Point of Care Testing for STI's A Look Back and a Nobel Cause

Robert L. Sautter, Ph.D. HCLD/CC (ABB) MS MT (ASCP) SM
Prinicpal Consultant
RL Sautter Consulting LLC
Lancaster, SC

Financial Connections

- *Dr. Robert L Sautter, faculty for this educational event, has no relevant financial relationship(s) with ineligible companies to disclose.*
- *He does serve on Committees for the Healthcare Action Alliance for Commission on Laboratory Accreditation (COLA) and ABB American Board of Bioanalysis*

Objectives

- Detail guidelines and history for Clinical Laboratory Medicine testing.
- The difficulty and the use of good laboratory methods throughout the healthcare system for accurate results.
- To work as a multi-disciplinary team to get good laboratory results to the clinician
- A brand new Volume and Supplement came out on the topic that I will be speaking on. I would recommend reading it CID Volume 82 Issue Supplement, ISN 1058-4838 , EISSN 1537-6591. 7 articles are here and I will be reading them and suggest that you do as well.

History of Microbiology Point of Care Testing

- On February 28, 1992, the regulations were published for CLIA 88
- Pre-CLIA 88
  - Microscopic assays of unstained and stained specimens
  - Particle agglutination assays for antibodies and antigens
  - Other tests such as the sniff test
- Following CLIA 88
  - Waived tests
  - Provider performed microscopy

Has Uncle Sam gone crazy?

Maybe or

Maybe Not!

- **Certification Boards for Laboratory Directors of High Complexity Testing**
- The qualification for a laboratory director of high complexity testing at 42 CFR 493.1443(b)(3)(i) is that the laboratory director must hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and be certified and continue to be certified by a board approved by HHS. The current approved boards are the following:

- ABB – American Board of Bioanalysis
- ABB public health microbiology certification
- ABCC – American Board of Clinical Chemistry
- ABFT – American Board of Forensic Toxicology (limited to individuals with a doctoral degree with Fellow status)*
- ABMGG – American Board of Medical Genetics and Genomics (formerly known as American Board of Medical Genetics (ABMG))
- ABMLI – American Board of Medical Laboratory Immunology (no longer accepting new exam applicants)
- ABMM – American Board of Medical Microbiology
- ACHI -American College of Histocompatibility and Immunogenetics (formerly known as American Board of Histocompatibility and Immunogenetics (ABHI))
- NRCC – National Registry of Certified Chemists (limited to individuals with a doctoral degree) *
- DMLI – Diplomate in Medical Laboratory Immunology (ASCP Board of Certification)
- * These boards certify non-doctoral individuals also.
- Page Last Modified: 09/10/2024 06:18 PM

The Start of the POCT Revolution

- POCT really took off when the waived test provision of CLIA was added.
- Waived tests are simple and are those that are:
  - Cleared by the FDA for home use, or
  - Employ methods that are simple so that erroneous results are negligible
  - Pose no reasonable risk of harm to the patient if the test is performed incorrectly
  - No personnel requirements

Laboratory Errors Suspected as Cause of Two Deaths: Warfarin is commonly associated with medication errors, and its appropriate use is an important indicator of patient safety

- The Centers for Disease Control and Prevention last August began an investigation of laboratory errors that may have contributed to the deaths of two patients taking warfarin.
- As arguably 70% of clinical decisions are made by lab tests including POC
- From June 4 to July 25, a hospital laboratory in Pennsylvania reported 2,146 tests with correct prothrombin time (PT) results but with incorrectly calculated international normalized ratio (INR) results. The mathematical formula required to calculate the INR uses a reagent-specific number, the international sensitivity index (ISI).

•*Emergency Medicine News* 24(6):p 58, June 2002. | *DOI:* 10.1097/01.EEM.0000334157.91493.66

Trends in Waived Testing Over Time

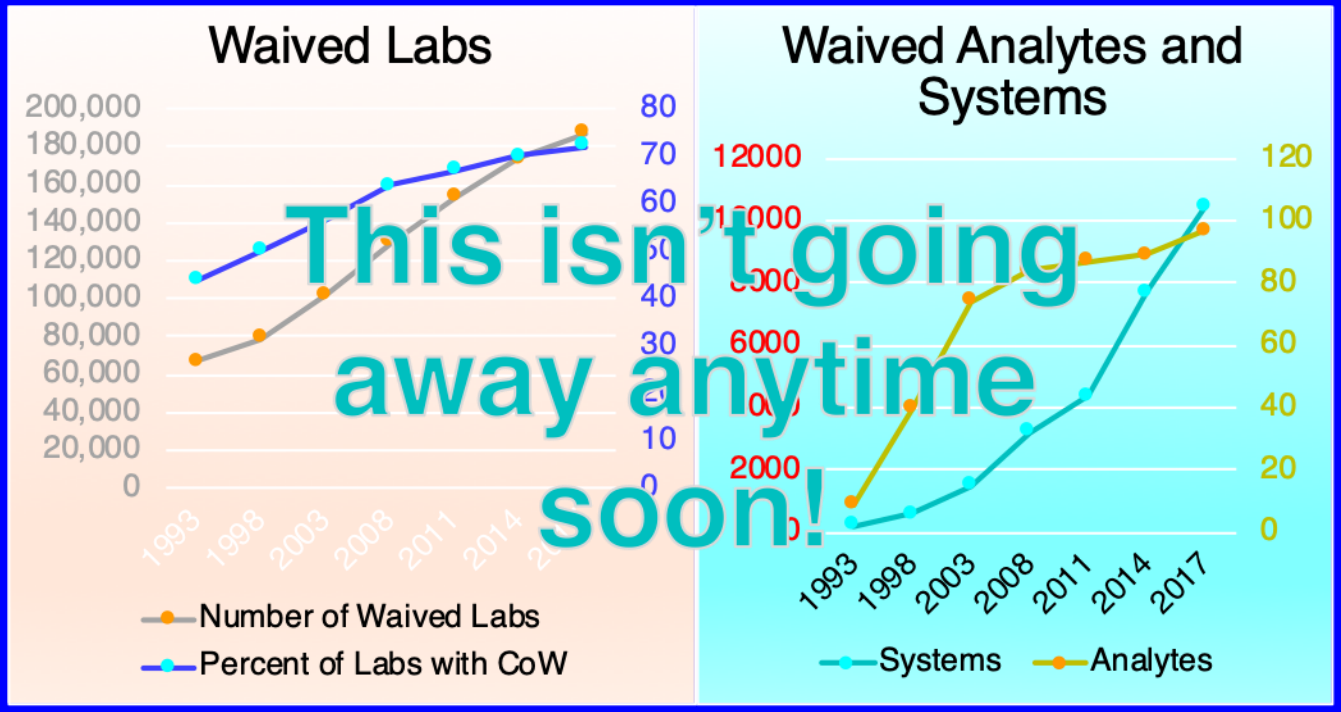
Waived Testing Measurement Parameter	1993	1998	2003	2008	2011	2013
No. of analytes for which waived test systems are available	9	40	74	84	87	88
No. of waived test systems*	203	608	1,495	3,228	4,369	6,852
No. of laboratories with a Certificate of Waiver†	67,294	78,825	102,123	129,219	153,702	161,589
Percentage of laboratories with a Certificate of Waiver†	44%	50%	57%	64%	67%	68%

*Numbers reflect multiple names under which individual tests are marketed and might include waived tests no longer sold.

†Does not include CLIA exempt laboratories in states of New York and Washington.

