should not be used with this test as it may cause false results.
- This test detects both viable (live) and non-viable, influenza A, influenza B, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.

- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Positive test results do not identify specific influenza A virus subtypes.
- Negative test results are not intended to rule in other non-influenza or SARS viral or bacterial infections.
- Negative results, from patients with COVID-19 symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
- Negative influenza A or influenza B results should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control.
- Children tend to shed influenza virus more abundantly and for longer periods of time than adults. Therefore, testing samples from adults will often yield lower sensitivity than testing samples from children.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.
- Individuals who received nasally administered influenza A vaccine may have positive test results for up to 3 days after vaccination.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza A viruses that have undergone minor amino acid changes in the target epitope region.
- If differentiation of specific SARS or influenza A subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

The Sofia 2 Flu + SARS Antigen FIA Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

However, to assist in using the Sofia 2 Flu + SARS Antigen FIA ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

- Authorized laboratories[1] using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product will use your product as outlined in the "Sofia 2 Flu + SARS Antigen FIA" Instructions for Use and Quick Reference Instructions. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Quidel (via email: QDL.COV2.test.event.report@quidel.com, or via phone by contacting Quidel Customer Support Services at 800.874.1517 (in the U.S.) or 858.552.1100) any suspected occurrence of false positive or false negative

results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Quidel Corporation, authorized distributors, and authorized laboratories 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.

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation." as "authorized laboratories."

CLINICAL PERFORMANCE

The Sofia 2 Flu + SARS Antigen FIA is a lateral flow fluorescent immunoassay (FIA). It is a modification of the test cassette used in the FDA-cleared assay (Sofia Influenza A+B FIA (k112177, k131606, k153012, k162438)) to include monoclonal antibodies for the detection of SARS-CoV-2. Data for the detection of influenza A + B by the Sofia Influenza A+B FIA is presented below.

Sofia Influenza A+B FIA Performance vs. Cell Culture

The performance of the Sofia Influenza A+B FIA with Sofia was compared to viral cell culture methods followed by Direct Fluorescent Assay (DFA) in a multi-center clinical field study during February through March 2011 in the United States. This study was conducted by health care personnel at seventeen (17) distinct professional and CLIA waived sites (combined) in various geographical regions within the United States. In this multi-center, point-of-care (POC) field trial, two (2) nasal or two (2) nasopharyngeal swabs or nasopharyngeal aspirate/wash samples were collected from each of two thousand sixty-six (2066) patients. Six hundred seventy-one (671) provided a pair of nasal swab samples, seven hundred thirty-four (734) provided a pair of nasopharyngeal swab samples, and six hundred sixty-one (661) proved a nasopharyngeal aspirate/wash sample. All clinical samples were collected from symptomatic patients: 74% were <6 years of age, 22% 6-21 years of age, 4% 22-59 years of age, and 1% ≥60 years of age. Fifty-three percent (53%) were male and forty-seven percent (47%) were female.

A total of two thousand forty-seven (2047) prospective clinical samples were tested using the Sofia Influenza A+B FIA and gave valid results during this clinical study. These results were included in Tables 2-6. The invalid rate was 0.9% (19/2066) with 95% CI: 0.6% to 1.4%. The invalid results were excluded from Tables 2-6 because new patient samples were not collected for re-testing.

On-site testing of one nasal swab or nasopharyngeal swab, or a portion of nasopharyngeal aspirate/wash sample, was performed by medical personnel in the physician's office or hospital facility with the Sofia Influenza A+B FIA. All samples were freshly collected and tested. The remaining sample was placed in viral transport media for culturing. The paired swab samples or paired aspirate/wash samples were randomized with respect to the order of testing in the Sofia Influenza A+B FIA versus culture. Viral cell culture was performed either at a local clinical laboratory at the test site, or the samples were transported cold on ice packs, not frozen, overnight to a central laboratory for culture within 48 hours.

Sofia Influenza A+B FIA Nasal Swab Results Versus Culture (All Age Groups) – Influenza A								
		Viral Culture					95% CI	
		POS	NEG	Total	Sensitivity	90%	84%	94%
Sofia Influenza A+B FIA	POS	124	27	151	Specificity	95%	93%	96%
	NEG	14	500	514				
	Total	138	527	665				

Sofia Influenza A+B FIA Nasal Swab Results Versus Culture (All Age Groups) – Influenza B								
		Viral Culture					95% CI	
		POS	NEG	Total	Sensitivity	89%	82%	94%
Sofia Influenza A+B FIA	POS	100	23	123	Specificity	96%	94%	97%
	NEG	12	530	542				
	Total	112	553	665				

Sofia Influenza A+B FIA Nasopharyngeal Swab Results Versus Culture (All Age Groups) – Influenza A								
		Viral Culture					95% CI	
		POS	NEG	Total	Sensitivity	97.1%	91.8%	99.0%
Sofia Influenza A+B FIA	POS	100	34	134	Specificity	94.6%	92.6%	96.1%
	NEG	3	596	599				
	Total	103	630	733				

Sofia Influenza A+B FIA Nasopharyngeal Swab Results Versus Culture (All Age Groups) – Influenza B								
		Viral Culture					95% CI	
		POS	NEG	Total	Sensitivity	90%	83%	94%
Sofia Influenza A+B FIA	POS	101	19	120	Specificity	97%	95%	98 %
	NEG	11	602	613				
	Total	112	621	733				

Retrospective Comparison of the Sofia Influenza A+B FIA and Sofia 2 Flu + SARS Antigen FIA
To demonstrate the addition of the SARS-CoV-2 to the Sofia Influenza A+B FIA had no impact to the detection of influenza A or influenza B a study was performed using remnant clinical samples (72 influenza A positive, 15 influenza B positive, 56 negative). The specimens were tested with a FDA-cleared molecular device (Solana Influenza Assay, k161814) to confirm the presence or absence of influenza A or influenza B.

