Best Practices in Managing Point-of-Care Testing

Achieving a Single IT Infrastructure to Manage Point-of-Care Testing Results in Inpatient and Ambulatory Settings

Prepared by: Jeanne Mumford, MLS(ASCP)
Manager, Point-of-Care Testing
Johns Hopkins Medicine, Baltimore, MD

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Speaker Disclosures

Jeanne Mumford

- Financial - Honorarium, Expenses: bioMerieux, Cepheid Speaker Bureau, ADLM

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Johns Hopkins Medicine

JOHNS HOPKINS MEDICINE, HEADQUARTERED IN BALTIMORE, Maryland, is a $10 billion integrated global health enterprise and one of the leading health care systems in the United States.

Johns Hopkins University School of Medicine

- 3,200+ full-time faculty members
- 1,780+ part-time faculty members
- 1,380+ medical and doctoral students

The Johns Hopkins Hospital

- 1,146 patient beds including
  - 204 pediatric beds at Johns Hopkins Children's Center
- 2,500+ full-time attending physicians

https://www.hopkinsmedicine.org/-/media/jhm/documents/entity-fact-sheets/jhm-fast-facts.pdf

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What We Do

- 95,500+ inpatient admissions annually
- Magnet designations: The Johns Hopkins Hospital (5th time in 2024), Suburban Hospital, Johns Hopkins All Children's Hospital
- 337,100+ emergency visits
- 931,200+ annual patient visits at JHCP
- 164,427+ adults and children treated by Home Care Group

https://www.hopkinsmedicine.org/-/media/jhm/documents/entity-fact-sheets/jhm-fast-facts.pdf

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Who We Are

- JHH: 1146 beds; 204 pediatric beds; 2,500+ full time attending physicians
- JHBMC: 468 beds; 1,640 attending physicians
- HCGH: 244 beds; 410+ active medical staff
- SMH: 288 beds; 1,000+ active medical staff
- SH: 226 beds; 300 active medical staff
- JHACH: 259 beds; 369 active medical staff
- JHCP: 535 active medical staff

https://www.hopkinsmedicine.org/-/media/jhm/documents/entity-fact-sheets/jhm-fast-facts.pdf

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Mission

The mission of Johns Hopkins Medicine is to improve the health of the community and the world by setting the standard of excellence in medical education, research and clinical care.

Diverse and inclusive, Johns Hopkins Medicine educates medical students, scientists, health care professionals and the public; conducts biomedical research; and provides patient-centered medicine to prevent, diagnose and treat human illness.

Vision

Johns Hopkins Medicine pushes the boundaries of discovery, transforms health care, advances medical education and creates hope for humanity.

Together, we will deliver the promise of medicine.

