AMPLIFY

Overcoming Challenges of Molecular POC Testing in Non-Acute Care Settings

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There is a persistent, wide-spread need for rapid, accurate diagnosis of infectious diseases in the urgent care setting.

30-50%

Percent of annual urgent care visits that are due to respiratory illness[1,2]

30%

Percent growth in prevalence of chlamydia, gonorrhea, and syphilis from 2012-2022

20 min

Sample to results turn-around time for some CLIA-waived molecular POC solutions

1. Urgent Care Association (UCA) 2022 Benchmarking Report
2. Health Care Cost Institute. Respiratory-Related Illness is the Top Reason People Use Urgent Care
3. CDC. Sexually Transmitted Disease Surveillance 2022: National Overview

Multiple mPOCT solutions exist for diagnosis of infectious diseases

	Roche cobas® liat	Cepheid GeneXpert® Xpress	BIOFIRE® SPOTFIRE®	Abbott ID Now™	Binx io®
Technology	Real-time PCR	Real-time PCR	Real-time PCR	Isothermal Amplification	Real-time PCR
Assay run-time	15-20 minutes	18-45 minutes	15 minutes	2-13 minutes	30 minutes
Size (H x W x L) Weight	7.5" x 4.5" x 9.5" 8.3 lbs	18" x 11.5" x 16" 15 lbs	9.7" x 8.5" x 12.8 " 18 lbs	5.7" x 8.2" x 7.6" 6.6 lbs	10.9" x 10.8" x 15.1" 22.5 lbs
POC data manager enabled	Yes	Yes	Yes	Yes	Yes
Reagent storage	Refrigerated	Room Temperature	Room Temperature	Room Temperature	Refrigerated
CLIA-Waived	Yes	Yes	Yes	Yes	Yes
Respiratory Pathogens Targeted	•SARS-CoV-2 •SARS-CoV-2 & Influenza A/B •Influenza A/B & RSV •SARS-CoV-2, Influenza A/B & RSV •Strep A	•SARS-CoV-2 •Influenza •SARS-CoV-2 & RSV •SARS-CoV-2, Influenza & RSV •Strep A	•**R/ST mini:** SARS-CoV-2, Influenza, Rhinovirus, RSV, and S. pyogenes •**R/ST:** 15 of the most common viral and bacterial respiratory pathogens	•SARS-CoV-2 •RSV •Influenza A/B •Strep A	
Non-respiratory Pathogens Targeted	•*C. trachomatis* & *N. gonorrhoeae* •*C. trachomatis*, *N. gonorrhoeae*, & *M. genitalium*	•Mpox •HCV •Bacterial vaginosis, *Candida ssp*, and *T. vaginalis*			•*C. trachomatis* & *N. gonorrhoeae*

Considerations for implementation of mPOCT

Operational

- Supply chain
- Instrument placement
- Reagent storage
- Verification and quality control
- Staff training and competency
- Clinical workflow integration
- Resource allocation
- Data integration

Financial

- Capital investment
- Cost constraints
- Vendor agreements
- Seasonality
- Reimbursement

Today’s panelists

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Hobart William Smith College, Keuka College
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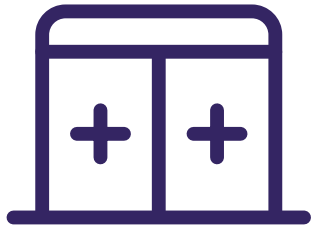
Which **metrics** convinced your leadership to invest in **mPOCT**?

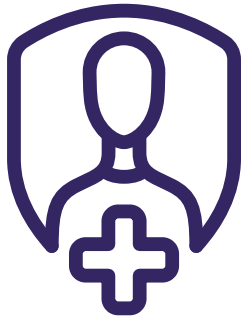
MGB's story

Urgent Care

Understanding Our Commitment

- **Access to care**
- **Timely and cost-effective diagnosis and treatment**
- **Positive contribution to overall Public Health**





Why my organization and I were convinced to invest in mPOCT:

- Multiple options beyond capital outlay to secure equipment
- Projected revenue was greater than projected expense
- Ability pilot prior implementation
- The availability of low risk, high reward products
- Multiple vendors to select from with a demonstrated commitment to excellence and customer service

Summit's story

ROI Metrics

Send-out cost reduction
- Reimbursement/test
- Cost/test
- Margin/test
- Gross testing revenue potential
- Send-out lab cost savings

LOS reduction
- Increased patient throughput
- Patient satisfaction

Assay Performance

Benefits of molecular vs antigen testing
- Sensitivity
- Specificity

Validation approach
- PCR comparison
- Method concordance

What haven't I thought of?