The samples were tested according to the respective Package Inserts for both devices.

Influenza A Performance

Influenza A results for both the Sofia 2 Flu + SARS and Sofia Influenza A+B assays were combined in the following Table:

Influenza A Performance								
		Sofia Influenza A+B					95% CI	
		POS	NEG	Total	PPA	100.0%	94.8%	100.0%
Sofia 2 Flu + SARS Antigen FIA	POS	70	2*	72	NPA	96.6%	88.3%	99.0%
	NEG	0	56	56				
	Total	70	58	128				

*2 Discrepant samples were confirmed Positive for Influenza A on Solana

Influenza A results for both the Sofia 2 Flu + SARS and Solana Influenza A+B assays were combined in the following Table:

Influenza A Performance								
		Solana Influenza Assay					95% CI	
		POS	NEG	Total	PPA	100.0%	94.9%	100.0%
Sofia 2 Flu + SARS Antigen FIA	POS	72	0	72	NPA	100.0%	93.6%	100%
	NEG	0	56	56				
	Total	72	56	128				

Influenza B Performance

Influenza B results for both the Sofia 2 Flu + SARS and Sofia Influenza A+B assays were combined in the following Table:

Influenza B Performance								
		Sofia Influenza A+B					95% CI	
		POS	NEG	Total	PPA	100.0%	78.5%	100.0%
Sofia 2 Flu + SARS Antigen FIA	POS	14	1*	15	NPA	98.2%	90.7%	99.7%
	NEG	0	56	56				
	Total	14	57	71				

* Discrepant sample was confirmed Positive for Influenza B on Solana

Influenza B results for both the Sofia 2 Flu + SARS and Solana Influenza A+B assays were combined in the following Table:

Influenza B Performance								
		Solana Influenza A+B					95% CI	
		POS	NEG	Total	PPA	100.0%	79.6%	100.0%
Sofia 2 Flu + SARS Antigen FIA	POS	15	0	15	NPA	100.0%	93.6%	100.0%
	NEG	0	56	56				
	Total	15	57	71				

Prospective Study of the Sofia 2 Flu + SARS Antigen FIA

A study of one hundred sixty-five (165) direct nasal swabs was performed. The samples were enrolled from symptomatic patients suspected of COVID-19 at six (6) locations and tested fresh with the Sofia assay at either a single central laboratory (113-specimens) or at the collection site (52-specimens). All patients had a matched nasal swab collected for RT-PCR at the central location. The order of swab collection was randomized between assays. The Sofia 2 Flu + SARS Antigen FIA was compared to the Reference Extracted RT-PCR assay.

Patient Demographics

Patient demographics (age, elapsed time from date of on-set) are available for the one hundred sixty-five (165) samples used in the study. Demographics are shown in the table below.

Patient Demographics for Nasal Swabs (Sofia Positive = 40)			
	Sofia SARS Antigen FIA		
Age	Total #	Total Positive	Prevalence
≤ 5 years	0	0	N/A
6 to 21 years	15	4	26.7%
22 to 59 years	123	33	26.8%
≥ 60 years*	26	3	11.5%

* One specimen was Invalid in the Sofia Flu + SARS Antigen Assay and removed from further analysis

The specimen positivity breakdown based on days post onset:

Days Post Symptom Onset for Nasal Swabs (Sofia Positive = 33)			
Days Post Symptom Onset	# Specimens Tested	# Positive Specimens	% Positive
0	1	0	0
1	32	14	43.8%
2*	39	10	25.6%
3***	36	4	11.1%
4	32	10	31.3%
5**	25	2	8.0%

* One specimen was Sofia 2 Flu + SARS Antigen FIA Negative and Positive by Reference Extracted RT-PCR
** One specimen was Sofia 2 Flu + SARS Antigen FIA Negative and Positive by Reference Extracted RT-PCR
*** One specimen was Invalid in the Sofia Flu + SARS Antigen Assay and removed from further analysis

Sofia 2 Flu + SARS Antigen FIA Performance Compared to Reference Extracted RT-PCR Assays for Influenza A and Influenza B and for SARS-CoV-2								
	Reference Extracted Influenza A + B RT-PCR assay – Influenza A						95% CI	
Influenza A		POS	NEG	Total	PPA	N/A	N/A	N/A
Sofia 2 Flu + SARS Antigen FIA Assay	POS	0	0	0	NPA	100.0%	97.7%	100.0%
	NEG	0	164	164	PPV	N/A	N/A	N/A
	Total	0	164	164**	NPV	100.0%	97.7%	100.0%
					Prevalence	0.0%	0.0%	3.0%

	Reference Extracted Influenza A + B RT-PCR assay – Influenza B						95% CI	
Influenza B		POS	NEG	Total	PPA	N/A	N/A	N/A
Sofia 2 Flu + SARS Antigen FIA Assay	POS	0	0	0	NPA	100.0%	97.7%	100.0%
	NEG	0	164	164	PPV	N/A	N/A	N/A
	Total	0	164	164**	NPV	100.0%	97.7%	100.0%
					Prevalence	0.0%	0.0%	3.0%
	Reference Extracted SARS-CoV-2 RT-PCR assay						95% CI	
SARS-CoV-2		POS	NEG	Total	PPA	95.2%	84.2%	98.7%
Sofia 2 Flu + SARS Antigen FIA Assay	POS	40	0	40	NPA	100.0%	96.9%	100.0%
	NEG	2*	122	124	PPV	100.0%	91.2%	100.0%
	Total	42	122	164**	NPV	98.4%	94.3%	99.6%
					Prevalence	25.6%	19.5%	32.8%

***** The two discordant samples (Sofia 2 Negative/Reference Extracted RT-PCR assay Positive) had Ct Values of 31.95 and 38.72.