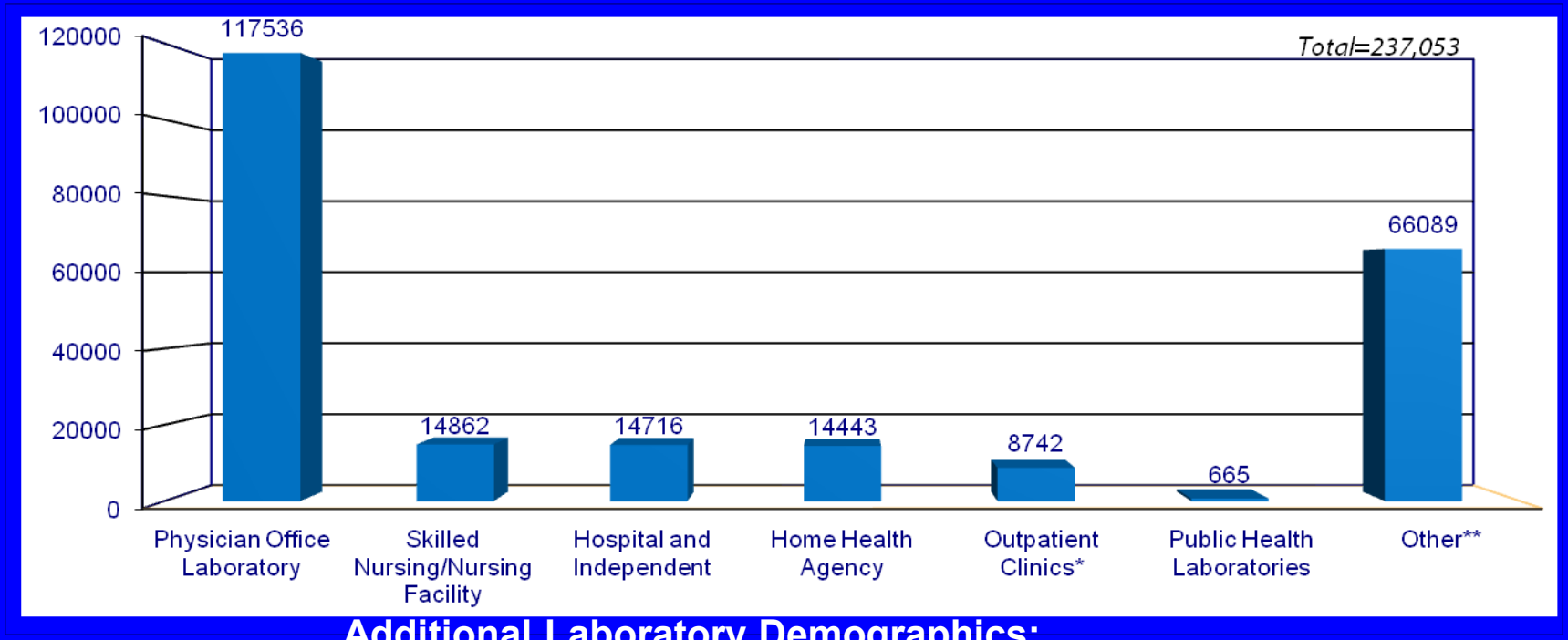
Source: CDC and FDA CLIA Test categorization databases and CMS On-line Survey, Certification, and Reporting database.

The Rise of POC Testing…



Data From: Trends in Waived Testing Over Time. Anderson N, Stang H. Promoting good laboratory practices for waived infectious disease and provider-performed microscopy testing. Clin Microbiol Newsl 2017;39:183-8.

U.S. Laboratory Demographics, 2013 Laboratory types, all CLIA-Certified Laboratories[1]



Additional Laboratory Demographics:

- ❑333,000 laboratory personnel[2]
- ❑>13 billion tests/year[1]
- ❑>$70 billion/year in laboratory revenues[3]

[1]Data obtained from CMS OSCAR database, 02/06/2013. OSCAR data are self-reported.
[2]Data obtained from US Department of Labor Bureau of Labor Statistics Occupational Employment Statistics (OES) at http://www.bls.gov/oes/#tables
[3]Data obtained from http://www.aacc.org/publications/cln/2013/february/Pages/Outreach.aspx#
*Community clinic, rural health clinic
**Insurance, pharmacy, tissue bank/repositories, blood banks, ambulance and mobile units, industrial, health fair, ancillary test sites, school/student health service, other not specified.

Division of Clinical Laboratory Improvement and Quality Centers for Medicare & Medicaid Services March 2024

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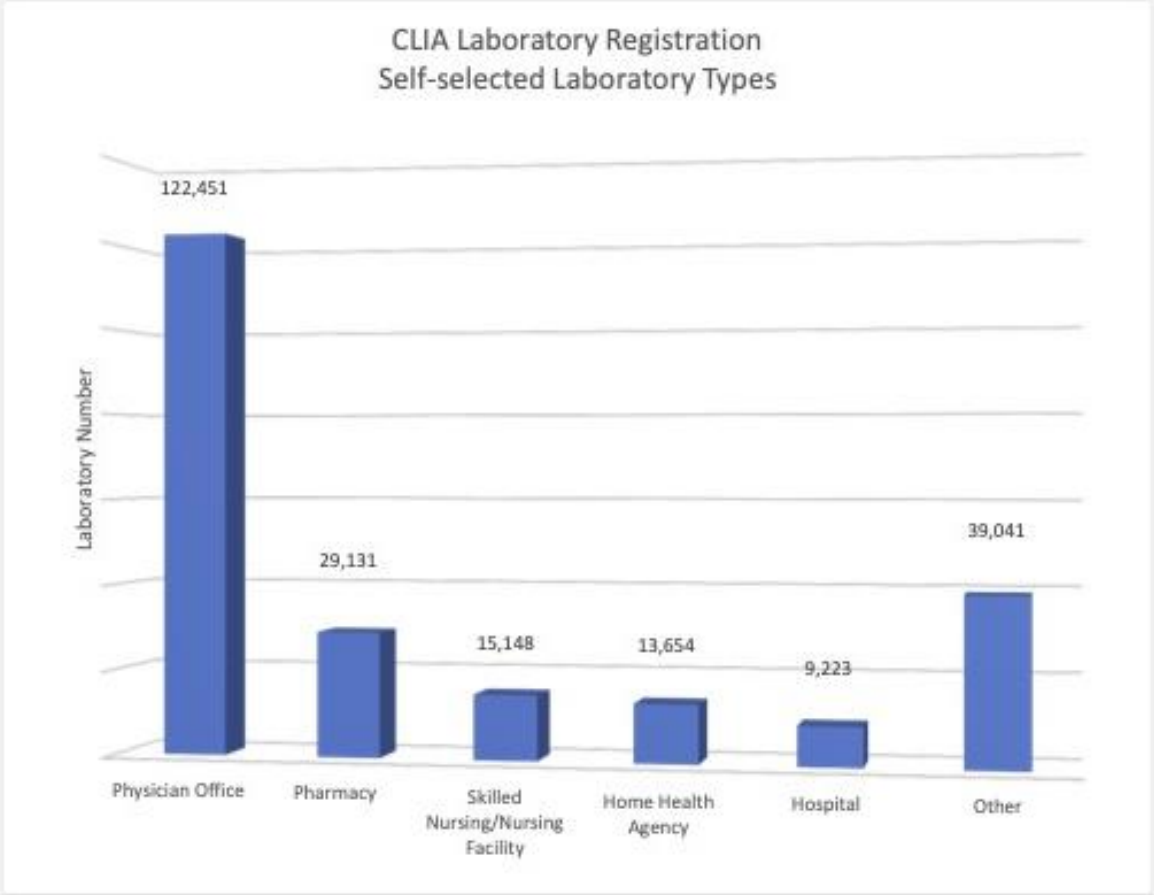
March 2024