Product Validation Testing

- Ensures both the patients and the providers have faith in the results
- How is my testing program governed and what are the requirements for validation?

Staff Training & Education

- Beyond startup, determine what a sustainable training ecosystem looks like
- How can the vendor support implementation?

Supply Chain

- What are the space requirements for testing equipment?
- What are the necessary testing supplies and, what storage is required?
- Is the product readily available in periods of high-demand?
- How do I determine par levels with fluctuating demand?

Other Considerations

- Patient turnaround time
- Electronic medical record-keeping integration
- Technology requirements
- Development of standard operating procedures for testing
- Periodic equipment maintenance
- Applicable CPT Codes

Consider your off ramps

Avoid the crash if things do not go as planned!

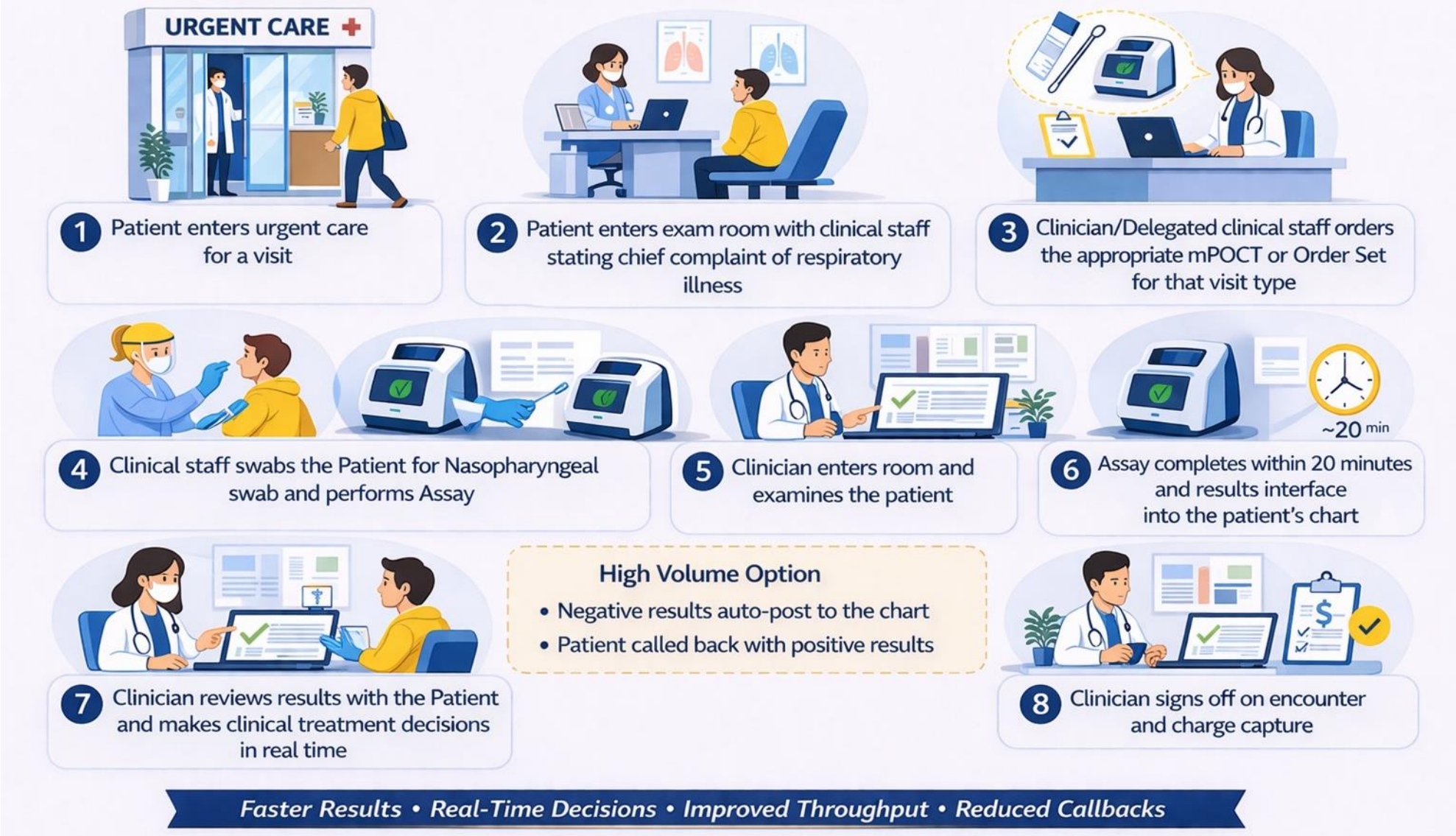
- Healthcare changes quickly
- Financial risk is high
- Design an off-ramp that will ensure your business' success

