



—
The *voice* of the
community
pharmacist.

The Point-of-Care Testing Playbook

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Disclosure Statement

Matthew Meyer has a financial interest with Abbott Rapid Diagnostics and the relationship has been mitigated through peer review of this presentation.

There are no relevant financial relationships with ACPE defined commercial interests for anyone else in control of the content of the activity.



Pharmacist and Technician Learning Objectives

1. Describe point-of-care testing value propositions, key partnerships, and reimbursement opportunities.
2. Discuss state variability in scope of practice and requirements for pharmacy team members to perform point-of-care testing services.
3. Differentiate opportunities in point-of-care testing as it pertains to chronic disease management and acute infectious disease management.



What is POCT?

Medical diagnostic/screening testing ***at or near the point of care***, which produce actionable results within minutes

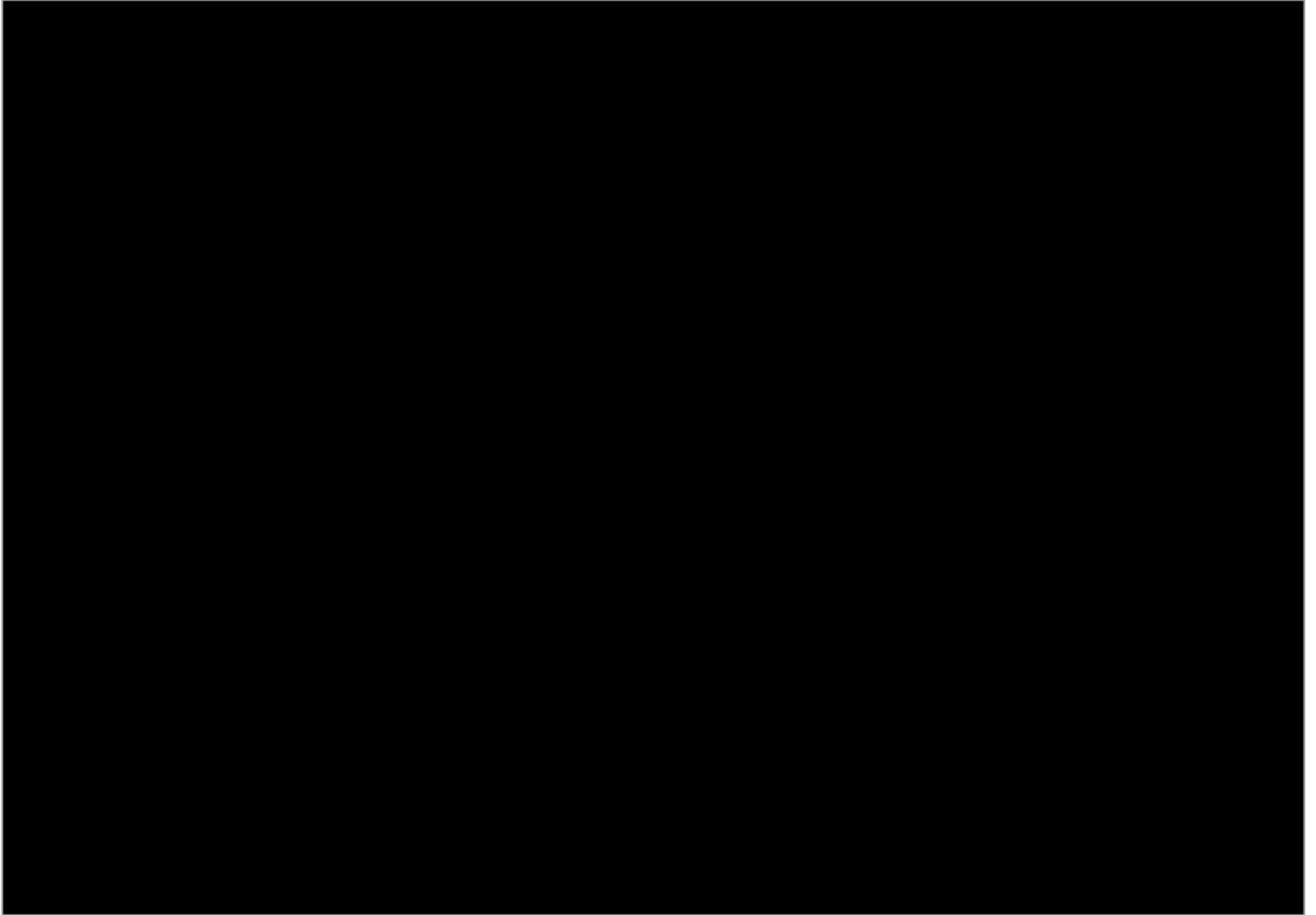
Four primary outcome goals of POCT:

Identify disease

Monitor parameters

Improve access to care

Modify behaviors



IDEAL POCT SITE CHARACTERISTICS

- Accessibility without a scheduled appointment
- Extended hours of availability
- Staff proficient in sample collection, preparation, and operation of analyzers
- Qualified providers to interpret results in context to patient history
- Immediate access to Rx and OTX therapies with authority to dispense medications when needed
- Prompt reporting and follow-up with patients, providers, and other required agencies



Value Proposition

Why Pharmacy?

- Convenient
- Accessible
 - Location proximity
 - Extended hours of operation
- One-stop shop
 - Medications onsite
- Earlier diagnosis
 - Reduced delay between symptom onset and time to being seen
- Physician shortage
- Consumer preferences
- Appropriate antibiotic use
 - Viral pharyngitis vs Strep Throat
- Reduce ED visits
- Cost-saving → Value-based
- Complete medication records



Key Partnerships

- Pharmacy wholesaler
- State pharmacy association
- Physicians
- Health department
- Local businesses
- Local legislators
- Medical Billing
Platforms/companies
- Airlines, schools, etc
- Telehealth services
- LTC/Assisted Living Facility



Key Supply Partnerships

- ***Pharmacy Wholesalers***

- Add-on service which provides turnkey solutions for POCT services in the pharmacy
 - Analyzers, testing supplies, policies and procedures, required documentation, PPE.
 - Access to education and training materials
 - Marketing materials and physician outreach
- Add-on Medical Billing Service

- ***Manufacturer Direct***

- Analyzers, testing kits, P&P, Documentation, Training, etc.

**How do you
successfully
collaborate with
physicians?**



Prescriber Collaboration

- Physician Collaboration is **ESSENTIAL**
- **Pharmacist vs Physician ordered tests** – check with BOP or State Association to clarify who can order
 - Primary wholesaler may have a physician on protocol or may assist in physician outreach
- Test and Treat or **Collaborative Practice Agreement**
 - Different requirements in each state
 - CPA requirements vary by state – check with BOP
- Patient referrals
 - Takes time. Deliver a consistent quality product!



Prescriber Collaboration

- Collaborative Practice Agreements
 - Formal agreement that allows the pharmacist to perform specific patient care functions
 - May cover an individual pharmacist or the entire pharmacy – check with BOP on what is allowed
- Start with a physician you already have a relationship with
- Identify in the agreement:
 - Group of patients you mean to serve
 - Care functions you are authorized to provide
- Have an attorney review the agreement prior to signing



Collaborative Practice Agreements

- A CPA should contain the following information
 - Purpose of the Agreement
 - Parties involved
 - Patient population (demographic group or a specific list of patients)
 - Care functions authorized
 - Pharmacist training and education requirements
 - Liability insurance requirements
 - Patient informed consent
 - Documentation plan
 - Physician - pharmacist communication plan
 - Quality Assurance Plan
 - Length of the Agreement (6 months, 1 year, specific date range)
 - Record Retention Details
 - How the agreement can be rescinded or amended
 - Clinical references
 - Signatures of parties involved
- ***Both Provider and Pharmacist should have legal consult prior to signing***

How do you get reimbursed for POCT?



Revenue Streams

Understand your costs!

Costs vary depending on supplier and type of test

- Flu antigen~ \$15
- Flu NAAT~ \$49
- Strep antigen~ \$4
- Strep NAAT~ \$28
- Covid antigen ~ \$16
- Covid PCR ~ \$60
- Covid NAAT~ \$41
- RSV NAAT~ \$38

Additional Costs

- Testing Supplies and PPE
- Marketing
- Training
- Failure rate
- Quality control



Revenue Streams

How do you plan to seek reimbursement for POCT services?

Cash

- Easiest method
- Market analysis
 - Urgent care
 - Chain pharmacies
 - Independents
- Better margins than prescriptions
- OTC sales for negative tests

Insurance

- Network vs Out-of-network provider
- Superbills for patients
- Medicare independent clinical laboratory – CMS 855B
- COVID test billing
- Research 3rd party billing vendors – **re-credentialing as a medical lab**

How do you get started with POCT?



