

Point-of-Care Testing

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Disclosures

None

We have received no financial support for any of the information or products mentioned during this presentation. The information is solely based on literature and each business owner's discretion.

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**Objectives
review**

- Define point-of-care testing
- Develop a point-of-care program in your pharmacy
- Identify benefits and drawbacks of testing in your pharmacy
- Identify ways to make a point-of-care program successful

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presentation agenda

Background & Literature Lackie Drug Teasley Drug Q&A

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Point-of-care testing definition

“ Tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories facilities

- Centers for Disease Control

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Point-of-care testing definition

“Point-of-care testing allows patient diagnoses in the physician’s office, an ambulance, the home, the field, or in the hospital. The results of care are timely, and allow rapid treatment to the patient. Empowering clinicians to make decisions at the “point-of-care” has the potential to significantly impact health care delivery and to address the challenges of health disparities.”

- National Institutes of Health

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Point-of-care testing
definition

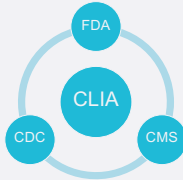
- Is it just a rapid test?
- There are no POC tests, only POC testing
- How the test is deployed or implemented makes it "point-of-care test"
 - Example – could implement a rapid diagnostic test in a reference lab, away from the patient, and that is not POCT

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Regulation
CLIA

- Clinical Laboratory Improvement Amendments of 1988
- Federal regulatory standards
 - All clinical laboratory testing performed on humans in the United States

"...materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease..."



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Regulation
Waived Tests

- Simple tests with a low risk for an incorrect result
 - All devices approved for home use
- Sites performing waived testing must have a CLIA Certificate of Waiver and follow the manufacturer's instructions
 - Other CLIA requirements do not apply to these sites

232 pharmacies have CLIA Waivers in Arkansas

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Analytes
Waived Tests

Select CLIA-waived Tests	
Calcium	Group A Streptococcus
Cholesterol	Thyroid Stimulating Hormone (TSH)
Helicobacter pylori	Opioids
Hepatitis C	Respiratory syncytial virus (RSV)
HIV	Hemoglobin A1C
Influenza	INR
Liver function tests	Serum chemistries
Renal function	B-Type natriuretic peptide

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Literature
Access to Care



Klepser, D. G., et al. (2018). "Utilization of influenza and streptococcal pharyngitis point-of-care testing in the community pharmacy practice setting." Res Social Adm Pharm 14(4): 356-359.

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11-28% Patients screened for influenza test positive

16-25% Patients screened for streptococcus test positive

13 ± 3.0 Minutes of pharmacists' time per encounter for strep screening

Klepser, D. G., et al. (2018). Res Social Adm Pharm 14(4): 356-359.
Klepser, D. G., et al. (2016). J Am Pharm Assoc (2003) 56(3): 323-329. doi:10.1016/j.jampharm.2016.03.001.
Klepser, M. E., et al. (2016). J Am Pharm Assoc (2003) 56(1): 14-21.


Kawachi, A., et al. (2017). J Pharm Health Care Sci 2: 22.
Papadimitrakou, J., et al. (2018). J Am Pharm Assoc (2003).
Corn, C. E., et al. (2017). J Pharm Pract (1531-1937) 897180017710518.

Training
NACDS Pharmacy-Based POCT Certificate

- 20 hours of ACPE continuing education credit
- Influenza, Group A streptococcus, HIV and HCV
- Specimen collection techniques
 - Oral swab, nasal swab, throat swab and finger stick
- Next available training
 - **Insert date**
 - Fayetteville, Arkansas



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Lackie Drug



Brandon Achor
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experience
Lackie Drug

- Getting started and **training** 
- Provider response** 
- Community impact** 
- Self-funded **revenue source** 



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**our patients
testimony**

I can't tell you how much we appreciate you guys doing this. The headache of trying to schedule 4 teenager's appointments and check them out of school and take time off work...this just really saved me and I'm beyond thankful


I'm so glad you can do this, I drove almost 2 hours to get to you because every clinic I called between me and you had a 4 hour wait and I'd rather drive then sit in a waiting room full of sick people

Single mother of 4

Male, late 50's


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Teasley Drug





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Gravette, Arkansas


Program Essentials


equipment


process


evaluation


testing


results/action

creating protocol

Physician Relationship & Buy-In

Requirements

Procedure

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Experiences
Teasley Drug

Program Performance

Physician Reception

Patient Reception

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Audience Response
1

Which organization oversees CLIA applications and issues CLIA certificates?

- a. Center for Medicare and Medicaid Services
- b. Food and Drug Administration
- c. Centers for Disease Control
- d. The Joint Commission

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Audience Response
2

What do you have to do in order to conduct POCT in a pharmacy?

- A. Watch a YouTube video
- B. Ask the Board of Pharmacy for permission
- C. Get a CLIA Certificate of Waiver
- D. Take NACDS Pharmacy-Based POCT Certificate Program

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Audience Response
3

In order to prescribe antibiotics or anti-virals on protocol, what must you do?

- A. Obtain Arkansas Disease State Management Credential
- B. Go to Medical School
- C. Request the State Medical Board
- D. Pharmacists can't prescribe via protocol in Arkansas

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