Key elements to consider in an agreement

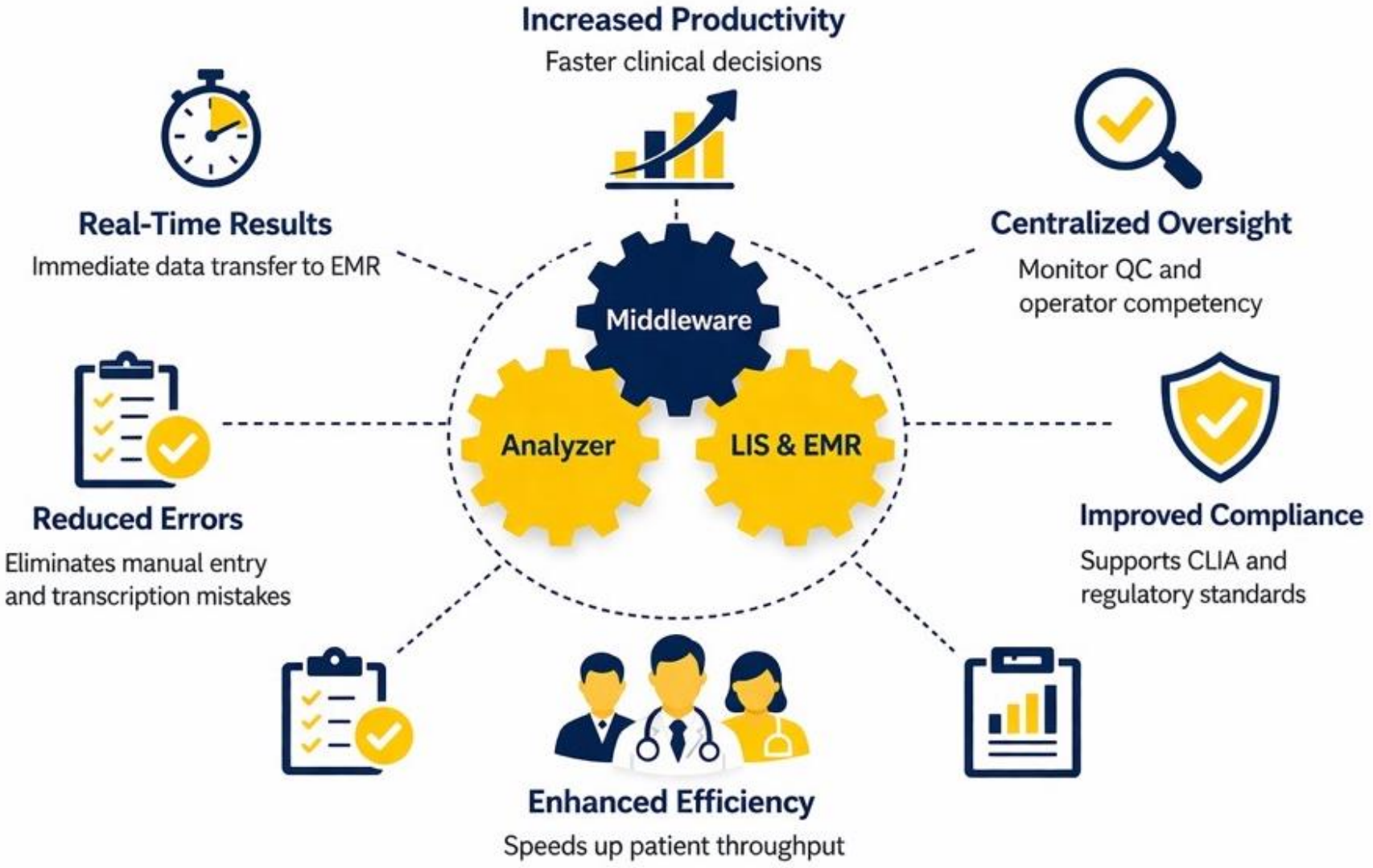
- Term length
- Minimum purchase requirements
- Force Majeure clause
- Penalty/early termination fees
- Supply chain expectations
- Equipment warranty

How did you **integrate** mPOCT into your **patient workflow**?

