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Clinical Laboratories versus Public Health Laboratories	
Clinical Laboratories — Individual Health	Public Health Laboratories — Population Health
<ul style="list-style-type: none"> <li>• Diagnostic testing</li> <li>• Some reference testing</li> <li>• Medical management</li> </ul>	<ul style="list-style-type: none"> <li>• Some diagnostic testing</li> <li>• Reference testing</li> <li>• Surveillance and monitoring</li> <li>• Emergency response support</li> <li>• Applied research</li> <li>• Workforce development and training</li> </ul>

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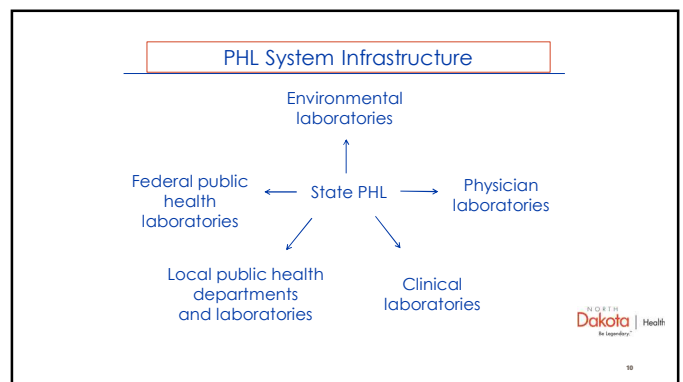
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**CALM BEFORE THE STORM**

- Tools that prepare the NDPHL for outbreak response
- Importance of maintaining competency and quality control
- Ways of providing transparency during the pandemic
- Enhancing response capabilities utilizing partnerships with local, state, and federal entities.

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4/19/2022 7

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• ND DoH Mission: Improve the length and quality of life for all North Dakotans.

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**PREPARING FOR OUTBREAK RESPONSE**


- Training
- Planning
- Establishing partnerships

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**TRAINING**


- Routine response drills and tabletop exercises
- After Action Meeting to discuss successes/failures
- NDPHL sends staff to training and participates in proficiencies as part of the Laboratory Response Network (LRN)
- Receive funding from the Public Health Emergency Preparedness (PHEP) grant



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**COMPETENCY AND QUALITY CONTROL**

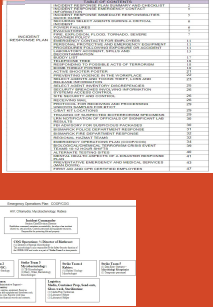
- Maintain sample integrity
- Ensure confidence in results
- Provide valid data for statistical and medical response



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**PLANNING**

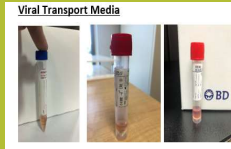
- Establish partnerships with local, state and federal agencies
- MOU with Civil Support Team (CST)
- Establish and maintain documents detailing critical incident responses
- Continuity of Government (COG) is a coordinated effort to ensure that governance and essential functions continue to be performed before, during, and after an emergency.
- Have document management system to track all updates (iPassport)



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**SAMPLE INTEGRITY**

- Correct collection type
- Holding time
- Storage conditions
- Patient information



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**PARTNERSHIPS**

- **Local** Public Health Units, Medical Community
- **State** Agencies-EPR, Disease Control, Governors' Office, National Guard, CST, NDSU, UND
- **Regional**-Northern Plains Consortium (SD, MT, ID, WY)
- **Federal**-APHL, CDC, FEMA, LRN, FERN, FDA, EPA



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**CONFIDENCE IN RESULTS**

- Quarantine decisions
- Treatment decisions



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## VALID DATA

- Daily reporting to Disease Control
- Accurate patient information
- Validation of EAU approved methods
- Verifying all testing QC is passing
- Documenting training and competency of analysts
- Performance tracking logs to monitor pre-analytical and analytical testing

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## SARS PCR MONTHLY FAILED TAT 2020

### TOTAL SPECIMENS 907,119

Time_Category	Instrument_Assay	MARCH	APRIL	MAY	JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER	TOTAL TESTS COMPLETED	48+ TOTALS	% OF TOTALS
48hrs+	Amplitude SARS-CoV-2 PCR	0	0	0	0	0	0	0	0	1,015	1,987	82,694	3,002	3.66%
48hrs+	Abbott SARS-CoV-2 PCR	0	1,368	2,545	190	5,021	5,662	2,842	3,468	474	1,882	228,289	23,452	10.27%
48hrs+	Hologic SARS-CoV-2 PCR	0	0	0	2,406	157	0	0	1,054	299	1,116	61,204	5,032	8.21%
48hrs+	ThermoFisher COVID-19 PCR	0	0	197	277	15,162	13,200	28,430	19,186	752	174	528,793	77,378	14.63%
48hrs+	CDC	1	0	0	0	0	0	0	0	0	0	6,659	1	0.02%