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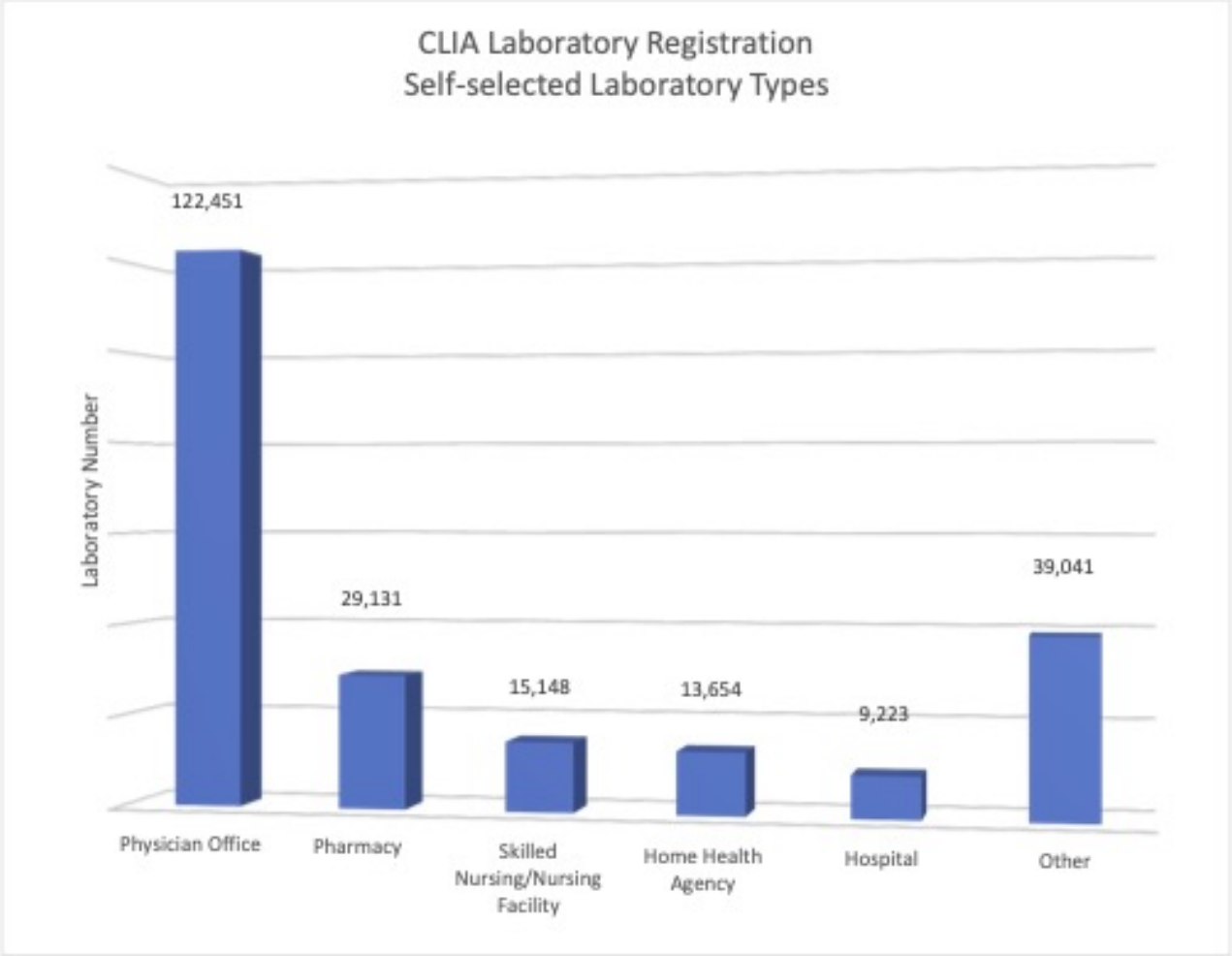
Centers for Medicare & Medicaid Services
March 2024



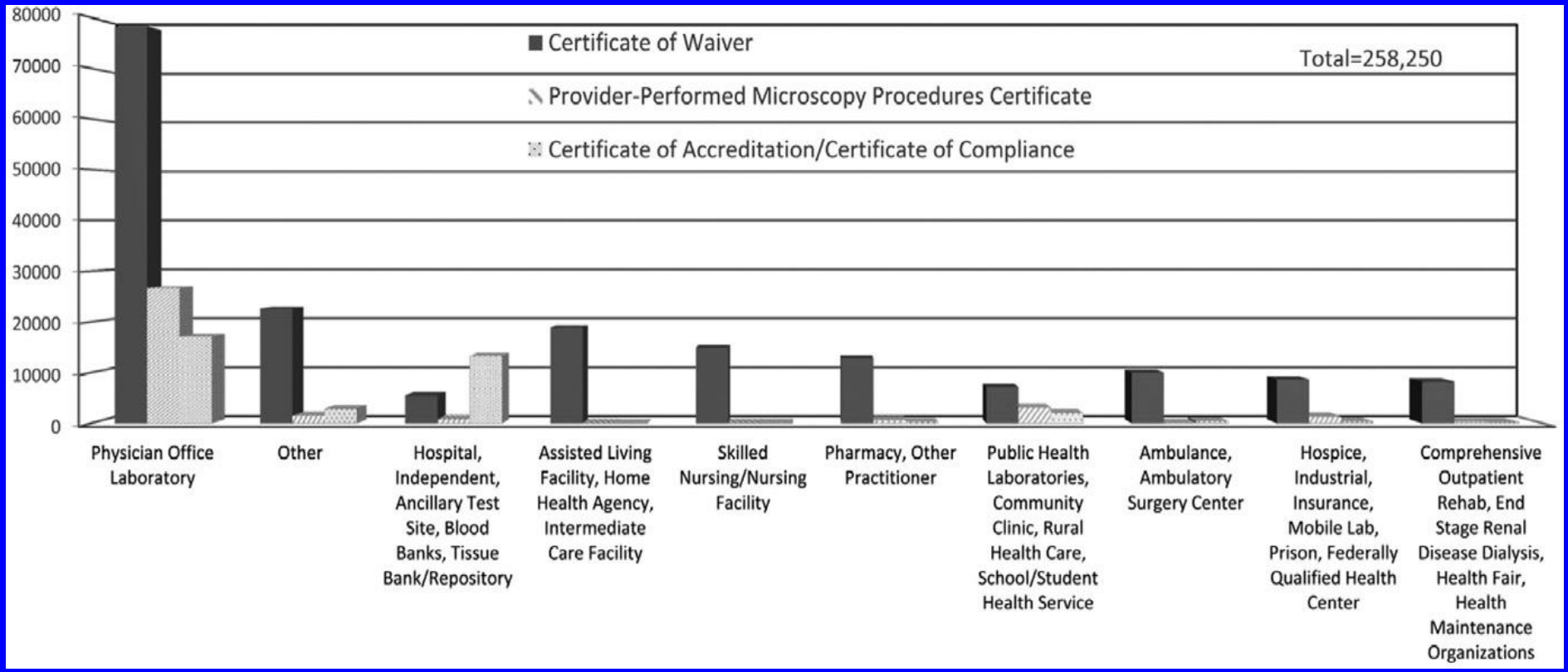


Fig. 1. US laboratory demographics, June 2017. (Data obtained from CMS Quality Improvement & evaluation System (QIES) database, 06/27/2017. Laboratory types in QIES data are self-reported. Numbers included laboratories in CLIA-exempt states of NY and WA. Data do not include CLIA certificate of registration laboratories. Anderson N, Stang H. Promoting good laboratory practices for waived infectious disease and provide-performed microscopy testing. Clin Microbiol Newsl 2017; 39:183-8.).