The patient journey with mPOCT



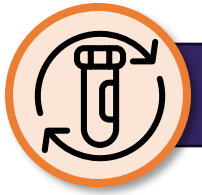
Benefits of workflow integration with middleware, LIS & EMR



What **clinical impacts** have you observed with mPOCT?

Clinical impacts of mPOCT

Has superior sensitivity and accuracy relative to antigen[1,2]



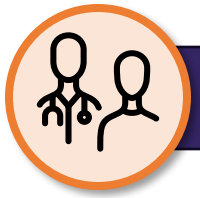
Reduces need for reflex testing[2,3]

Facilitates faster treatment initiation[3]

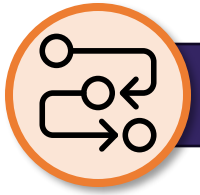
Contributes to antibiotic stewardship initiatives[2,4]

1. Miller, JM et al. 2024. Guide to utilization of microbiology laboratory for diagnosis of infectious diseases. Clin Infect Dis . PMID: 38442248
2. Rao, A et al. 2019. Diagnosis and antibiotic treatment of group a streptococcal pharyngitis in children in a primary care setting: impact of point-of-care polymerase chain reaction. BMC Pediatr. PMID: 3065115
3. Benirschke, RC et al. 2019. Clinical Impact of Rapid Point-of-Care PCR Influenza Testing in an Urgent Care Setting: a Single-Center Study. J Clin Microbiol. PMID: 30602445
4. Arnold, CG et al 2026. Combining an antibiotic stewardship program with a 15-pathogen viral panel to reduce inappropriate antibiotic prescribing. Microbiol Spetr. PMID: 41313024

Clinical impacts of mPOCT



Reduces repeat patient visits for the same complaint



Optimizes patient flow[1,3]

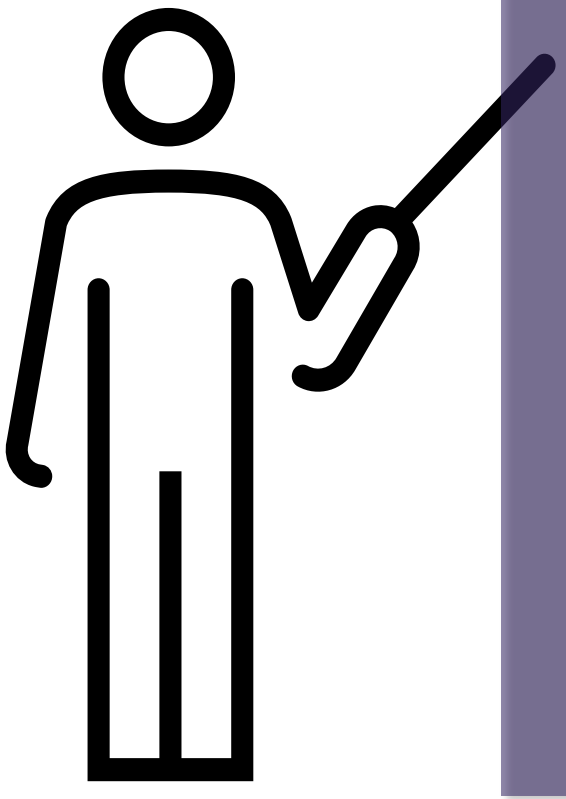
Improves resource allocation[1,2,4]

Supports patient satisfaction

1. Alexander, BD et al. 2025. Rapid Molecular Diagnostics for Lower Respiratory Tract Infections in Urgent Care: Filling a Selective Gap. J Urgent Care Med
2. Allen, AJ et al. 2020. Diagnostic and economic evaluation of a point-of-care test for respiratory syncytial virus. ERJ Open Res. PMID: 32832529
3. Evans A, et al. 2024. Molecular Testing for Respiratory Tract Infections May Have Favorable Impact on Real-world Healthcare Costs. Amer J Infect Dis.
4. Hansen GT, et al 2018. Clinical decision making in the emergency department setting using rapid PCR: Results of the CLADE stu dy group. J Clin Virol. PMID: 29494950

How have you built a **sustainable training ecosystem**?