****** One specimen was Invalid in the Sofia Flu + SARS Antigen Assay and removed from further analysis.

ANALYTICAL PERFORMANCE

Limit of Detection

The LoD for the Sofia 2 Flu + SARS Antigen FIA was determined using limiting dilutions of the following virus strains of Influenza A, Influenza B and SARS CoV-2 in negative nasal matrix in UTM:

LoD Virus Strains		
Influenza A H3N2 Hong Kong/8/68	Zeptometrix 0810250CF	4.57 x 10e6 TCID50/mL
Influenza B Florida/05/06	Zeptometrix 0810037CF	4.17 x 10e5 TCID50/mL
SARS CoV-2 USA-WA1/2020	Zeptometrix 0810587CHFI	4.17 x 10e5 TCID50/mL

The study to determine the Sofia 2 Flu + SARS Antigen FIA LoD was designed to reflect the assay when using direct swabs. In this study nasal swabs were spiked with approximately 50-µL of the virus dilution in saline. The spiked swab was added to the Sofia 2 Flu + SARS Antigen FIA extractant concurrently to a nasal swab containing NP matrix. The swabs were processed concurrently according to the Package Insert.

The table below provides the LoD of the Sofia 2 Flu + SARS Antigen FIA for influenza A, influenza B and SARS-CoV-2.

Virus	Concentration ($TCID_{50}$/mL)	N	Negative	Positive	% Positive	LL 95% CI	UL 95% CI
Influenza A H3N2 Hong Kong/8/68	**50**	20	0	20	100%	83.9%	100%
Influenza B Florida/05/06	**1.8**	20	0	20	100%	83.9%	100%
SARS CoV-2 USA-WA1/2020	**91.7**	20	1	19	95.0%	74.6%	99.1%

The 2020 CDC Human Influenza Panel was tested concurrently with the Sofia Influenza A + B FIA and Sofia 2 Flu + SARS FIA assays. The panel was tested per the **swab** protocol recommended by the CDC. Briefly, a series of 5-

fild dilutions were prepared with each panel member. These dilutions were tested with five replicates until two consecutive dilution were negative. Test results generated for each influenza strain are listed below:

Influenza Virus (Type/Subtype)	**Virus Strain Name**		**Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at Each Dilution (N=5)**								
			$10^{9.3}$ EID50/mL	**2 x $10^{8.3}$**	**4 x $10^{7.3}$**	**8 x $10^{6.3}$**	**1.6 x $10^{6.3}$**	**3.2 x $10^{5.3}$**	**6.4 x $10^{4.3}$**	**1.28 x $10^{4.3}$**	**2.56 x $10^{3.3}$**
A(H3N2)	A/Perth/16/2009	Sofia Influenza A+B FIA	# Detected	5	5	5	5	5	1	0	NA
			% Detection	100%	100%	100%	100%	100%	20%	0%	NA
		Sofia 2 Flu + SARS Antigen FIA	# Detected	5	5	5	5	5	5	5	0
			% Detection	100%	100%	100%	100%	100%	100%	100%	0%
Influenza Virus (Type/Subtype)	**Virus Strain Name**		**Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at Each Dilution (N=5)**								
			$10^{7.5}$ EID50/mL	**2 x $10^{6.5}$**	**4 x $10^{5.5}$**	**8 x $10^{4.5}$**	**1.6 x $10^{4.5}$**	**3.2 x $10^{3.5}$**			
A(H3N2)	A/Hong Kong/2671/2019	Sofia Influenza A+B FIA	# Detected	5	5	2	0	0			
			% Detection	100%	100%	40%	0%	0%			
		Sofia 2 Flu + SARS Antigen FIA	# Detected	5	5	5	0	0			
			% Detection	100%	100%	100%	0%	0%			
Influenza Virus (Type/Subtype)	**Virus Strain Name**		**Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at Each Dilution (N=5)**								
			$10^{10.2}$ EID50/mL	**2 x $10^{9.2}$**	**4 x $10^{8.2}$**	**8 x $10^{7.2}$**	**1.6 x $10^{7.2}$**	**3.2 x $10^{6.2}$**	**6.4 x $10^{5.2}$**	**1.28 x $10^{4.2}$**	
A9H1N1pdm09	A/Christ Church/16/2010	Sofia Influenza A+B FIA	# Detected	5	5	5	5	5	0	0	
			% Detection	100%	100%	100%	100%	100%	0%	0%	
		Sofia 2 Flu + SARS Antigen FIA	# Detected	5	5	5	5	5	0	0	
			% Detection	100%	100%	100%	100%	100%	0%	0%	
Influenza Virus (Type/Subtype)	**Virus Strain Name**		**Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at Each Dilution (N=5)**								
			$10^{9.1}$ EID50/mL	**2 x $10^{8.1}$**	**4 x $10^{7.1}$**	**8 x $10^{6.1}$**	**1.6 x $10^{6.1}$**	**3.2 x $10^{5.1}$**	**6.4 x $10^{4.1}$**		
A9H1N1pdm09	A/GuangDong-Maonan/1536/2019	Sofia Influenza A+B FIA	# Detected	5	5	5	5	0	0		
			% Detection	100%	100%	100%	100%	0%	0%		
		Sofia 2 Flu + SARS Antigen FIA	# Detected	5	5	5	5	0	0		
			% Detection	100%	100%	100%	100%	0%	0%		