Division of Clinical Laboratory Improvement and Quality
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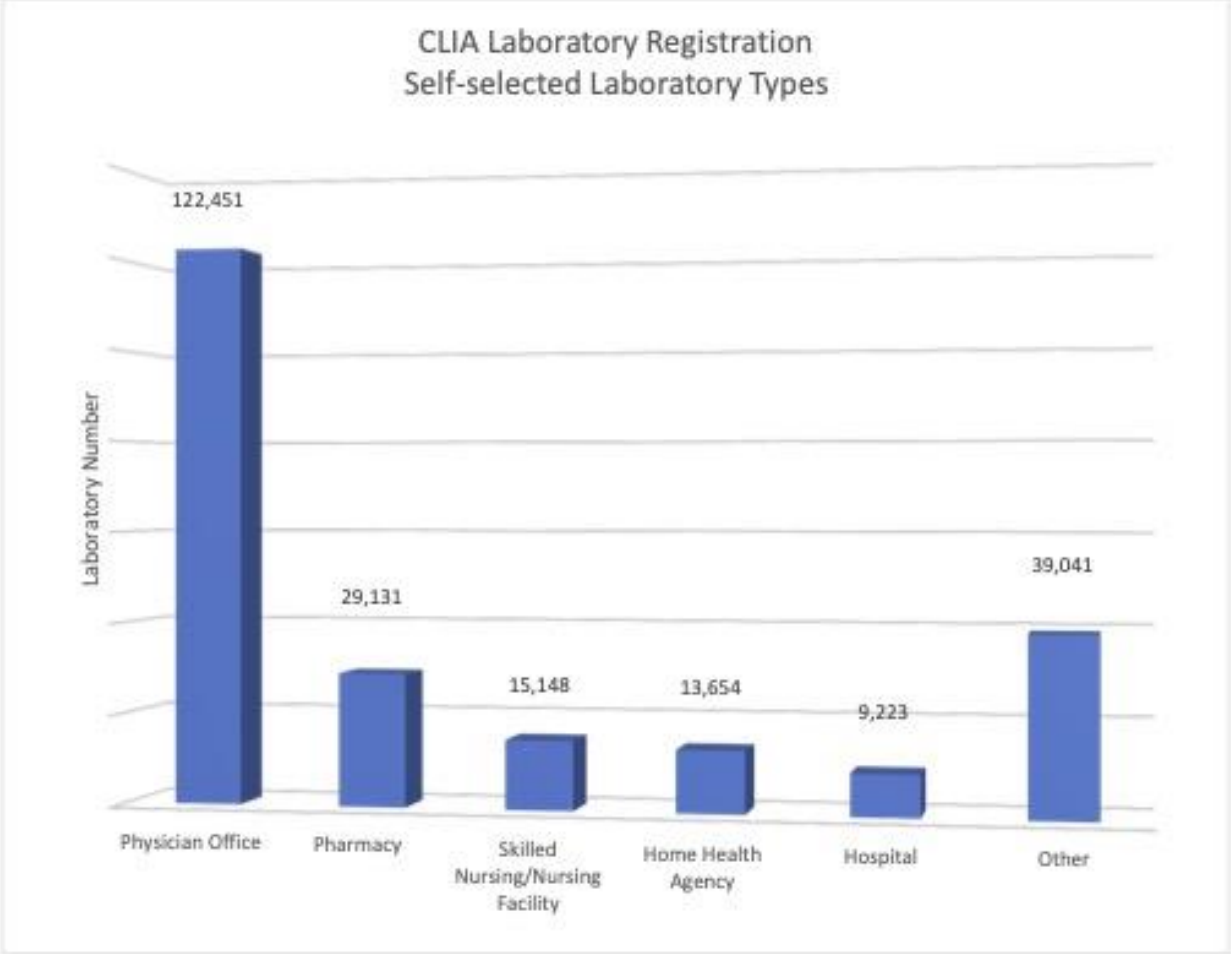
March 2024



Waived vs Non-waived Requirements

Requirement	Non-Waived	Waived
Personnel	Lab leadership and testing personnel must meet degree and experience requirements.	No requirements
Quality Management	Laboratory must have active QM plan and procedures.	Must follow manufacturer's instructions.
Proficiency Testing	External or alternative PT required for all tests.	No requirements
Safety	Safety procedures required.	No requirements
Validation and Verification	Required for all tests.	No requirements
Instruments and Equipment	Maintenance and performance must be documented.	No requirements
Enforcement	Biennial inspections.	None

Professional Societies- Infectious Disease POCT –

Where do we go for direction??

- CLSI- POCT 15
- ASM
  - Evidence based medicine
  - ASM Clinical and Public Health Microbiology Committee and the ASM Corporate Council (2019) 1
- AACC (now ADLM- Association for Diagnostics and Laboratory Medicine)
  - Laboratory Medicine Practice Guideline
  - POC chat groups
- IDSA
- CDC and WHO

1 Miller, M. B., Atrzadeh, F., Burnham, C. A., Cavalieri, S., Dunn, J., Jones, S.,ASM Clinical and Public Health Microbiology Committee and the ASM Corporate Council (2019). Clinical Utility of Advanced Microbiology Testing Tools. *Journal of clinical microbiology*, *57*(9), e00495-19. doi:10.1128/JCM.00495-19

A sampling of one state's requirements. Ex: PA State Regulations

- Procedure manual
- Reference/normal ranges
- Critical values (reporting system)
- Proficiency testing
- Temperature monitoring
- Retention of records
- Quality assurance program

Challenges

The most difficult and challenging are in red. If achieved the rest will come!!!

- Lack of compliance in performing laboratory testing
- Managing College of American Pathologists (CAP), The Joint Commission (TJC), COLA, and CLIA inspections at the POC
- Turning non-laboratorians into testing personnel
- Competency assessment and education
- QC—handling failures and review
- Managing outpatient clinics and family practice centers
- Gaining physician and nursing allies
- Evaluating new instrumentation and justification
- Controlling how POCT gets into the facility
- Challenges of data management

1. Sautter RL, Earnst, DM, Halstead DC. What's Old Is New Again: Laboratory Oversight of Point of Care Testing—Guidelines, Challenges, and Practical Strategies. Clin Microbio Newsletter. 2018;40:191-8.
2. Halstead DC, Sautter RL. New paradigm, new opportunities: laboratory stewardship. Clin Microbiol News 2018;40:175-80.

Compliance and Accountability of Users and Managers

- This is a difficult challenge to address for all laboratories but in particular for POC
- In the laboratory when issues arise- the laboratorians and managers directly report to laboratory administration and medical director
- However, when POC testing personnel have issues, their reporting structure is not under the administration or medical director of the laboratory
- It is time for the microbiology department/ laboratory to “step out of the lab” to oversee POC

Turning Non-laboratorians into Testing Personnel

- It is imperative that the POC coordinator be accessible to the testing personnel.
- This task is very demanding, since in most institutions, the POCT personnel could be anyone on the hospital floor or in outpatient clinic, or the physician.
- In our experience, all health care professionals want to deliver the best care possible to the patient.
- For non-laboratorians, POCT is not one of their top priorities. It is up to the POC team to share how important laboratory testing can be in the scope of caring for patients.
- This can be accomplished by sharing patient case reports with a focus on how POCT can modify therapy in a positive way.
- Regular dialog with the manager on the floor can also aid this endeavor. Constant two-way communication is a must in any successful POCT program.