Best practices to maintain staff competency



- [x] Invest in training
- [x] Transition from “on the fly” to “structured” training
- [x] Implement continuous, “bite-sized” learning
- [x] Build a robust onboarding system
- [x] Pair new hires with experienced champions
- [x] Don’t rely on “shadowing”
- [x] Invest in cross-training
- [x] Conduct regular competency audits

*Having a **well-trained staff** correlates with **higher employee satisfaction**.*

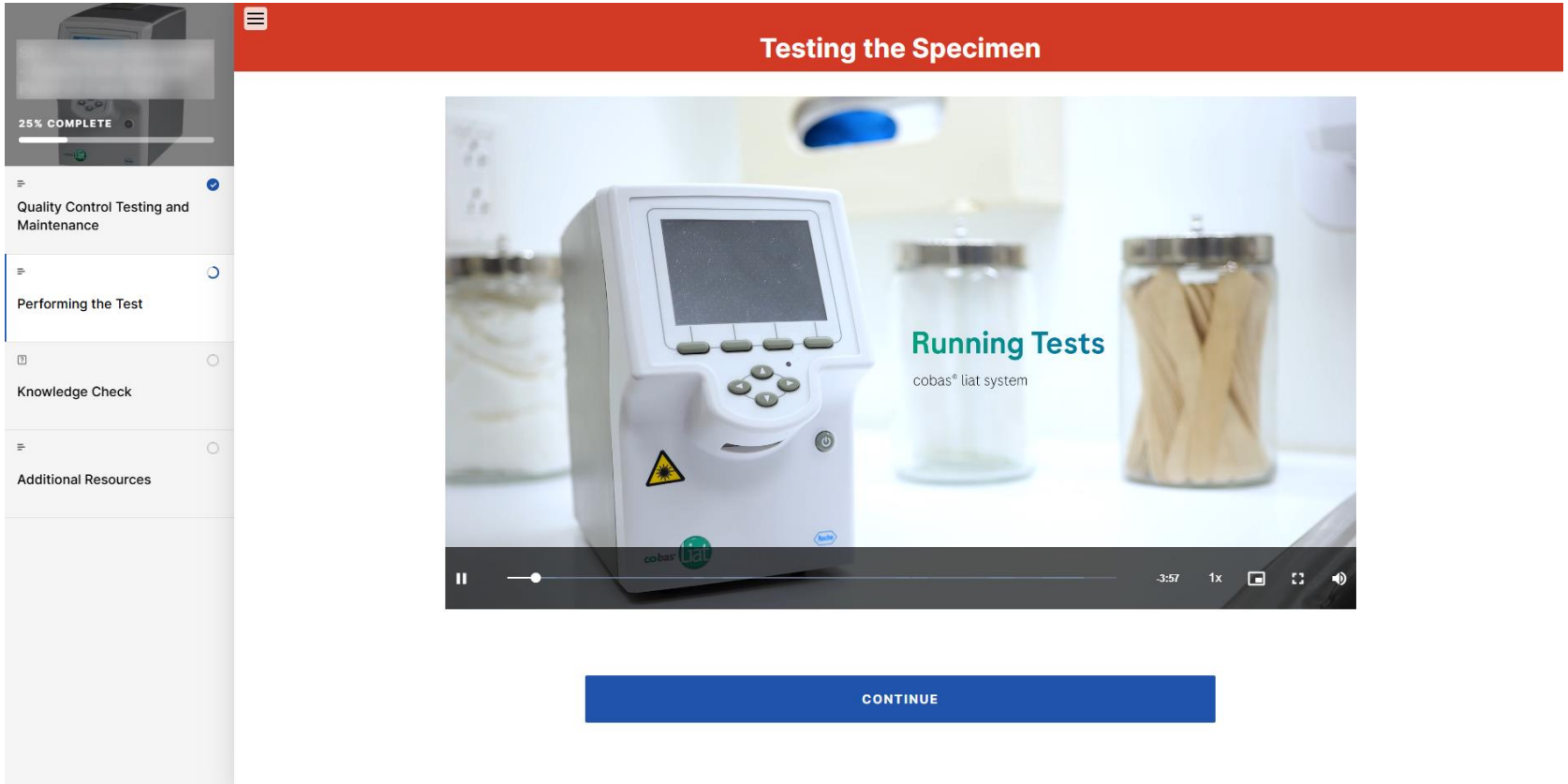
Summit’s system for sustaining competency

Standardized onboarding
On-demand digital training

Super-user model

Competency checklists
Annual reassessment

Standardized onboarding & On-demand digital training



Cobas LIAT Operator Competency Assessment

EMPLOYEE: _____ DATE: _____
DEPARTMENT: _____ LOCATION: _____

The Testing Personnel is responsible for understanding, demonstrating and complying with the following testing criteria. If the Testing Personnel feels that they need more training, it is their responsibility to notify the trainer. Write N/A where applicable if a task is outside the operator's scope of service.