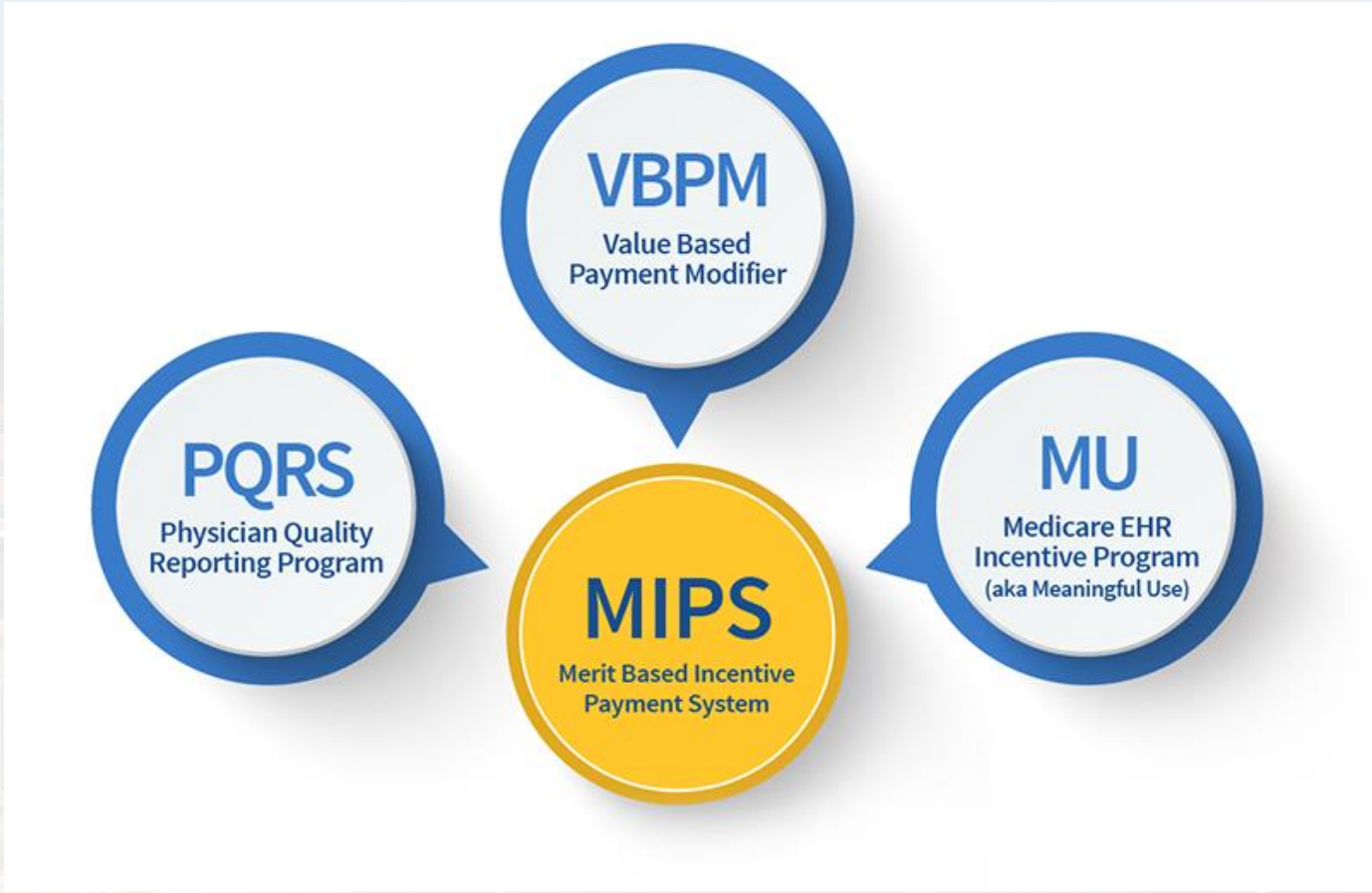
Core Values

Excellence & Discovery
Leadership & Integrity
Diversity & Inclusion
Respect & Collegiality

How We Help Our Patient Population

Meaningful Use → MIPS

- 4 purposes:
  - Improve quality
  - Improve safety
  - Improve efficiency
  - Reduce health disparities



https://www.healthit.gov/topic/meaningful-use-and-macra/meaningful-use

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What is Meaningful Use of Testing?

- Meaningful use of testing can be thought of as implementation of testing services/devices to realize these desired outcomes
  - Quality
  - Safety
  - Efficiency
  - Reduction of health disparities
- Important to have a quality structure and metrics to assess success relative to the desired outcomes
- Focus for us today is on the 4th goal in underserved populations

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Who We Serve

- Underserved populations demonstrate one or more of these characteristics:
  - Receive fewer healthcare services
  - Challenges in accessing primary healthcare services
  - Lack familiarity with or understanding of the healthcare system
  - Encounter shortages of providers in their area
- Underserved is often used interchangeably with vulnerable; the differences are subtle, and these populations overlap
  - Broadly – underserved is about limited access, vulnerable is about barriers to care

Underserved in Baltimore – a snapshot

- >30% of Baltimore households earn <$25K per year; 1 in 3 Baltimore children are in households below the federal poverty line
- 35% of Baltimore HS students are obese or overweight
- 11.5% of babies born in the city are low birthweight
- Challenges with homicide and substance use disorders are well-chronicled
- Despite high-level hospital care in the City, in many areas access to primary care is limited
  - Both due to availability and institutional distrust