Influenza Virus (Type/Subtype)	Virus Strain Name		Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at Each Dilution (N=5)								
			$10^{6.9}$ EID50/mL	**2 x $10^{5.9}$**	**4 x $10^{4.9}$**	**8 x $10^{3.9}$**	**1.6 x $10^{3.9}$**	**3.2 x $10^{2.9}$**	**6.4 x $10^{1.9}$**		
B (Victoria Lineage)	B/Michigan/09/2011	Sofia Influenza A+B FIA	# Detected	5	5	5	5	0	0		
			% Detection	100%	100%	100%	100%	0%	0%		
		Sofia 2 Flu + SARS Antigen FIA	# Detected	5	5	5	5	0	0		
			% Detection	100%	100%	100%	100%	0%	0%		
Influenza Virus (Type/Subtype)	**Virus Strain Name**		**Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at Each Dilution (N=5)**								
			$10^{8.3}$ EID50/mL	**2 x $10^{7.3}$**	**4 x $10^{6.3}$**	**8 x $10^{5.3}$**	**1.6 x $10^{5.3}$**	**3.2 x $10^{4.3}$**	**6.4 x $10^{3.3}$**	**1.28 x $10^{3.3}$**	**2.56 x $10^{2.3}$**
B (Yamagata Lineage)	B/Texas/81/2016	Sofia Influenza A+B FIA	# Detected	5	5	5	5	5	5	0	0
			% Detection	100%	100%	100%	100%	100%	100%	0%	0%
		Sofia 2 Flu + SARS Antigen FIA	# Detected	5	5	5	5	5	5	0	0
			% Detection	100%	100%	100%	100%	100%	100%	0%	0%
Influenza Virus (Type/Subtype)	**Virus Strain Name**		**Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at Each Dilution (N=5)**								
			$10^{9.2}$ EID50/mL	**2 x $10^{8.2}$**	**4 x $10^{7.2}$**	**8 x $10^{6.2}$**	**1.6 x $10^{6.2}$**	**3.2 x $10^{5.2}$**	**6.4 x $10^{4.2}$**	**1.28 x $10^{4.2}$**	
B (Victoria Lineage)	B/Washington/02/2019	Sofia Influenza A+B FIA	# Detected	5	5	5	5	5	0	0	
			% Detection	100%	100%	100%	100%	100%	0%	0%	
		Sofia 2 Flu + SARS Antigen FIA	# Detected	5	5	5	5	5	0	0%	
			% Detection	100%	100%	100%	100%	100%	0%	0%	
Influenza Virus (Type/Subtype)	**Virus Strain Name**		**Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at Each Dilution (N=5)**								
			$10^{9.9}$ EID50/mL	**2 x $10^{8.9}$**	**4 x $10^{7.9}$**	**8 x $10^{6.9}$**	**1.6 x $10^{6.9}$**	**3.2 x $10^{5.9}$**	**6.4 x $10^{4.9}$**	**1.28 x $10^{4.9}$**	
B (Yamagata Lineage)	B/Phuket/3073/2013	Sofia Influenza A+B FIA	# Detected	5	5	5	5	0	0	NA	
			% Detection	100%	100%	100%	100%	0%	0%	NA	
		Sofia 2 Flu + SARS Antigen FIA	# Detected	5	5	5	5	3	0	0	
			% Detection	100%	100%	100%	100%	60%	0%	0%	

Analytical Reactivity/Inclusivity

The analytical reactivity of the monoclonal antibodies targeting SARS-CoV-2 in the Sofia 2 Flu + SARS Antigen FIA were evaluated with the currently available SAR-CoV-2 strains (see table below).

2019-nCoV Strain/Isolate	Source/Sample Type	Concentration
USA-WA1/2020	BEI NR-52286	3.40 x10^5 $TCID_{50}$/mL
USA CA3/2020-P2	BEI NR-52385	1x10^7 $TCID_{50}$/mL

The analytical reactivity of the monoclonal antibodies targeting influenza A and influenza B was demonstrated with Sofia Influenza A+B FIA and Sofia using a total of 30 strains of human influenza viruses comprised of 21 Influenza A and 9 influenza B viruses. Additional information detailing this testing can be found in Table 11 of the Sofia Influenza A + B FIA Package Insert.

To further demonstrate analytical sensitivity with contemporary influenza strains, the Sofia 2 Flu + SARS Antigen FIA tested the 2020 CDC Human Influenza Panel. The panel was tested per the swab protocol recommended by the CDC. Test results generated for each influenza strain are listed below:

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID_{50}/mL) and Number of Positive Results at Highest Detectable Dilution (N=5)
A(H3N2)	A/Perth/16/2009	1.28 x $10^{4.3}$
		5/5
A(H3N2)	A/Hong Kong/2671/2019	8 x $10^{4.5}$
		5/5
A(H1N1)pdm09	A/Christ Church/16/ 2010	3.2 x $10^{6.2}$
		5/5
A(H1N1)pdm09	A/GuangDong-Maonan/1536/2019	1.6 x $10^{6.1}$
		5/5
B (Victoria Lineage)	B/Michigan/09/2011	1.6 x $10^{3.9}$
		5/5
B (Victoria Lineage)	B/Texas/81/2016	6.4 x $10^{3.3}$
		5/5
B (Yamagata Lineage)	B/Washington/02/ 2019	3.2 x $10^{5.2}$
		5/5
B (Yamagata Lineage)	B/Phuket/3073/2013	3.2 x $10^{5.9}$
		3/5

Cross-Reactivity

The cross reactivity of the monoclonal antibodies used for the detection of influenza A and influenza B was determined as part of the Sofia Influenza A+B FIA (K112177) 510k submission. Additional information detailing this testing can be found in Table 13 of the Sofia Influenza A + B FIA Package Insert.