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## DIVISION OF LABORATORY SERVICES

- Continuous Quality Improvement tracking
- Totals for 2020 and 2021

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## VALIDATION/COMPARISON STUDIES - 2020

Study Name	Instrument	Assay	Method	Results
Abbott SARS-CoV-2 PCR	Abbott	SARS-CoV-2	PCR	100%
Hologic SARS-CoV-2 PCR	Hologic	SARS-CoV-2	PCR	100%
ThermoFisher COVID-19 PCR	ThermoFisher	COVID-19	PCR	100%
CDC	CDC	SARS-CoV-2	PCR	100%

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## SARS COV-2 PCR: ANALYTICAL CORRECTIVE ACTIONS 2020

- Total Error Rate among all SARS CoV-2 PCR platforms: 0.00035%

SARS CoV-2 PCR Tests Resulted Analytical - Corrected Reports	Total SARS CoV-2 Tests Resulted
324	928,197

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## CORRECTIVE ACTION TOTALS

### JANUARY 1 – DECEMBER 31, 2021

- Total Error Rate 2021: 0.005%

Pre-Analytical	Analytical	Post-Analytical	Total
540	2,984	5	3,529

### 2021

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COVID PCR TEST VOLUME 2021-535,463

Instrument/Assay	JAN	FEB	MARCH	APRIL	MAY	JUNE	JULY	AUGUST	SEPT	OCT	NOV	DEC
Amplitude	63836	43692	26270	38586	22849	12093	9946	23629	59825	57703	33693	43779
Abott M2000	6816	6194	9491	4,632	4042	3430	0	0	0	0	0	0
Hologic	8072	10238	10297	5259	5476	3806	2212	6521	12337	15356	12794	7761
				1,705								
ThermoFisher	5297	9486	18004		1574	378	2681	8157	4033	2993	2053	2503
	5416	69610	64962	50002	34041	19707	12128	38307	76465	70662	66522	54043

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## PARTNERSHIPS

- South Dakota Public Health
- Civil Support Team
- National Guard
- Emergency Preparedness and Response (EPR)- PPE supplies

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## VALIDATION/COMPARISON STUDIES - 2021

[illegible]

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MORE PARTNERS...

- Northern Plains Laboratory contract for lab technicians
- Other state agencies provided support staff
- Local community
- NDSU borrowed equipment and brought under our CLIA license
- UND-transferred instrument

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## TRANSPARENCY

- Documentation of all failed runs and corrective actions
  - Press Releases
  - Media updates and interviews
  - Posted several videos on social media
  - Audit by State Auditors Office
- <https://www.facebook.com/mhhealth/videos/1050484930404040>  
- process 03/1/2020 5:37 p

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## SOME INITIAL CHALLENGES

- The PHL was in the process of updating the building and LIMS
- Building upgrade was able to be delayed until summer of 2020 when specimen load was reduced
- LIMS upgrade was delayed a year and completed April of 2021
- Supplies were being sent out on allotment
- PPE shortages
- Staff shortages
- Limited space for equipment
- Do we continue/discontinue routine testing
- The lab need to operate 24/7
- State fax lines could not support the volume of reports we were generating.

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## COVID TIMELINE

- December 12, 2019 a cluster of patients in Wuhan, Hubei Province, China begin to experience shortness of breath and fever.
- January 2, 2020, The World Health Organization activates its incident management system across the three levels of WHO (country office, regional office, and headquarters).
- January 7, 2020, Chinese authorities identify and isolate a novel coronavirus as the causative agent of the outbreak
- January 20, 2020, CDC confirms the first U.S. laboratory-confirmed case of COVID-19 in the U.S. from samples taken on January 18 in Washington state.
- January 22, 2020 The World Health Organization confirms human-to-human spread of the novel coronavirus.
- February 4, 2020, The U.S. Food and Drug Administration approves the Emergency Use Authorization (EUA) PACC for the CDC developed SARS-CoV-2 diagnostic test. CDC distributes 200 test kits through its Influenza Reagent Resource program to laboratories across the U.S.
- March 11, 2020, The World Health Organization declares COVID-19 a pandemic.
- March 13, 2020, President Donald J. Trump declares a nationwide emergency.

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## CONTINUED

- Discontinued dairy product testing and moved rabies to NDSU
- Limited summer mosquito/tick program
- Rescheduled lab certifications
- Added multiple instruments that would have future use in the laboratory
- Due to multiple collections devices, validated platforms for multiple sources.