Gaining Physicians and Nursing Allies

- Building relationships among stakeholders is paramount to success in a POCT program.
- Whether on the outpatient side or inpatient floors, helping providers with questions and giving laboratory consults, interpreting laboratory results, and/or suggesting follow-up testing (suggested by the CLIA medical director) all helps to strengthen the health care team.
  - These were most often face-to-face meetings at the site of testing.
  - Also, for those that have a PPMP license, providing assistance in maintaining microscopes really helps to form a good working relationship.
  - Unfortunately, many PPMP laboratories do not perform regular cleaning or maintenance for the microscope being utilized. The scopes are often dirty and/or non-functioning. One example of how the POC team was able to improve this was by having a set of microscopes that traveled with the team to each site visit.
  - Bringing a functioning, clean microscope and training them how to use it and take care of it, as well as fix it when it was not functioning, was a way to gain physician and nursing allies. This type of oversight and collaboration

Regulatory Approach to Point-of-Care/At-Home Testing in the United States

Robert L. Sautter, PhD HCLD/CC (ABB), MS, MT (ASCP), SM

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- "Performing waived testing in the near patient setting with appropriate oversight to ensure accurate results."
- "Modification of regulations to allow home-based testing and appropriate confirmatory testing."
- "Consequences of failing to follow testing guidelines and possible effect on patient well-being. "

"As of September 27, 2022, more than 430 COVID-19 tests have been approved for EUAs (Emergency Use Authorization)"

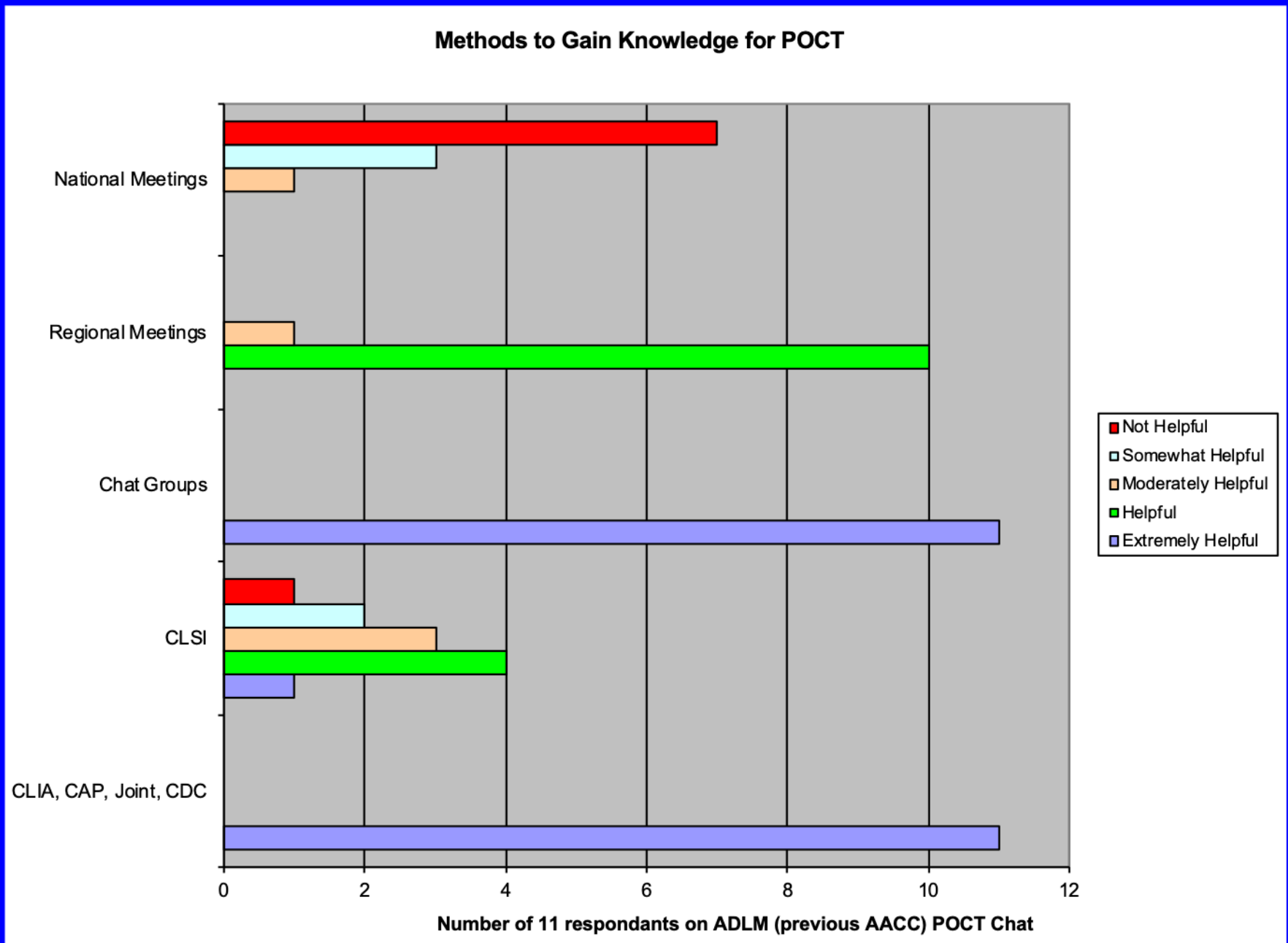
1.Positives in Health Care for Doing Point-of-Care Testing

(1) rapid results, laboratory results available while the patient is evaluated by care givers;
(2) current testing methods (NAAT [Nucleic Acid Amplification Test] and improved antigen testing) are robust and are sensitive and accurate;
(3) some NAAT POC testing methods are now comparable with those methods offered in the core laboratory (https://www.cdc.gov/cliac/ past-meetings.html); and
(4) these are similar tests to sexually transmissible diseases, group A streptococcus, and some urine tests that clinics and physician's offices are used to running.[20]

1.Home test advantages are they allow families to test those that are sick and then distance them from their families if positive and if negative to not modify their activities, and they give caregivers reason to expedite office visits for a positive patient. Negative antigen tests in symptomatic patients and positive antigen tests in asymptomatic patients are recommended to be confirmed with a NAAT test "Given rapid tests' lower sensitivities and specificities, it's a good idea to use a PCR tests to confirm positive antigen tests in asymptomatic individuals and negative antigen tests in symptomatic individuals, as well as close contacts of positive cases. A PCR test can act as a 'second opinion

Are we part of the problem?

- Survey of Two professional websites, ASM and AACC POC chat groups were taken.
- Items to include: For those of you that have a Medical Technology program, do you take students for a time in POC?
- What is POC?
- Who is qualified to run the tests?
- What tests are included?
- How is it regulated?
- Do you give them an exam?