Cobas LIAT System Basics

Met	Not Met	
o	o	Knows system parts and where they are located
o	o	Understands basic system methodology
o	o	Understands intended use
o	o	Understands the principle of Internal Process Controls (IPC)
o	o	Understands the policy and frequency of external QC testing
o	o	Understands system limitations
o	o	Reviews testing procedure
o	o	Follows all safety and infection control policies correctly

Cobas LIAT Pre-Analytical

Met	Not Met	
o	o	Properly handles and stores patient samples
o	o	Properly handles/stores LIAT assay tubes
o	o	Make sure patient blows nose prior to sample collection for Influenza/RSV testing

Cobas LIAT Strep A Patient Testing

Performing Strep A Test

Met	Not Met	
o	o	Understands proper throat specimen collection & handling
o	o	Gathers all needed materials
o	o	Properly scans tube barcode
o	o	Properly enters patient sample ID (MRN) by scanning the Athena barcode label
o	o	Adds patient sample to Cobas Liat Strep A tube properly

- Avoid mucus
- Avoid bubbles
- Avoid puncturing seal of LIAT assay tube
- Avoid contamination / use new pipettes each time

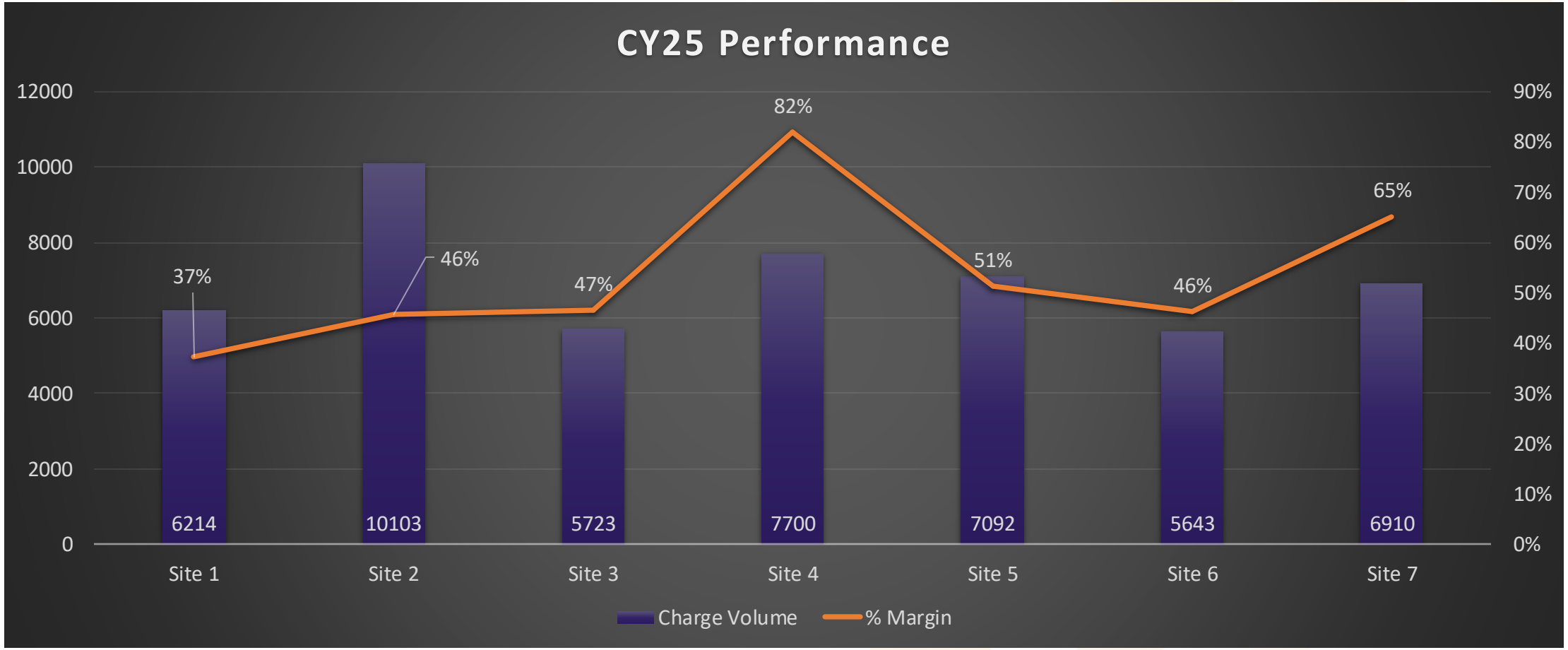
o	o	Completes testing processes properly (ex. Insert/remove Liat tube)
o	o	Interprets results properly (ex. Detected, Not Detected, INVALID, INDETERMINATE, aborted)