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## STATE TIMELINE

- March 7, 2020 Started CDC assay-testing 197/day
- March 11, 2020 First positive case in Ward County
- March 13, 2020 Governor declares State of Emergency (ends April 30, 2021)
- March 19, 2020 Governor suspends licensing requirements
- May 31, 2020 National Guard duty at lab complete
- April 8, 2020 Abbott M2000 validated
- April 16, 2020 Cepheid Xpert Xpress validated
- April 18, 2020 Thermofisher validated
- June 8, 2020 Hologic Aptima Panther validated
- June 15, 2020 Liaison TrimericS IgG validated
- September 23, 2020 BioFire validated
- November 9, 2020 Amplitude Capacity 7500/day
- March 10, 2022 Pandemic to Endemic

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## OUTCOMES

- Scaled to meet COVID-19 testing demand from 197 COVID samples per day in March 2020 to 7,500 COVID-19 samples per day in December 2020
- Validated and confirmed 61 new tests, equipment and procedures in nine months
- Added 37 new instruments for SARS-CoV-2 related tests
- In 2020, resulted over 930,000 COVID samples, of the last 400,000 COVID samples received, 97% were resulted in less than 36 hours and 65% were resulted in less than 24 hours

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## RAPID RESPONSES IN LAB

- Added staff, went from 18 to 180
- Purchased "SLING" for staff scheduling
- Added Dynamics and eventually lab web portal for patient info
- Changed phone lines to streamline calls
- Utilized all possible space in laboratory
- Added three mobile labs
- Leased space for supply distribution center/ warehouse
- Increased WGS to monitor for variants
- Established daily meetings for communication

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## CONTINUED

- Scaled a distribution program from 150 COVID-19 sample collection orders a day, to over 9,000 a day supplied to more than 300 laboratories and/or facilities
- Collaborated with research universities to increase laboratory capacity. Worked with the NDSU vet diagnostic laboratory to establish CLIA accreditation to perform COVID-19 tests and transferred equipment to the UND Medical Laboratory Science program
- Supported an increase in COVID-19 testing capacity at two hospital laboratories in North Dakota by providing equipment and reagents – Altru in Grand Forks, ND and Essentia in Fargo, ND

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**ABBOTT M2000**

- The lab had one M2000 and we were able to lease/purchase four additional instruments.



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**CEPHEID XPRT**

- The Cepheid Xpert Xpress SARS-CoV-2 test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in either nasopharyngeal, nasal, or mid-turbinate swab and/or nasal wash/ aspirate specimens.
- Used for high priority testing.

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**ABBOTT M2000**

- 96 well plate with ~ 8 hour TAT
- The Abbott RealTime SARS-CoV-2 assay is a real-time (rt) reverse transcriptase (RT) polymerase chain reaction (PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal (NP) and oropharyngeal (OP) swabs from patients suspected of COVID-19
- Generally had 3-4 M2000 instruments running 24/7 for the first 12 months for a capacity of ~ 1000 tests/day

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**HOLOGIC PANTHER**




- The PHL was able to purchase/lease three
- Random access
- Full automation
- Able to load primary sample tube



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**CEPHIED XPRT**

- The PHL was currently used for CRE and MTB. We were able to purchase 8 additional drawers for a total capacity of 16.
- Fastest results ~ 40 minutes



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**HOLOGIC PANTHER**

- The Aptima SARS-CoV-2 assay combines the technologies of target capture, Transcription Mediated Amplification (TMA), and Dual Kinetic Assay (DKA).
- The Panther could run 1000 samples in 16 hours
- Initial limitation was that instrument waste could not be emptied while running, but this was later updated
- Also added later - MTU expansion module providing 13.5 hours of walkaway time before additional loading was required

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## LIFE TECHNOLOGIES AMPLITUDE

- The amplitude took 6 weeks to set up and validate.
- The Amplitude™ Solution with the TaqPath™ COVID19 HighThroughput Combo Kit is an automated, high-throughput realtime PCR testing system that detects SARS-CoV-2 RNA in human samples.
- The system is designed to perform over 8,000 tests in a 24-hour period. Four employees are required to supply and support the system

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<p><b>SPINNAKER</b></p> 	<p>▪ "Hotel" where extraction plates from module 1 are loaded</p> <p>▪ Spinnaker that moves plates through system</p>	<p><b>HOTEL</b></p> 
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## LIFE TECHNOLOGIES AMPLITUDE


Run time per batch 55 mins  
< 60 minutes hands-on time per 6-8 hour shift  
Two techs for each module



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## MODULE 2


- Tecan Fluent 780
- Dispenses amplification reagents
- Combines four 96 well plates to one MicroAmp plate



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## MODULE 1


- Tecan "Fluent" 1080
- Specimens loaded and barcodes scanned
- Four 96 well plates
- Need 376 samples to do run



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## MODULE 2

- Module 2 computer station
- QuantStudio7 Real-Time PCR System



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## THERMOFISHER

- KingFisher Flex Extraction 
- ABI 7500 Fast DX 

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## THERMOFISHER

- The most manual method typically had a team of 5/shift and ran ~ 1400 tests per shift
- TaqPath™ COVID-19 Combo Kit contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARSCoV-2 in nasopharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19

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