Methods to Gain Knowledge for POCT
National Meetings
Regional Meetings
Chat Groups
CLSI
CLIA, CAP, Joint, CDC
0
2
4
6
8
10
12
Not Helpful
Somewhat Helpful
Moderately Helpful
Helpful
Extremely Helpful
Number of 11 respondants on ADLM (previous AACC) POCT Chat

Possible Negatives of Performing Point-of-Care Testing

There some obvious negatives of performing COVID testing at the POC.[20]

1. The overall cost of performing testing at the POC is a negative.
2. Both reagent cost and the cost of instrumentation is high. This is why administration must be behind bringing the testing to multiple sites because the cost of running multiple sites with the same testing is large, so confirmation of the need to do this is extremely important. Another negative is that most of the testing at POC contains limited analytes.
3. Some challenges with POC include test performance by nonlaboratory personnel without training and guidance.[4]
4. Quality concerns for waived laboratory testing includes: lack of training in testing and quality assessment, constant turnover of employees, and a total lack of personnel training. Strategies to address these concerns include administrative structure for organization and oversight before instituting testing.
5. A laboratory stewardship team to oversee POC testing for good quality results is of utmost importance.[4,5,9]
6. This is extremely important to address, training, constant oversight, following procedures, and maintaining procedure manuals (manufactures procedures), taking into account preanalytical, analytical, and postanalytical parameters to allow good samples, testing, and data management.[4,5] The flu variant of 2009 H1N1 actually was detected with higher sensitivity using DFA (Direct Fluorescent Antibody) and polymerase chain reaction when respiratory cells were detected in the sample at levels of greater than 60.[22,23]

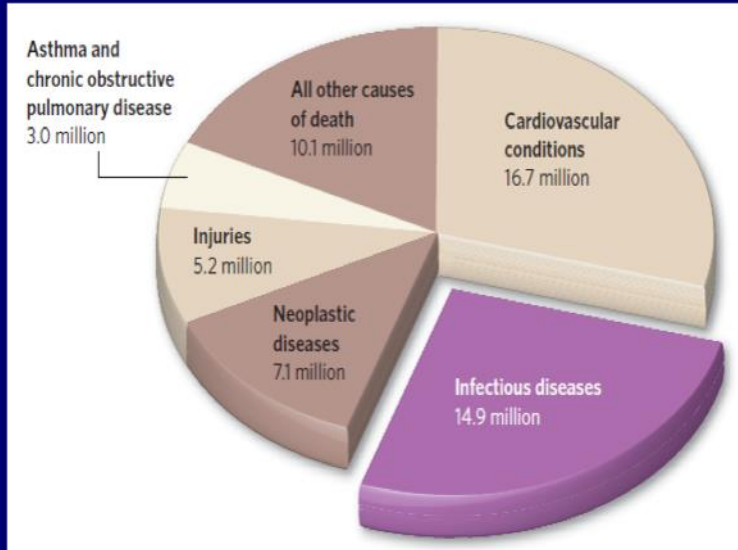
At-home testing during COVID showed a rise in the numbers tested and also opens up questions about its reliability and future of testing and diagnosing infectious diseases

Sheldon M. Campbell, Robert L. Sautter, Ellen Jo Baron, Suzanne E. Dale, Charlotte A. Gaydos, Mitch Gonzales, Barbara Haller, Ralf Labugger, Cindy B. McCloskey, Norman Moore, Heather Stang; CLSI Point of Care Testing for Infectious Diseases. 1st Edition, CLSI Report. POCT15, Wayne, Pa. Clinical and Laboratory Standards Institute; 2020

Outline

- An overview of POCT
- POCT-15: Purpose and Description
- Technology Summary
  - Antigen/Antibody Testing
  - Molecular Diagnostics
- Discussion by Pathogen
  - Respiratory Pathogens
  - Genitourinary Pathogens
  - Helicobacter pylori
  - Human Immunodeficiency Virus
  - Hepatitis Viruses
- Other Health Care Associated and Community Pathogens of Importance
- Procalcitonin
- Use of Point-of-Care Tests in Low-Resource Settings

Impact of Infectious Diseases



Infectious diseases	Annual deaths (millions)
Respiratory infections	3.96
HIV/AIDS	2.77
Diarrhoeal diseases	1.80
Tuberculosis	1.56
Vaccine-preventable childhood diseases	1.12
Malaria	1.27
STDs (other than HIV)	0.18
Meningitis	0.17
Hepatitis B and C	0.16
Tropical parasitic diseases	0.13
Dengue	0.02
Other infectious diseases	1.76

•The importance of infections is even greater when one considers years of life lost, and morbidity without mortality.

Fig. from Morens et al 2004; The Challenge of Emerging and Re-emerging Infectious Diseases, Nature 430:242-9

POCT 15: Point of Care Testing for Infectious Diseases

- For the major types of point-of-care tests, discusses indications, limitations, appropriate use, and reporting and interpretive issues.
- Summary of potential uses of point-of-care tests in community outreach and public health testing, and in resource-limited settings.
- Intended for use by laboratory professionals, public health professionals, clinicians, and health care managers to guide in the selection, implementation, and effective use of point-of-care tests in the diagnosis and management of infectious diseases.

In Vitro Diagnostics EUAs For Covid

https://www.cdc.gov/csels/dls/locs/2020/fda_clarifies_clia-waived_status.html

- **Diagnostic Tests** - Tests that detect parts of the SARS-CoV-2 virus and can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests and antigen tests.

- **Serology/Antibody Tests** - Tests that detect antibodies (e.g., IgM, IgG) to the SARS-CoV-2 virus. Serology/antibody tests cannot be used to diagnose a current infection.

- **Tests for Management of COVID-19 Patients** - Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Quality of Waived Testing: Ohio and Colorado Studies- preliminary

- State authorities concerned with quality of waived testing
  - Focused on-site inspections (195 labs)
  - Prior notification & screening
  - Significant problems in >50%
  - Testing beyond certificate (10% Ohio & 7% Colorado)

Quality of Waived Testing- CMS Survey in 2001-expanded

- Inspected 2.5% of labs in 8 states (436 labs)
  - 32% mfg instructions not available
  - 32% required QC not performed
  - 16% mfg instructions not followed
  - 7% calibration not appropriate
  - 20% cut dipsticks, occult cards
  - 19% personnel not trained or evaluated

CMS Study of Waived Labs

- Ongoing process; survey 2% of waived labs/year, began in 2001, expanded in 2002-4
- In 2001, 20% of waived labs cut urine dipsticks or occult blood cards
- Subsequent years; Notified prof. organizations, trained surveyors, etc.

	2001	2002	2003
# labs surveyed	460	897	1,756
Did not have mfr instructions	32%	13%	12%
Did not perform recommended QC	32%	31%	20%
Did not follow mfr storage & handling	9%	3%	3%
Personnel not trained/evaluated	19%	21%	16%
Enrolled in proficiency testing	ND	8%	5%

CMS Waived Project-Performance w/ Voluntary PT*

CW Survey Response	PT	No PT
Lab has current Manufacturer's in instructions	98%	88%
Performs required QC	95%	75%
Performs required function checks/ calibration	75%	62%
Performs confirmatory testing	25%	15%

*Not proficiency testing

CMS Waived Project- 2006 & Ongoing

- 2006 Initial visits- 1947 visited, 69% were following the manufacturer's instructions.
- 2006 Follow-up visits- of 414 labs revisited for not following manufacturer's instruction, 353 or 85% of them IMPROVED UPON REVISIT
- For many issues found, upon follow-up visits those labs improved.
- Short Term Goal- continue the project indefinitely
- Long Term Goal for CLIA law will be to enhance oversight of Waived laboratories.

After looking at this, it is a major problem in at home testing.

