Assessing the Status of Advanced Molecular Detection (AMD) in Clinical Laboratories in New Jersey

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Introduction

The New Jersey Public Health and Environmental Laboratories (PHEL) conducted a survey of clinical laboratories in New Jersey to determine the current state of molecular testing for reportable diseases in highly complex, CLIA-certified, New Jersey licensed clinical laboratories, located in hospitals and commercial sites. Information regarding these laboratories will be used to:

- Improve inter-laboratory communications and operations for routine and emergency response
- Maintain and update the PHEL Electronic Test Ordering and Reporting (ETOR) customer databases
- Solicit clinical laboratory partners for surveillance studies
- Provide training

Findings indicate:

- Clinical microbiology laboratory services continue to consolidate, with 38 clinical microbiology laboratories now serving 72 acute care hospitals, and 40 rehabilitation, specialty hospitals and other healthcare agencies within the state. [1]
- 87% of participants reported using molecular methods for testing respiratory pathogens, including SARS-CoV-2, Influenza and RSV and, 47% use molecular methods for detecting *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.
- Most did not report offering Point of Care (POC) testing in-house.
- About 20% of laboratories used molecular methods for testing other reportable diseases.
- Nearly all reporting laboratories (87%) used Cepheid GeneXpert and a frequent number (58%) were using BioFire Syndromic Surveillance panels.
- Only two laboratories reported performing Next Generation Sequencing (NGS).
- 50% were interested in sending specimens to our laboratory for sequencing.
- 20% were interested in sequencing training.

Methodology

Design Team:

- APHL Fellows (Eagle Bui, Hannah Schrader)
- Clinical Laboratory Improvement Services (CLIS) Inspectors (Jacquelyn Guthrie and Daria Wasilewski)
- Outreach Program staff (Susan Mikorski and Tiffany Frez)

Questions

- Fellows researched FDA approved tests for NJAC Title 8, Chapter 57 reportable diseases[2] listed in the FDA website[3].
- CLIS team reviewed fellows' list and recommended the most utilized tests encountered during inspections.
- A modified list based on CLIS recommendations was used to develop survey questions.

Survey Tool

- Considered NoviSurvey; (fellows were trained on NoviSurvey), selected MS Forms.

Survey Design

- The survey was divided into three sections: 1 - Demographics, 2 - COVID testing information, and 3 - molecular testing information.

Survey Administration

- The survey was emailed to all CLIA certified high complexity clinical laboratories in New Jersey and included Medical Directors, Administrative Directors, and Microbiology Managers at each site. Redundancy is important when conducting surveys, as roles and responsibilities vary between facilities.
- One response was requested per site.
- To obtain maximum participation, the survey was emailed four times: July 14, July 17, August 11, August 25 of 2023. After the four mailings, phone calls were made to nonrespondents.

References

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10. Comparison of the Allplex™ Respiratory Panel Assays and the automated Fast Track Diagnostics Respiratory pathogens 21 assay for the diagnosis of pediatric respiratory viral infections https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7105963/
11. Comparison of Panther Fusion Respiratory Panels to Routine Methods for Detection of Viruses in Upper and Lower Respiratory Tract Infections https://www.sciencedirect.com/science/article/abs/pii/S0732889319311988
12. FDA and CMS Joint Memorandum on Laboratory Developed Tests https://www.fda.gov/medical-devices/medical-devices-news-and-events/fda-and-cms-americans-deserve-accurate-and-reliable-diagnostic-tests-wherever-they-are-made
13. Emergency Use Authorization for IVD Tests https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua
14. Tri-Agency Task Force for Emergency Diagnostics https://www.fda.gov/media/120328/download?attachment
15. CDC Next Generating Sequencing Quality Initiative https://www.cdc.gov/labquality/qms-tools-and-resources.html