Which metrics do you track to ensure mPOCT is **delivering value**?

KPIs to consider for mPOCT

- Financial performance
- Product usage rate and seasonality impacts
- Staff satisfaction
- Patient satisfaction
- Antibiotic stewardship

Real world data: tracking financial performance



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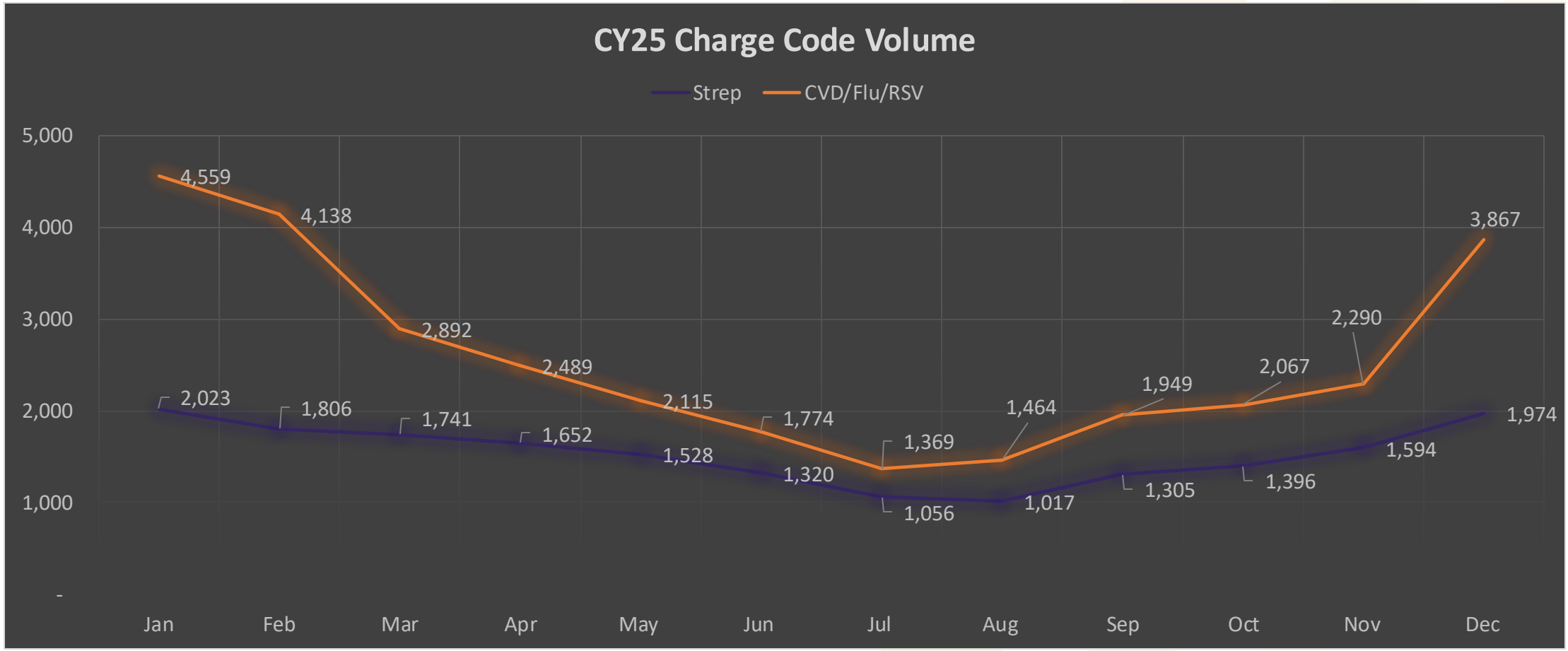
Real world data: plan for seasonality