More Recent Molecular Advances

- Molecular ID testing is rapidly evolving and being downsized
- Nanotechnology is growing by leaps and bounds and being aggressively applied to molecular testing
- Advances in microelectronics, microfluidics and microfabrication have paved the way for new technologies and simplified molecular platforms
  - Ultimate goal is sample-in/answer-out testing for all laboratories regardless of size, resources, or capacity

Conclusions

- The laboratory field needs more accurate POC tests for infectious disease. Some PCR methods are on the market, but miniaturized handheld devices will be a reality soon.
- Point of Care testing literature has been lacking in outcome studies, however, literature has been published as far back as 1991 calling for more accurate methods. The article below calls for more sensitive methods for wet preparations. We are just now getting around to this endeavor. The way we look at this disease changed with more accurate tests, how many other infectious diseases will also?

Lossick JG, Kent HL. Trichomoniasis: trends in diagnosis and management. Am J Obstet Gynecol. 1991 Oct;165(4 Pt 2):1217-22.

Conclusions

- “In the coming years, further evolution of POC tests may lead to new diagnostic approaches, such as panel testing, targeting not just a single pathogen but all possible agents suspected in a specific clinical setting. To achieve this goal, the development of serology-based and/or molecular-based microarrays/multiplexed tests will be needed.”
- The Future is here!!! New Technologies and Challenges!!

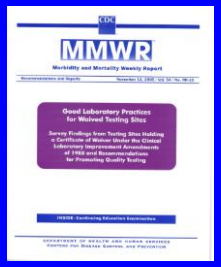
Moore NM, Cantón R, Carretto E, Peterson LR, Sautter RL, Traczewski MM, the Carba-R Study Team. 2017. Rapid identification of five classes of carbapenem resistance genes directly from rectal swabs by use of the XPERT Carba-R assay. J Clin Microbiol55:2268–2275. doi:10.1128/JCM.00137-17.

O. Clerc and G. Greub: Routine use of point-of-care tests: usefulness and application in clinical microbiology, Clin Microbiol Infect 2010; 16: 1054–1061.

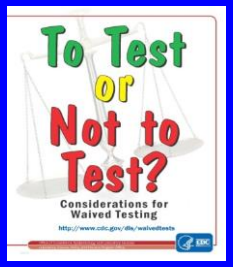
CDC Releases Free Educational Products to Promote Accurate and Reliable Testing

www.cdc.gov/dls/waivedtests

The products shown below provide information on considerations needed prior to initiating testing and describe recommended practices for those who perform testing in point-of-care and other sites under a CLIA Certificate of Waiver.

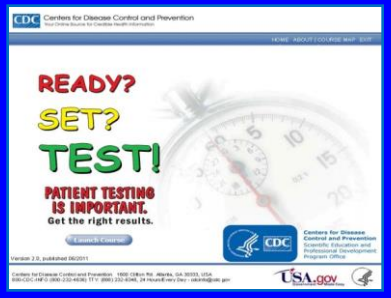


MMWR R&R: Good Laboratory Practices for Waived Testing Sites



Educational booklets with links, forms, and helpful tips

Posters and postcards with top 10 recommendations



Online course with continuing education credits available

For questions, comments, or to request hardcopies of the products, please e-mail WaivedTesting@cdc.gov.

Additional References

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- Sheldon M. Campbell, Robert L. Sautter, Ellen Jo Baron, Suzanne E. Dale, Charlotte A. Gaydos, Mitch Gonzales, Barbara Haller, Ralf Labugger, Cindy B. McCloskey, Norman Moore, Heather Stang; CLSI Point of Care Testing for Infectious Diseases. 1st Edition, CLSI Report. POCT15, Wayne, Pa. Clinical and Laboratory Standards Institute; 2020

I would recommend watching the movie “The Sound of Freedom” about child/sex trafficking

- This is a recent “true life” movie about trafficking on our border as well as in the USA.
- Also the producers and the actors encourage to share with others as this is something that our population should know.

The Hero in this movie was a real person and member of Homeland Security

Agenda

- History
- Consider for Litigation
- Specimen collection and transport
- Statute of Limitations
- Examination of victims
- Methods
- Conclusions

Background of Working with Child Resource Center

1. Over a five-year period from 1999 through 2004, 1,780 children being evaluated for suspicion of sexual abuse at the Children's Resource Center (CRC) (prior to this w/o CRC the lab tested < 5 per year)
2. Underwent testing for Ct and GC using the same swab for both cultures and NAATs.
3. When a culture was negative, but the NAAT was positive, a confirmatory NAAT was performed on the same specimens.
4. 28 Chlamydia (Ct) or GC NAATs were positive in 22 children, all positive on confirmatory NAAT.
5. Most Cts were missed by culture.
6. None of the children with Ct were symptomatic.
7. Many GCs were missed by culture.
8. Some children with GC were asymptomatic.
9. Some disclosures did not occur till after examination.
10. No STD detected by culture was missed by NAAT.

Some Important Things to Consider when Working on this Noble Task

- **Collaboration with caregivers and specialized caregivers.**
- **Collection and transport to the laboratory to minimize molecular cross contamination of the sample**
- **Institution of a chain of custody with sample collection and delivery to the laboratory**
- **Laboratory guidelines to minimize co-mingling of samples in the testing process, (one specimen per container).**
- **A robust laboratory process to freeze and save original samples in order to return them for additional testing.**
- **A predetermined algorithm to initiate confirmatory testing.**

Note: All above are so very important considering that arguably 70% of lab errors are associated with pre-analytical testing

Sautter RL. The Role of Microbiologists and the Clinical Laboratory in Identifying Infections in Survivors of Pediatric Sexual Abuse: a Difficult Task and an Ethical Responsibility. Clinical MicrobiologyNewsletter Volume 42, Issue 9, 1 May 2020, Pages 71-76

Collaboration with caregivers and specialized caregivers

- One of the most important processes is to form a team with caregivers at the patient’s side.
- Knowledgeable of challenges for care givers and also having the caregivers knowing the laboratories requirements and difficulty in offering robust test results.
- For child abuse requires a deviation from “normal” processes and an open communication to assure the best results are obtained with those that will stand the test of legal prosecution.

- About 1 in 4 girls and 1 in 13 boys experience child sexual abuse at some point in childhood.

- 91% of child sexual abuse is perpetrated by someone the child or child's family knows.

- The total lifetime economic burden of child sexual abuse in the United States in 2015 was estimated to be at least **$9.3 billion.** Although this is likely a low estimate of the true impact of the problem since child sexual abuse is underreported.

https://www.cdc.gov/violenceprevention/childsexualabuse/fastfact.html

Multidisciplinary Teams are important in all areas of the Lab

- Pre-analytical, analytical and post-analytical testing.

https://www.youtube.com/watch?v=hJpz1HVSXH8

Multidisciplinary Team

- Using a Multidisciplinary team has been shown to improve prosecution of perpetrators of abuse
- Amy D. Hendrix ,1 M.A.; Lauren K. Conway,1 D.O.; and Michael A. Baxter,1 D.O. Legal Outcomes of Suspected Maltreatment Cases Evaluated by a Child Abuse Pediatrician as Part of a Multidisciplinary Team Investigation, J Forensic Sci, September 2020, Vol. 65, No. 5doi: 10.1111/1556-4029.14463 Available online at: onlinelibrary.wiley.com
- However, in this particular article it does not mention the laboratory as part of that team.