First, identify CLIA-waived test(s) to offer

The screenshot shows the FDA website's 'CLIA - Clinical Laboratory Improvement Amendments - Currently Waived Analytes' page. The page header includes the FDA logo and navigation links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. A search bar is also present. The main content area features a list of waived analytes, each with a link to its details. The list includes:

| Analyte Name |
|--|
| FERN TEST, SALIVA |
| URINE QUALITATIVE DIPSTICK NITRITE |
| URINE QUALITATIVE DIPSTICK PH |
| HEMOGLOBIN BY COPPER SULFATE, NONAUTOMATED |
| HELICOBACTER PYLORI |
| HIV-1 ANTIBODY |
| ETHANOL (ALCOHOL) |
| LDL CHOLESTEROL |
| OVULATION TEST (LH) BY VISUAL COLOR COMPARISON |
| PROTEIN, TOTAL |
| SPUN MICROHEMATOCRIT |
| HDL CHOLESTEROL |
| ERYTHROCYTE SEDIMENTATION RATE, NONAUTOMATED, WAIVED |
| WHITE BLOOD CELL COUNT (LEUKOCYTE COUNT) (WBC) |

- For simple laboratory examinations and procedures
- Minimal risk of patient harm if performed correctly
- FDA determines which tests are CLIA-waived
- [FDA List of Waived Tests](#)



Second, apply for a CLIA certificate of waiver

- CLIA Certificate of Waiver
 - Allows a “non-clinical” facility to utilize CLIA-waived tests
 - Must apply to CMS
 - \$180 Investment
 - Certificate valid for 2 years
- CLIA Waiver Application
 - [CMS Form 116](#)
 - 5-minute process
 - Written instructions on pages 6&7
 - ***Know which tests you want to offer first!***
 - Must list manufacturer test name for each test offered



What does POCT look like in your state?

Do you have *prescriptive authority* to order a POC Test?

Do you need a *Collaborative Practice Agreement*?

Do you need *testing protocols* developed first?

What are the requirements for *reporting results*?

Reach out to your state authority for answers

- State Association, Board of Pharmacy, Health Department



Recent POCT legislation (2022)

Alaska HB 145: authorizes pharmacists to independently provide patient care services related to a condition that has a CLIA-waived test that is used to guide diagnosis or clinical decision-making, also **ads pharmacists to the list of providers in the insurance statutes**

Kansas SB 200: allows pharmacists to initiate therapy for: influenza, streptococcal pharyngitis, urinary tract infection

New York A 9007: permits pharmacists to direct limited-service labs and **order/administer COVID-19 and influenza tests**



Training

- [NASPA Pharmacy-based Point-of-Care Testing Certificate Program](#)
 - Virtual and in-person trainings
 - For entire pharmacy staff
 - Practical hands-on-training
 - Build confidence in your technique
 - Learn from experienced POCT providers
- CDC Laboratory Training website
 - Ready, Set, Test – introduction to good laboratory
- OSHA Bloodborne Pathogen Training
- Disease specific training (ie. HIV counseling)



Before You Start

1. Review current legislation and scope of practice
 - Complete CPAs as needed – verify CPA meets BOP requirements
2. Determine how much space will be dedicated to POCT
 - Patient exam and sample collection
 - Analyzer footprint
 - Supplies storage, etc.
3. Review community market access, competition, and needs to determine which tests to bring to market
 - Analyzers may be able to perform single or multiplex tests, screening vs diagnostic tests, etc.
4. Establish supply lines, order process, and workflow



Before You Start

5. Education and training – clinical and support staff
6. Re-credential with areas major 3rd party payers
 - Contact provider relations, sign up for access to the medical provider's websites
7. Utilize Medical Billing Platform or Company if billing 3rd parties
 - Complete CMS 855B and CMS 460 if billing Medicare (Covid 19)
8. Appoint Medical Laboratory Director
 - Complete CLIA Waiver Certification Application – CMS-116
9. Reach out to local providers and notify medical offices promoting your new services