Cross-reactivity of the monoclonal antibodies used for the detection of SARS-CoV-2 was evaluated by testing various microorganisms (9), viruses (16) and negative matrixes (3) that may potentially cross-react with the Sofia 2 SARS FIA. Each organism and virus were tested in triplicate. The final concentration of the organisms and viruses are documented in the table below:

Cross-Reactivity/Interference of SARS-CoV-2					
Virus/Bacteria/Parasite*	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Adenovirus	Type 1	Isolate	1 x $10^{5.53}$ U/mL	No Cross-Reactivity	No Interference
Coronavirus	229e	Isolate	1 x $10^{5.10}$ U/mL	No Cross-Reactivity	No Interference
Coronavirus	OC43	Isolate	9.55 x 10^{5} $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Coronavirus	NL63	Isolate	5 x $10^{3.67}$ U/mL	No Cross-Reactivity	No Interference
MERS-CoV (heat-inactivated)	Florida/USA-2_Saudia Arabia_2014	Isolate	1.17 x 10^{5} $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Mycoplasma pneumoniae	M129	Isolate	3 x 10^{6} CCU/mL	No Cross-Reactivity	No Interference
Streptococcus pyogenes	Z018	Isolate	3.8 x 10^{6} cfu/mL	No Cross-Reactivity	No Interference
Influenza A H3N2	Brisbane/10/07	Isolate	1 x $10^{5.07}$ U/mL	No Cross-Reactivity	No Interference
Influenza A H1N1	New Caledonia/20/99	Isolate	1 x $10^{5.66}$ U/mL	No Cross-Reactivity	No Interference
Influenza B	Brisbane/33/08	Isolate	1 x $10^{5.15}$ U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 1	Isolate	1 x $10^{5.01}$ U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 2	Isolate	1 x $10^{5.34}$ U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 3	Isolate	8.5 x 10^{5} $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 4b	Isolate	1 x $10^{5.53}$ U/mL	No Cross-Reactivity	No Interference
Enterovirus	Type 68	Isolate	1 x $10^{5.5}$ U/mL	No Cross-Reactivity	No Interference
Human Metapneumovirus	A1 (IA10-s003)	Isolate	1 x $10^{5.55}$ U/mL	No Cross-Reactivity	No Interference
Respiratory Syncytial Virus	Type A (3/2015 Isolate #3)	Isolate	1 x $10^{5.62}$ U/mL	No Cross-Reactivity	No Interference
Human Rhinovirus	N/A	Inactivated virus	Not available	No Cross-Reactivity	No Interference
Chlamydophila pneumoniae	AR-39	Isolate	2.9 x 10^{6} IFU/mL	No Cross-Reactivity	No Interference
Haemophilus influenzae	Type b; Eagan	Isolate	7.87 x 10^{6} cfu/mL	No Cross-Reactivity	No Interference
Legionella pneumophila	Philadelphia	Isolate	6.82 x 10^{6} cfu/mL	No Cross-Reactivity	No Interference
Streptococcus pneumoniae	Z022; 19f	Isolate	2.26 x 10^{6} cfu/mL	No Cross-Reactivity	No Interference
Bordetella pertussis	A639	Isolate	6.37 x 10^{6} cfu/mL	No Cross-Reactivity	No Interference
Pneumocystis jirovecii-S. cerevisiae Recombinant	W303-Pji	Isolate	1.56 x 10^{6} cfu/mL	No Cross-Reactivity	No Interference
Mycobacterium tuberculosis	H37Ra-1	Isolate	6.86 x 10^{7} cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus epidermidis	MRSE; RP62A	Isolate	1.21 x 10^{10} cfu/mL	No Cross-Reactivity	No Interference

Cross-Reactivity/Interference of SARS-CoV-2					
Virus/Bacteria/Parasite*	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Staphylococcus aureus MSSA	NCTC 8325	Isolate	5.5×10^9 cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus MRSA	0801638	Isolate	1.38×10^{10} cfu/mL	No Cross-Reactivity	No Interference
Coronavirus HKU1 was not tested for cross-reactivity due to lack of availability. 19 specimens containing Coronavirus HKU1 were tested and all resulted as negative, additional cross-reactivity wet testing was not required.					

* Testing was performed in triplicate

Hook Effect

The effects of high concentrations of the different viruses (high dose hook effect) were tested on the Sofia 2 Flu + SARS Antigen FIA. The general procedure was to test contrived samples prepared with virus at the maximum concentration possible.

When testing high concentrations of influenza A, influenza B, or SARS CoV-2 virus levels, the Sofia 2 Flu + SARS Antigen FIA demonstrated 100 % positive results for all tested for each analyte. The concentrations tested represent the maximum available concentrations for the viral strains evaluated. There was no hook evident for this assay.

The results generated in this study support the conclusion that in cases of SARS and Influenza coinfections, when the specimen has a high influenza A viral load, the test will generate 100% positive results for SARS. It also indicates that when the specimen has a high influenza B viral load, the test will generate 100% positive results for SARS.

Endogenous Interference Substances Studies

The potential interference or cross-reactivity of the monoclonal antibodies used for the detection of influenza A and influenza B by endogenous substances was determined as part of the Sofia Influenza A+B FIA (K112177) 510k submission. Additional information detailing this testing can be found in Table 14 of the Sofia Influenza A + B FIA Package Insert.