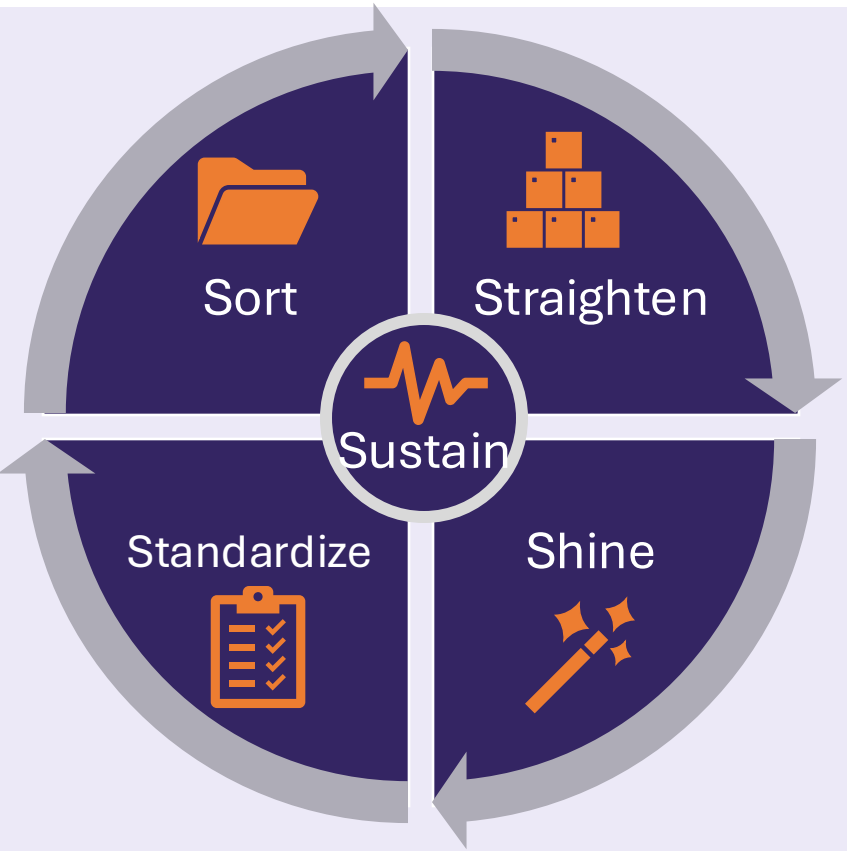
Data on file at institution; not publicly available

Summit’s metrics

- Utilization rates
- Turnaround time
- Cost per test
- Patient throughput
- QC and error monitoring

Alignment and improvement

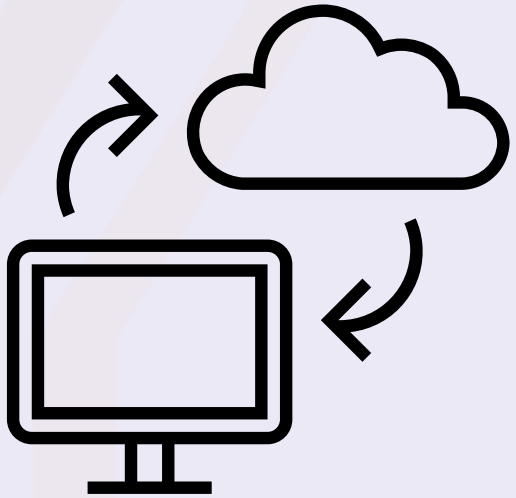
Apply lean, 5S methodology



Conduct a SWOT analysis

	helpful	harmful
internal	S *strengths*	W *weaknesses*
external	O *opportunities*	T *threats*

Integrate with EMR



Key takeaways - tips on how to get started with mPOCT

Choose the right solution for your network and your patients.

Consider assay performance and intended use, especially in relation to current standard of care.

Negotiate a vendor agreement that supports a successful partnership.

Integrate test result reporting into your EMR.

Partner early with your IT team for successful integration.

Leverage real-time reporting to improve efficiency, minimize errors, maintain compliance, and track clinical metrics.

Build a resilient and sustainable training model.

Leverage digital training to meet the learner where they are and track competency.

Empower super-users to own on-site training and troubleshooting.

Monitor your progress and make improvements when necessary.

Track KPIs from day one – consider how mPOCT impacts your patients, staff, and workflow.

Carefully evaluate your long-range revenue versus expense.

We need your feedback

Prefer paper?

On the form in front of you, please score me and the content I shared with you today.

Thank you for your attention!

Panelists will be available after the session for additional questions.