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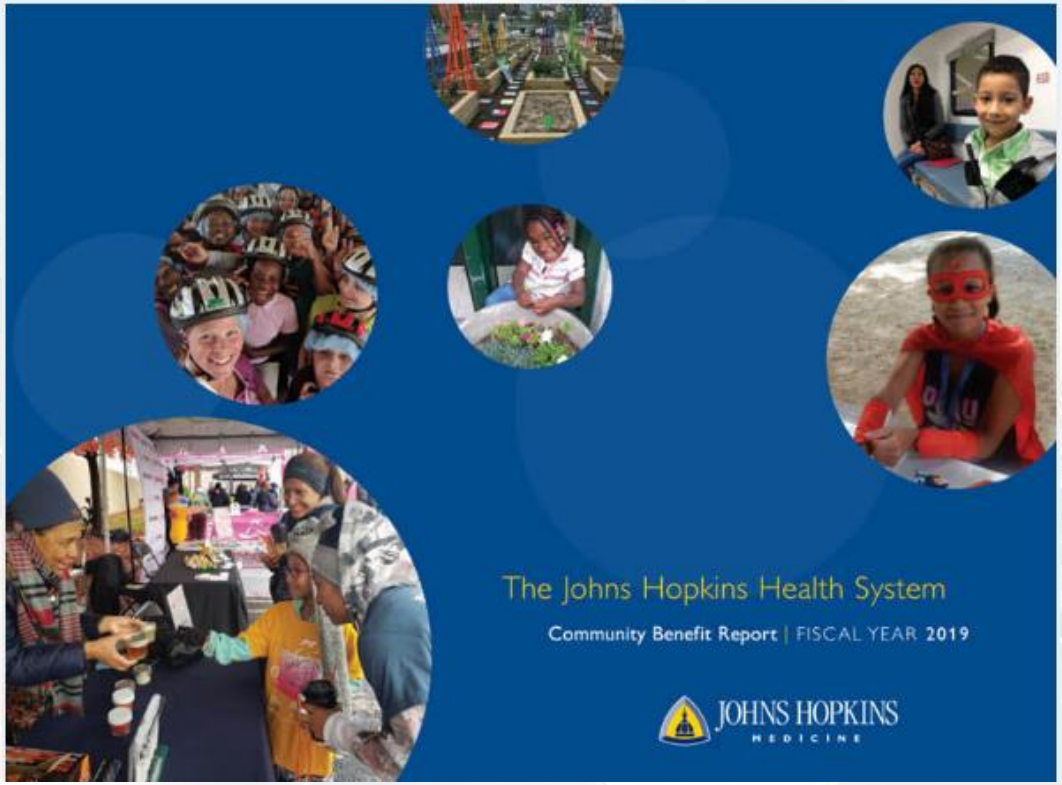
Social Determinants of Health

- Contribute to health disparities and inequities.
- Contribute to wide health disparities and inequities.
- Have a major impact on people's health, well-being, and quality of life.
- Examples of SDOH include:
  - Housing, transportation, and neighborhoods
  - Racism, discrimination, and violence
  - Education, job opportunities, and income
  - Access to nutritious foods and physical activity opportunities
  - Air and water quality
  - Language and literacy skills

https://www.hopkinsmedicine.org/-/media/about/documents/community-health/health-needs-assessment/bayview-jhh-chna-2021.pdf

Community Benefit Initiative

- Community Health Services
- Health Professional Education
- Mission Driven Health Services
- Research
- Financial Contributions
- Community Building Activities
- Charity Care



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Esperanza Center

- Nonprofit run by Catholic Charities
- Provides essential services immigrant community
- Serving 11,500 immigrants in Baltimore in each year

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Research and Testing Initiatives

- Sexually transmitted disease in the ED
  - HIV, HCV
  - GC/CT, and Trich
- Bartlett Clinic

Bartlett Clinic at Johns Hopkins

- Clinic established to provide clinical infectious disease care for all (underserved focus)
- Onsite pharmacy, phlebotomy, HCV and HIV counseling, as well as social services and case management
- Also offers subspecialty care and substance use treatment
- 23 exam rooms and ~70 providers