The potential interference or cross-reactivity of the monoclonal antibodies used for the detection of SARS-CoV-2 by endogenous substances was determined by testing fourteen substances in negative clinical matrix at target concentrations in the absence (negative) and presence (positive) SARS-CoV-2. Each condition (negative or positive) was tested with three replicates per substance.

Positive virus samples were prepared at approximately 4x LoD concentration in clinical negative matrix. Interfering substance samples were prepared at 2 times the final test concentration. Final samples were prepared by mixing 100-µL of the virus sample with 100-µL of the interfering substance sample. The target concentration for each virus was approximately 2 to 3 times the Limit of Detection (LoD).

None of the substances demonstrated interference or cross-reactivity with the SARS-CoV-2 antibodies. All samples prepared in the clinical negative matrix produced the expected negative Sofia 2 SARS result (cross-reactivity results), and all samples prepared at 4x LoD produced the expected positive Sofia 2 SARS result (interference results). The final concentrations of the non-interfering substances are summarized in the table below.

Interfering Substances for SARS-CoV-2				
Interfering Substance	**Active Ingredient**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Afrin – nasal spray	Oxymetazoline	5%	No Cross-Reactivity	No Interference
Blood (human)	Blood	5%	No Cross-Reactivity	No Interference
Chloraseptic, Cepacol	Benzocaine, Menthol	0.7 g/mL	No Cross-Reactivity	No Interference
Flonase	Fluticasone	5%	No Cross-Reactivity	No Interference
Halls Relief Cherry Flavor	Menthol	0.8 g/mL	No Cross-Reactivity	No Interference
Nasocort Allergy 24 hour	Triamcinolone	5.00%	No Cross-Reactivity	No Interference
Neo-Synephrine	Phenylephrine hydrochloride	5%	No Cross-Reactivity	No Interference
Oseltamivir	Oseltamivir	2.2 µg/mL	No Cross-Reactivity	No Interference
Purified mucin protein	Mucin protein	2.5 mg/mL	No Cross-Reactivity	No Interference
Rhinocort	Budesonide (Glucocorticoid)	5%	No Cross-Reactivity	No Interference
Saline nasal spray	Saline	15%	No Cross-Reactivity	No Interference
Tobramycin	Tobramycin	1.25 mg/mL	No Cross-Reactivity	No Interference
Zanamivir	Zanamivir	282.0 ng/mL	No Cross-Reactivity	No Interference
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5%	No Cross-Reactivity	No Interference

* Testing was performed in triplicate

Competitive Inhibition

For Competitive Interference, SARS-CoV-2 at levels near LoD was tested in the presence of high levels of influenza A or influenza B and near LoD influenza A and influenza B in the presence of high levels of SARS-CoV-2.

Competitive Virus	**Strain**	**Concentration**	**Competitive Target Virus**	**Concentration**	**Competitive Target Percent Positivity**
Influenza A H3N2	Brisbane/10/07	$1 \times 10^{5.07}$ U/mL	SARS-CoV-2	2.26×10^{2} U/mL	100%
Influenza A H1N1	New Caledonia/20/99	$1 \times 10^{5.66}$ U/mL	SARS-CoV-2	2.26×10^{2} U/mL	100%
Influenza B	Brisbane/33/08	$1 \times 10^{5.15}$ U/mL	SARS-CoV-2	2.26×10^{2} U/mL	100%
SARS-CoV-2	USA-WA1/2020	7.55×10^{5} U/mL	Flu A Hong Kong 6/68 H3N2	2.34×10^{1} U/mL	100%
SARS-CoV-2	USA-WA1/2020	7.55×10^{5} U/mL	Flu A Brisbane 10/07 H3N2	1.41×10^{2} U/mL	100%
SARS-CoV-2	USA-WA1/2020	7.55×10^{5} U/mL	Flu B Massachusetts 2/12	5.6×10^{0} U/mL	100%

In this testing there does not appear to be any competitive interference.

ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a test system problem, please call Quidel Technical Support at 800.874.1517 (in the U.S.) or 858.552.1100, Monday through Friday, from 7:00 a.m. to 5:00 p.m., Pacific Time. If outside the U.S. contact your local distributor or technicalsupport@quidel.com. Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 800.FDA.1088; fax: 800.FDA.0178; http://www.fda.gov/medwatch).

REF 20377 – Sofia 2 Flu + SARS Antigen FIA – 25 Test (Nasal Swab)
20390 – Sofia 2 Flu + SARS Antigen FIA – 25 Test (Nasopharyngeal Swab)

IVD

CE

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany

Quidel Corporation
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San Diego, CA 92121 USA
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1449200EN00 (10/20)

REF Catalogue number	CE CE mark of conformity
EC REP Authorized Representative in the European Community	LOT Batch code
 Use by	 Manufacturer
 Temperature limitation	 Intended use
Rx ONLY Prescription use only	 Consult instructions for use
IVD For *In Vitro* diagnostic use	 Contains sufficient for 25 determinations
CONT Contents/Contains	CONTROL + Positive control
CONTROL – Negative control	

REFERENCES

[i] Murphy B.R. and Webster R.G., 1996, Orthomyxoviruses, pp. 1397-1445. In: Fields Virology, 3rd edition, B.N. Fields, D.M. Knipe, P.M. Howley, et al. (eds.), Lippincott-Raven, Philadelphia.

[ii] CDC, Key Facts About Seasonal Influenza. www.cdc.gov/flu/keyfacts.htm accessed 7/2011.

[iii] Baker, S., Frias, L., and Bendix, A. Coronavirus live updates: More than 92,000 people have been infected and at least 3,100 have died. The US has reported 6 deaths. Here's everything we know. Business Insider. March 03, 2020.