Results

Survey Respondents

COUNTY		LABORATORY	LAB LOCATION	HEALTH SYSTEM
ATLANTIC	1	AtlantiCare Regional MC	Atlantic City	AtlantiCare
	2	Shore Medical Center	Somers Point	-
BERGEN	3	Englewood Hospital and MC	Englewood	-
	4	HMH-Pascack Valley	Westwood	HMH*
	5	Holy Name Medical Center	Teaneck	-
	6	The Valley Hospital	Ridgewood	-
BURLINGTON				
CAMDEN	7	Virtua Voorhees Hospital	Voorhees	Virtua Health
	8	Cooper University Hospital	Camden	-
	9	Jefferson Cherry Hill Hospital	Cherry Hill	Jefferson Health
CAPE MAY	10	Cape Regional Med Ctr.	Cape May Court House	-
CUMBERLAND	11	Inspira Medical Center	Vineland	Inspira Health
ESSEX	12	Mountainside Medical Ctr.	Montclair	HMH
	13	St. Michael's Medical Center	Newark	Prime Healthcare
	14	University Hospital	Newark	-
GLOUCESTER				
HUDSON	15	Bayonne Medical Center	Bayonne	CarePoint Health
	16	Christ Hospital	Jersey City	CarePoint Health
	17	Hoboken Univ. Med. Center	Hoboken	CarePoint Health
	18	Quest Diagnostics	Secaucus	N/A
HUNTERDON	19	Hunterdon Medical Center	Flemington	-
MERCER	20	Capitol Health Medical Ctr.	Hopewell	Capitol Health
	21	RWJBarnabas - Hamilton	Hamilton	RWJBarnabas
MIDDLESEX	22	Penn Medicine Princeton	Princeton	Penn Medicine
	23	RWJBarnabas -NB	New Brunswick	RWJBarnabas
	24	St. Peter's. University Hosp.	New Brunswick	-
	25	Aculabs Inc.	East Brunswick	N/A
MONMOUTH	26	CentraState Medical Ctr.	Freehold	-
	27	Jersey Shore Univ. Med. Ctr.	Neptune	HMH
	28	Monmouth Med Ctr - North	Long Branch	RWJBarnabas
MORRIS	29	Atlantic Consolidated Labs	Morris Plains	AtlanticHealth
OCEAN	30	Ocean University Med. Ctr.	Brick	HMH
	31	Southern Ocean Med. Ctr..	Manahawkin	HMH
PASSAIC	32	St. Joseph's Regional MC	Paterson	St. Joe's HC System
	33	St. Mary's Hospital	Passaic	Prime Healthcare
SALEM				
SOMERSET	34	LabCorp	Raritan	N/A
	35	RWJBarnabas - Somerset	Somerville	RWJBarnabas
SUSSEX	36	Newton Medical Center	Newton	Atlantic Health
UNION	37	Trinitas Regional Med. Ctr.	Elizabeth	RWJBarnabas
WARREN	38	St. Luke's Hospital	Phillipsburg	-

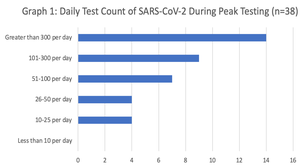
* HMH = Hackensack Meridian Health

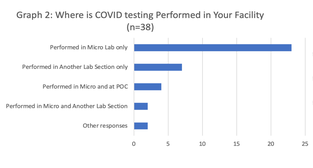
Survey Respondents

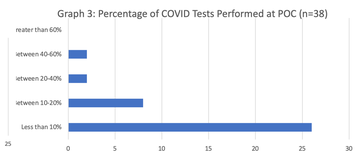
- 38 laboratories responded
- All 21 counties represented*
- 24 laboratories part of Healthcare systems
- 3 commercial laboratories
- 11 serve stand alone hospitals

**Burlington, Gloucester and Salem are served by Jefferson, Virtua and Inspira*

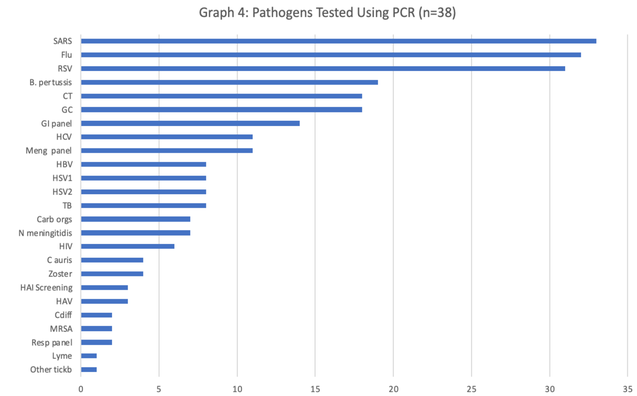
COVID Response Data







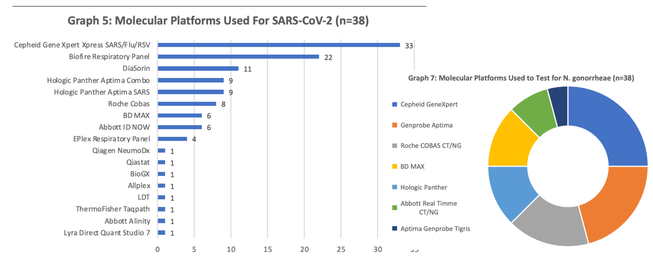
Molecular Testing for Reportable Diseases