Ordering Tests and Supplies

- Have multiple avenues to obtain tests and ancillary supplies
- Primary Pharmacy Wholesaler
 - Analyzers and test kits available for pharmacies enrolled in add-on services – generally limited to contracted device
- Manufacturer Direct
 - Multiple test manufacturers will contract directly with the clinical laboratory for the purchase or lease of equipment and test kits. Does not include ancillary supplies such as PPE, VTM, etc.
- Medical Wholesale Supply Companies
 - Requirements vary depending on the company. May require a contract and minimal purchase requirement. Products generally sold in bulk
- Mass Merchants (online too) with medical and laboratory departments can be utilized for small orders of ancillary products such as nasopharyngeal swabs, viral transport media, etc

**How do you make
POCT workflow more
efficient?**



Screening

- Signs and symptoms
- Medical History
- Do they qualify?
 - Ex. Group A Strep (GAS) scoring requirements.
- Do they need emergency care?
 - Does the patient need an immediate referral for full medical evaluation?
 - Ex. Oxygen Sat of 82%



Testing Workflow – Best Practices

- Scheduling (particularly for monitoring)
- One swab, one patient, one basket, one timer
- Policies & Procedures
- Workflow process for +/- results
- Appointments, payments
- Documentation
- Clinical algorithm



Testing Workflow – Best Practices



COVID Rapid Antigen Testing Sign Up

Appointment *

01/11/2021 Monday, January 11

January 2021

| SUN | MON | TUE | WED | THU | FRI | SAT |
|-----|-----|-----|-----|-----|-----|-----|
| | | | | | | 1 |
| 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| 24 | 25 | 26 | 27 | 28 | 29 | 30 |
| 31 | | | | | | |

2:00 PM 2:10 PM
2:20 PM 2:30 PM
2:40 PM 2:50 PM
3:00 PM 3:10 PM
3:20 PM 3:30 PM
3:40 PM 3:50 PM

America/Chicago (GMT-06:00)

Name *

First Name Last Name

Address *



Testing Workflow

Non-pharmacist staff should be involved!

Pharmacist x POCT

- The Pharmacists' Patient Care Process
- Identify, prevent and manage health conditions
- Test administration and interpretation
- Referral to a higher level of care
- Collaborate with physicians and other providers

Support Staff x POCT

- Patient registration and intake
- Collection of vital signs
- Prescription processing
- Inventory and supplies preparation
- Specimen collection
- Documentation

Strep Workflow

- Identify candidates
- Patient intake
- Insurance?
- Vitals
- Authorization

Pharmacist assessment,
GAS score, does patient
qualify for POCT

If no then OTC treatment or refer
for evaluation.*

Sample collection, preparation,
analyzer processing

Swab tonsil to tonsil.
Target white patches, twist swab.
Do not touch tongue, gums,
cheeks, etc.

Interpret results, patient
education, plan
development

*RADTs negative results require
culture confirmation. (recommended)

**negative – OTC treatment or refer
Positive – ABX, consult MD, refer.**

Notify Pt Primary/ CPA provider
Document encounter and results
Bill Claim

Work surfaces/equipment
cleaning

Patient follow up

Abx – 24 hrs, OTC – 72 hrs

**Patient instructed to follow
up with pharmacy and PCP if
condition changes after test**

Influenza/COVID-19/ RSV

- Identify candidates
- Patient intake
- Insurance?
- Vitals
- Authorization

Pharmacist assessment, meets testing criteria, vitals stable for POCT without a referral

* Temp > 103 F, HR > 100 bpm, RR > 20 bpm, O2 sat < 87%, BP < 90/60 or > 180/120, altered mental status requires referral!*

Sample collection, preparation, processing through the analyzer

Follow analyzer's collection method indicted in package inset either direct nasal or nasopharyngeal.

Results interpretation, patient discussions, and plan development

*RADTs negative – viral culture or molecular test confirmation recommended

*Positive test within 48 hrs symptom onset – antiviral treatments

- Notify Pt Primary/ CPA provider
- Document encounter and results
- Submit DOH communicable disease reporting form
- Work surfaces/analyzer cleaning
- Bill claim to 3rd party

Patient follow up

Workflow for Chronic Illness Monitoring/Screening

15 minutes prior to the appointment remove test reagents from the refrigerator.

Pull and basket patient chart, testing supplies, and test reagents needed for appointment

- Upon patient arrival, complete new authorization
- Verify insurance coverage
- Record vital signs
- Update medications, allergies, problems, and provider lists.