[iv] https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen

[v] Clinical and Laboratory Standards Institute. Viral Culture; Approved Guidelines. CLSI document M41-A [ISBN 1562386239] Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2006.

[vi] Lauer, S.A., et. al. The incubation period of Coronavirus disease 2019 (COVID-19) from publicly reported confirmed cases: estimation and application, Ann Intern Med. 2020

Salt Lake County Health Department
2021-2022 K-12 School Response Plan

Introduction

Investigating individual cases and responding to outbreaks of COVID-19 in the school setting are highly important to help slow the spread of disease in the community. Doing so in a timely and thorough manner is vital, as infection can spread rapidly among staff and students in this setting. This investigational response plan is aimed to create an effective procedure that is both fluid and collaborative between schools, districts, and local and state health departments in a school setting.

Main priorities of this protocol are one, to help schools effectively isolate sick staff and students as well as quarantine those that were exposed to disease within the school setting. Two, provide testing to those that are sick and those exposed within the school setting. Three, provide opportunities to vaccinate those that are not yet vaccinated and to those that meet criteria for third or booster doses as the school year progresses. Lastly, to respond to outbreaks, including those that reach a 2% threshold that meet state law for school-wide testing. Surveillance will be used for each of these priorities with the goal of detecting those school settings that can profit from early intervention to help prevent the 2% threshold from being met.

Response Description

Staffing

The Salt Lake County Health Department (SLCoHD) has staffing broken down into three district groups: school testers, school liaisons, and surveillance staff. All have distinct roles and interact when needed.

School testers:
School testers are used at each of our four school testing sites and within our two mobile testing units. Each testing side and mobile testing unit have a lead. There is one supervisor over all the testers to aid in mentoring, staffing, supply management and dispatching.

Testing Site	Number of Staff
Northern Testing Site	3
Eastern Testing Site	3
Southern Testing Site	3
Western Testing Site	3
Mobile Testing Unit 1	2
Mobile Testing Unit 2	2
Supervisor	1

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School Liaisons:
Staff is broken down into 7 distinct groups: charter schools, private schools, Granite School District, Jordan School District, Murray School District, Canyons School District and Salt Lake School District. Each group has one group lead and there is one supervisor over all the staff to aid in training, mentoring and administrative duties.

Group	Number of Staff
Charter Schools	3
Private Schools	2
Granite School District	5
Jordan School District	5
Murray School District	2
Canyons School District	3
Salt Lake School District	2
Supervisor	1
Program Manager	1
	23

Surveillance Staff:
Surveillance staff will be looking for two or more cases within classrooms and extracurricular activities. They will provide spreadsheets for each school liaison group to track positive cases, and their classes, extracurricular activities, contacts, and isolation dates. If a school resides in a current hotspot, they will reach out to the school liaison lead and recommend they reach out the school to offer additional testing and a vaccine clinic. Surveillance staff will also be tracking outbreaks and the 2% threshold for senate bill 107. There are two surveillance staff working on these activities.

Case Ascertainment

Cases are reported through several methods. Most come from the electronic laboratory reports (ELR) that occur through the Utah National Electronic Disease Surveillance System (NEDSS) EpiTrax system. In order to more quickly identify what school K-12 children attend, we have a data sharing agreement with the Utah Board of Education. We obtain quarterly data from them with name, birthdate, and name of school. This data is linked three times daily with the incoming reports in EpiTrax and shared with school liaisons. School liaisons work with their point of contact (POC) in each school to verify if the positive cases identified through linkage are school related. Positive cases that are confirmed to be school related are tracked in a moving 14-day time period to ensure that the 2% threshold isn't met. Cases are also reported through the school points of contact and shared with the school liaisons. Cases are also identified through contact tracers. In summary school related cases are reported by:

- Board of Education enrollment data linked with EpiTrax positive cases
- Cases and parents call in cases to the school and staff such as coaches
- Contact tracers obtain information from positive cases

Positive Cases

Once identified, positive cases are instructed to isolate at home until they are:

- Fever-free for 24 hours, and
- Respiratory symptoms have improved for 24 hours, and
- It has been at least 10 days since they first got sick.
- If they did not have symptoms, they will isolate for 10 days from the day they were tested

Cases will be called by the school liaisons and asked about their school classes and extracurricular activities, days they went to school while infectious, and whether they wore a mask or not at school and during participation in extracurricular activities. These guidelines will be followed even if the case was vaccinated prior to testing positive. They will not be allowed to come to school or participate in extracurricular activities during the above period. These cases will be counted towards the school 2% threshold if they were a school related case and a student. Staff will not be counted toward the threshold but will be tracked in outbreaks and appropriately isolated.

Contact Tracing

School liaisons will work with school staff to determine the infectious period of positive school related cases. Once determined, the school will verify which days the positive case was in school during this time. All students and staff that were in contact with the positive case during these days for at least 15 minutes in a space of less than or equal to six feet will be identified for each 24-hour period. This list of exposed contacts is sent to school liaisons to look up:

- Vaccination status (must be at least 14 days from last dose), AND
- If there was a COVID positive test result in the prior 90 days of exposure

Those that do not meet either of the two criteria above are sent back to the school as cases that should be quarantined. School liaisons will send an official health department letter by email to either the parent of the exposed child (or staff member), or to the school POC to send the email to the parent of the exposed child (or staff member). The letter will specify that the exposed individual has a choice of the following:

1. Quarantine for 10 days from last exposure to the positive case, OR
2. Continue attending school wearing a mask for 10 days from the last exposure to the positive case
3. In addition to the above, the exposed may choose to be tested on day 7 or after if they have no symptoms. If they are negative, they may return to school without a mask.