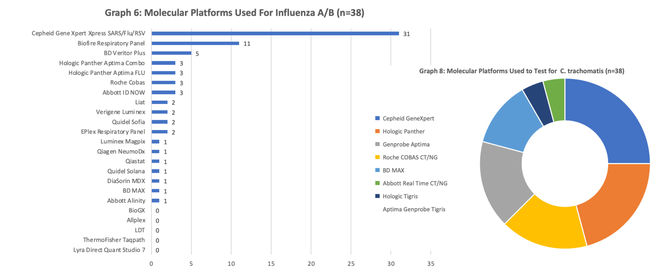


B. pertussis = *Bordetella pertussis/parapertussis*
C. auris = *Candida auris*
Carb Orgs = Carbapenemase resistant *Enterobacteriales*
Cdiff = *Clostridium difficile*
CT = *Chlamydia trachomatis*
Flu = Influenza virus
GC= *Neisseria gonorrhoeae*
GI panel = panel of gastrointestinal pathogens
HAI Screening = Hospital Acquired Infections Screening
HAV = Hepatitis A Virus
HBV = Hepatitis B Virus
HCV = Hepatitis C Virus
HIV = Human Immunodeficiency Virus
HSV-1 = Herpes Simplex Virus-1
HSV-2 = Herpes Simplex Virus-2
Lyme = *Borrelia burgdorferi* and related borrelia
Meng. Panel = panel of meningitis and encephalitis pathogens
MRSA = Methicillin Resistant *Staphylococcus aureus*
N. meningitidis = *Neisseria meningitidis*
Other tickb = Tickborne diseases other than Lyme
Resp panel = panel of respiratory pathogens
RSV = Respiratory Syncytial Virus
SARS = SARS CoV-2 virus
TB = *Mycobacterium tuberculosis*, and related mycobacteria
Zoster = Herpes Zoster

Results (continued)

Molecular Platforms Used





Discussion

2009: H1N1 Pandemic

- Public health laboratories quickly became overwhelmed with PCR test requests [5,6,7]
- Rapid antigen test methods used in clinical labs for influenza varied in reliability[8]

2019: COVID19 Pandemic

- **NJ PHEL focused on**
  - Testing vulnerable populations
  - Helping clinical sites and DOH Rapid Response Team:
    - Distribution of testing materials to local laboratories and other test sites
    - Grants to 17 hospital laboratories to increase AMD capacity
    - Field Deployable Laboratories as requested by Rapid Response Team
  - Sequencing viruses
  - Data Modernization – ETOR and Advanced Analytics
  - Certifying clinical laboratories for COVID testing
  - Developing DPHLI Partnerships i.e. DHSTS (Division of HIV/TB/STD Services)
- **NJDOH contracted with commercial laboratories** for high volume testing
- **FDA rapidly released**
  - PCR EUA methods for SARS-CoV-2 for clinical testing
  - OTC tests - at home use
  - Waived tests
- **NJ PHEL to create an After-Action Report with Improvement Plan**

Distributed Public Health Laboratory Infrastructure (DPHLI)

PHASE I : 2024 – 2026

- **Center for Advanced Molecular Detection (CAMD) for High Throughput Sequencing**
  - Build and manage a biorepository
  - Convert to high through put sequencing methods
  - Develop partnerships for new surveillance models
- **Advanced informatics Team**
  - Build genomic databases using CDC Pipelines
  - Train PHEL staff, clinical laboratorians, LHDs and epidemiologists on advanced informatics
- **Outreach and Workforce Development Program**
  - Solicit clinical laboratory participation to expand surveillance programs
  - Develop interactive webpage and Learning Management System
  - Engage fellows and interns in all improvements
- **Clinical Laboratory Improvement Services (CLIS)**
  - Train epidemiologists and LHDs on CLIA, FDA and NJ Lab Licensing requirements

PHASE II : 2026 – 2027

- Continue PHASE I Implementation activities
- Hire genomic epidemiologist to share genomic data
- Solicit other partners to expand surveillance i.e. wastewater etc.

PHASE III: 2027 and Beyond – One Health initiatives with multiple state partners