- A very good article about using a Multidisciplinary team for investigating CSA
- However the team did not include the laboratory
- The team included:
  - The multidisciplinary team at one location of the study and includes the following: child abuse pediatricians, child protective services (CPS), several law enforcement agencies, a child advocacy group, and representatives from local district attorney offices
- A commentary was recently published on this article mentioning that the laboratory should be a member of the team.
- This commentary discussed the use of the laboratory in the investigation and other things mentioned in this talk.
- The author's response was good but mentioned that the lab was involved when they were needed. However, they are involved with every sample collected and tested.
  - Sautter RL et al Commentary on: Hendrix AD, Conway LK, Baxter MA. Legal outcomes of suspected maltreatment cases evaluated by a child abuse pediatrician as part of a multidisciplinary team investigation. J Forensic Sci. 2020;65(5):1517–23. doi: 10.1111/1556-4029.14463

A joint investigative PA team

- The medical team (physician, social worker, child abuse nurse specialist, medical assistant, Laboratory)
- Child Youth Services (CYS) (when appropriate)
- Law enforcement
- District attorney
- Victim advocacy service (rape crisis or victim services)

Collection and transport to the laboratory to minimize molecular cross contamination of the sample:

- Use of the correct collection device, one sample at a time to minimize cross contamination (in sealed container).
- Care givers contact the lab to make sure the samples are handled separately.
- Proper labelling of the sample
- Assure the paperwork is filled out correctly.

Institution of a chain of custody with sample collection and delivery to the laboratory

- Instituting a chain of custody form should be discussed and approved as required by hospital lawyers as well as the local district attorney
- This chain of custody was kept as evidence that the sample was delivered timely and went directly to the laboratory for testing
- Doing a chain of custody helps assure that no contamination or sample transport error occurs
- This is often asked during litigation by the defending attorney of the potential perpetrator

Avoid Co-mingling of Different Patient Samples

- This is true for receipt of samples and also transmitting to the testing lab.
- It is especially important to prevent comingling of samples when testing for DNA or RNA fragments
- It is important to respond to attorney's question if there was a chance that there was contamination of the sample with other positive samples
- However "bundle of samples" on the same patient has been used successfully.
  - "Whenever possible, cross validation of the ESwab kit for NAATs would be ideal, given the challenges of collecting 3 test modalities per site"

Qin X, Melvin AJ. Laboratory diagnosis of sexually transmitted infections in cases of suspected child sexual abuse. J. Clin. Microbiol. 2020;58(2):e01433–e1519. https://doi.org/10.1128/JCM.01433-19.

A robust laboratory process to freeze and save original samples in order to return them for additional testing

- Maintaining samples and isolates from culture techniques is imperative as the “statute of limitations” on prosecution varies from state to state. https://www.rainn.org/state-state-guide-statutes-limitations

Florida

- “The new statute of limitations mean that if you were sexually abused at age 16 or younger that you can file a lawsuit against the abuser no matter how much time has passed—allowing you to seek justice through a court of law and recover damages for the harm you suffered.”[1,2]

1.https://www.news4jax.com/i-team/2021/05/06/florida-lawmaker-to-push-again-for-lookback-window-allowing-sex-abuse-survivors-to-sue/

2.https://www.mallardlawfirm.com/blog/statute-of-limitations-for-child-sexual-abuse-in-florida.cfm

Storage of samples

- The statute of limitations (SOL) at every state make it essential to save the organisms and actual samples for a very long time.
- Some states may have a SOL of 10 years. As an example a 5yo as long as 23 years.

Constant Oversight of Lab Processes

- It is imperative that looking at technology changes, curtailing test contamination, quality assurance and quality control and adequate storage is imperative to run good forensic testing in CSA cases.
- The following slides show the process we used.

When to Consider Children- Evaluating for an STD

1.Child has experienced penetration or has evidence of recent or healed penetrative injury to the genitals, anus, or oropharynx.

2.Child has been abused by a stranger.

3.Child has been abused by a perpetrator known to be infected with an STD or at high risk for STDs (e.g., intravenous drug abusers, MSM, persons with multiple sexual partners, and those with a history of STDs).

4.Child has a sibling, other relative, or another person in the household with an STD.

5.Child lives in an area with a high rate of STD in the community.

6.Child has signs or symptoms of STDs (e.g., vaginal discharge or pain, genital itching or odor, urinary symptoms, and genital lesions or ulcers).

7.Child or parent requests STD testing.

https://www.cdc.gov/std/tg2015/sexual-assault.htm

Physical examination

- Examinations are performed by a physician or by a child abuse nurse specialist.
- The child is examined from head to toe, literally.
- Videocolposcopy and videotaping are used for the genital examination and are the most accurate for determining outcome[ref].
- GC and Ct true cultures are taken from all orifices, and GC and Ct amplifications are taken from the genital Ct swab.
- The child (and, occasionally the mother) selects a stuffed animal for being brave.

Killough E, Spector L, Moffatt M, Wiebe J, Nielsen-Parker M, Anderst J. Diagnostic agreement when comparing still and video imaging for the medical evaluation of child sexual abuse. Child Abuse Negl 2016;52:102-9.

Cossins A, Jayakody A, Norrie C, Parkinson PJ. The role of photographic and video documentation in the investigation and prosecution of child sexual assault. Law Med 2016;23:925-37.

Testing compared with history and physical - some victims show STD and do not show abnormal exam and have not come forward

Name	Age	+/-	Hx	Exam
GB	5	CT	+	-
CS	10	GC	+	+
CS	10	GC	+	+
ST	4	CT	+	-
JM	6	CT	+	-
JC	12	CT	+	+
SG	8	-	-	-
SG	6	CT & GG	-	+
JF	13	CT	+	+
MB	6	CT	-	-
TB	6	-	+	+
MW	3	GC	N/I	N/E
MW	3	GC Anal	+	+
AG	5	CT	-	-
CL	7	CT	+	+
KR	7	CT	-	-
MK	3	CT	-	-
TR	5	GC	+	+

N/I = Not interviewed GC = Gonorrhea CT = Chlamydia N/E = Not examined

Robert L. Sautter, William D. LeBar, Earl Greenwald, The Laboratory's Role in Evaluating Sexually Transmitted Diseases as a Result of Sexual Abuse, Clinical Microbiology Newsletter, Volume 31, Issue 19, 1 October 2009, Pages 145-150

Recommendations

- If you are performing testing of any type in cases of child abuse, you should….
  - Set up transport from the site using a “chain of custody”. Minimally, a sealed package with courier “sign off” at the site and delivery to the laboratory.
  - Follow STD guidelines for the identification of isolates
  - Store isolates at -70C. Do not allow the organisms to die on the bench!!!! [in PA litigation may proceed for a period of 12 years after their 18th birthday].
  - Use at least two methods for the identification of *N. gonorrhoeae.*

Always be Prepared for Litigation

- “The most common laboratory questions from the defense attorney are related to having to do with a robust chain of custody procedure which includes steps in delivery of samples to the laboratory, testing to minimize co-mingling of samples, reliability of procedures used and quality control including minimizing contamination, confirmation of test results, and storage of these collected samples”

Sautter RL et al Commentary on: Hendrix AD, Conway LK, Baxter MA. Legal outcomes of suspected maltreatment cases evaluated by a child abuse pediatrician as part of a multidisciplinary team investigation. J Forensic Sci. 2020;65(5):1517–23. doi: 10.1111/1556-4029.14463

Conclusions

- Nucleic acid amplification tests provide a sensitive and specific alternative to cultures for diagnosis of STIs in sexual abuse
- Manufacturers need to realize the need for confirmatory testing in these situations as well as in the testing of low risk, low prevalence populations

Conclusions

- The publications sited believe that NAATs are acceptable for use in forensic evaluation of children.
- Positive tests must be confirmed by a second method.