Children or staff involved in extracurricular activities must follow the above recommendations as well. If it is impossible to determine exposures in a classroom or extracurricular group, the whole classroom or group will be considered exposed. If at any point in the investigation it is determined that the positive case and all or some contacts wore masks, quarantines will not need to occur

Outbreaks

Outbreaks will be defined at two different levels. Outbreaks will first appear with 2 or more in a classroom or extracurricular activity. Once two or more are identified, testing will be offered to the classroom or group. An outbreak will be created in EpiTrax to ensure that the outbreak is documented, and cases are tracked.

Cases will also be tracked at the school level. Positive cases reported in a 14-day moving timing period will be tracked and monitored for reaching the threshold set by Senate Bill 107. This requires schools to do a Test to Stay event when:

- Schools with 1,500 or more students have 2% of their students test positive for COVID-19 within the previous 14 days.
- Schools with fewer than 1,500 students have 30 students test positive for COVID-19 within the previous 14 days.

The SLCoHD has a dashboard that tracks this information at https://slco.org/health/COVID-19/data/.

Testing

Testing will be targeted at difference levels of the investigation.

1. Provide testing to those that were exposed at school and not symptomatic on day 7
2. Ensure that kids and staff within schools that are ill have a place to test
3. Provide testing to classrooms or extracurricular groups that have 2 or more cases associated with them
4. Test to Stay when the threshold is met.
5. If the school resides in a hotspot

Four school-based clinics will be set up in the North, East, West and South ends of the valley. Locations will be advertised within schools. Mobile units will be deployed for Test to Stay events and for other group testing such as classrooms, teams, and other extracurricular groups. Testing will be offered at a school level for those schools geographically located in hotspots.

Vaccinations

Vaccinations will be offered at the four school-based testing locations. They will also be offered during Test to Stay events and if a school resides geographically in a hotspot. Schools can request a vaccine clinic at their school at any time through their school liaison.

Hotspots

Each week the hotspot team will prioritize communities that have high case rates, low vaccination rates and rank highly with the hotspot identification tool that prioritizes communities with high social vulnerability. Once the communities have been identified the hotspot team will identify schools to prioritize for outreach. Testing, vaccination, and other resources will be made available by the hotspot team to the schools in the prioritized areas.

Resource Documents Appendix

Utah Department of Health. (2022, Aug). K-12 School Recommendation. Retrieved from https://coronavirus.utah.gov/education/

Salt Lake County Health Department. (2021, Aug). COVID-19 School Exposures Guidelines: Quarantine and Isolation Guidelines for Students and Staff. Retrieved from https://slco.org/globalassets/1-site-files/health/programs/covid/school_quarantine.pdf

Salt Lake County Health Department. (2021, Aug). General Expectations between Schools and SLCoHD for COVID, 2021–22 School Year. Figure 1 below.

Figure 1

SALT LAKE COUNTY HEALTH DEPARTMENT

General Expectations between Schools and SLCoHD for COVID, 2021–22 School Year

Positive Cases:

- Positive students and staff reported to either SLCoHD or school will be reported to the other entity on the day they were reported to ensure both know of the positive case
- Schools will ensure the positive case is not attending school during the isolation period
- SLCoHD will contact positive cases and provide education about isolation (contact tracers)
- Schools will determine who the close contacts are for the positive case:
    - those who are within 6 feet for more than 15 minutes in a 24-hour period **OR**
    - list of all students/teachers within classroom(s) and extracurricular group(s)

Contacts of Positive Cases:

- Schools will provide SLCoHD with a list of close contacts to positive cases
- SLCoHD will determine if the close contacts are vaccinated or have had COVID-19 within the last 90 days
- SLCoHD will provide a letter to schools with names of the close contacts who must quarantine
- Schools will send the letter to students who must quarantine
- Schools will manage which option quarantined students choose:
    - Quarantined at home with online school
    - In-person school with mask always worn indoors
- SLCoHD will provide testing at clinics for students choosing to test on day 7 to return to school without a mask
- Family members of positive cases who also attend the school should be reported to the other entity immediately to ensure both the school and SLCoHD know of the exposure

Test To Stay:

- SLCoHD will track positive cases within a moving 14-day period for their public dashboard and the Test to Stay threshold:
    - Schools with 1,500 or more students have 2% of their students test positive for COVID-19 within the previous 14 days.
    - Schools with fewer than 1,500 students have 30 students test positive for COVID-19 within the previous 14 days.
- Once the threshold is met, the school representative and SLCoHD will set a date for school testing
- SLCoHD will provide a letter to the school/superintendent notifying the threshold is met
- SLCoHD will provide a letter for schools to send to parents explaining test to stay and what is expected of them
- SLCoHD will provide testing/results to the school

SLCoHD Points of Contact for Schools:

- **Canyons:** Hannah Rose; hrose@slco.org or 385-267-8244
- **Granite:** Mary Hill; mhill@slco.org or 385-468-4207
- **Jordan:** Jennie Schouten; jschouten@slco.org or 385-221-7580
- **Murray:** Cheryl McFall; cmcfall@slco.org or 801-462-5189
- **Salt Lake:** Greg Galloway; ggalloway@slco.org or 385-343-9556
- **Charter:** Paige Allen-Rife; pallen-rife@slco.org or 801-448-9620
- **Charter:** Adheu Arok; aarok@slco.org or 801-448-8352
- **Private:** Ava Anderson; avanderson@slco.org or 801-512-5615

Other:

- Schools can request testing events for classes or sports teams, etc. at any time through their SLCoHD point of contact.