- Pharmacist reviews previous encounters and results, and the visits vitals/updates.
- Pharmacist verifies the correct test reagents pulled and tests are appropriate for related medical conditions

- Sample site is cleaned and prepped, and then sample is collected.
- Sample is immediately processed as instructed according to the test's package insert

- Pharmacist reviews results and documents in patient chart.
- Pharmacist reviews results with the patient
- Plan development and patient rescheduled at the recommended interval

- Patient's PCP is notified of the encounter, test results, and any plan recommendations.
- Equipment and work surfaces cleaned.
- Additional follow-up with patient as needed based on primary's assessment of test results

Quality Control and Documentation

Equipment and Work Area Cleaning

1. Start off each day – clean all work surfaces and analyzers – document monthly log
2. After each use –document in the testing log
3. Immediately following any possible spill or surface contamination

Positive and Negative Quality Control Checks

1. A (+) and (-) QC must be run prior to offering any new test on an analyzer – Document
2. Each Lab Tech must complete a successful QC prior to testing any patients and should be repeated at regular intervals and for PRN refreshers - Document
3. Follow the Manufacturer's recommendations – each open box, each received order - Document

Other required documentation

1. Lab/Storage area's temp range and humidity – daily
2. Employee education, training, and competencies – annual
3. Testing logs – date, test, lot, exp, who ran, patient ID, expect result, act result, cleaning
4. Any device or test failure/invalid and possible explanations
5. Any maintenance, software upgrades or device repairs/replacement



Physician Notification

- Template fax forms
- Standard notice
- Therapy initiation
- Therapy modification



Education, Monitoring, Follow-Up

- Proper self-care
- OTC Products
- Follow-Up
- Insurance forms

Helpful Resources

- FDA listing of CLIA Waived Tests
 - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>
- NASPA Pharmacy Based POC Test and Treat Certificate Program
 - <https://naspa.us/pharmacy-based-point-of-care-testing-certificate-program>
 - /
- CDC publication on Collaborative Practice Agreements
 - <https://www.cdc.gov/dhds/pubs/docs/CPA-Team-Based-Care.pdf>

Helpful Resources

[Sample Collaborative Drug Therapy Management Agreement](#)

[HIV POCT Study Protocol](#)

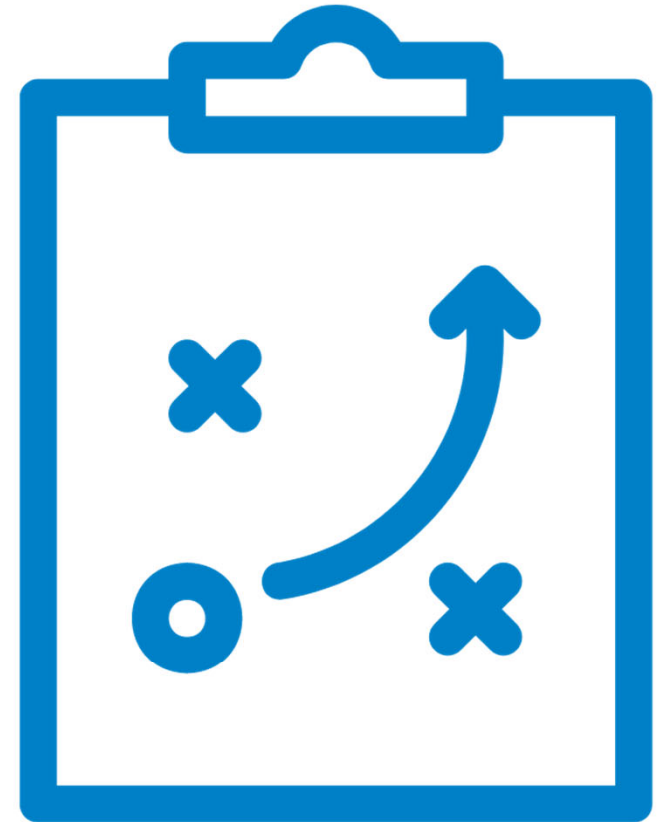
[POCT Self-Assessment Checklist](#)

5 Steps to Success

Understand that your pharmacy is an ideal location for POCT with growth potential

Review state statutes and BOP scope of practice to be compliant

Follow testing procedures outlined in package insert to the letter!!



Questions?





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