- COVID
- HbA1C
- hCG
- Glucose
- INR
- HIV/HCV
- Fecal Occult Blood

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Patient Safety and Quality Improvement

- Patient Experience
- Infection Prevention
- Delivery and Newborn Care
- Surgical Volumes
- Quality of Care Ratings
- Pediatrics
- Hospital Readmissions

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Standardizing Pathology Quality

Oversight of Quality	• For all Johns Hopkins Hospital labs
CQI Department	• Enterprise-wide
Performance Improvement	• Enhance initiatives across Enterprise

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Continuous Quality in Pathology

Quality Indicators

Request quality indicators

Build Report Card and Dashboard

CURRENT

Facilitate Development of QI

Aggregate Reports

FUTURE

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JHCP Hagerstown
JHCP Westminster
Johns Hopkins White Marsh
JHCP Water's Edge
JHCP Green Spring Station
Johns Hopkins Green Spring Station
JHCP White Marsh
JHCP Frederick
The Johns Hopkins Hospital
JHCP Wyman Park
East Baltimore Medical Center
JHCP Canton Crossing
Baltimore
JHCP Greater Dundalk
JHCP Bayview Internal Medicine
Johns Hopkins Bayview Medical Center
Howard County General Hospital
JHCP Germantown
JHCP Howard County
JHCP Fulton
JHCP Glen Burnie
JHCP Montgomery
Suburban Hospital
JHCP Odenton
JHCP North Bethesda
JHCP Laurel
Johns Hopkins Odenton
JHCP Rockledge
Sibley Memorial Hospital
JHCP Bowie
Johns Hopkins Bethesda
Washington D.C.
JHCP Annapolis
JHCP I Street
JHCP Downtown Bethesda
JHCP Sibley Memorial Hospital
JHCP Ballston
Not shown on map
All Children's Hospital St. Petersburg, Florida
JHCP Charles County
Hospitals
Health Care & Surgery Centers
Johns Hopkins Community Physicians

POCT Timeline

4

- Before 2000
- GLU, INR, ACT and Gases (small volumes, few units)
- Manual urine hCG, urinalysis, pH, PPM

12

- 2010
- Interface for GLU and CREAT; upload ACT and INR manually
- Manual urine hCG, urinalysis, pH, PPM

32

- 2024
- Single Middleware for all instruments. SARS-CoV-2 assays, automated UA and hCG
- Manual urine hCG, urinalysis, pH, PPM – ambulatory sites across state (higher sample volumes)

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Current JHM POCT

Interfaced Devices:

- ✓ ACT-LR, ACT Plus
- ✓ ACT, Heparin
- ✓ Creatinine
- ✓ INR
- ✓ Hgb
- ✓ Urinalysis
- ✓ HBA1c
- ✓ Urine HCG
- ✓ Glucose, whole blood
- ✓ O2 Saturation
- ✓ Blood Gases, electrolytes
- ✓ SARS-CoV-2 Only and 4PLEX Molecular
- ✓ SARS-CoV-2 AG

Non-Interfaced Tests/Devices:

- ✓pH (gastric, Hydrion, Nitrazine)
- ✓Strep A
- ✓Rapid HIV 1/2 Antibody
- ✓Rapid HCV
- ✓Urine Drug Screen
- ✓PPM (multiple)
- ✓Tear Osmolality
- ✓Fecal Occult Blood
- ✓Specific Gravity
- ✓Urine HCG
- ✓SARS-CoV-2 AG

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Point-of-Care Testing Breakdown

Hospital	Beds	Glucose Operators	POCT TYPES	# of POCC's
Johns Hopkins Hospital	1,146	8,000	32	5
Bayview Medical Center	468	1,300	20	1.5
All Children's	259	900	12	3
Howard County General Hospital	244	1,466	3	1
Sibley Hospital	288	800	9	1
Suburban Hospital	226	1,343	9	1
JHCP Sites	50+ Sites	1,600	15	3

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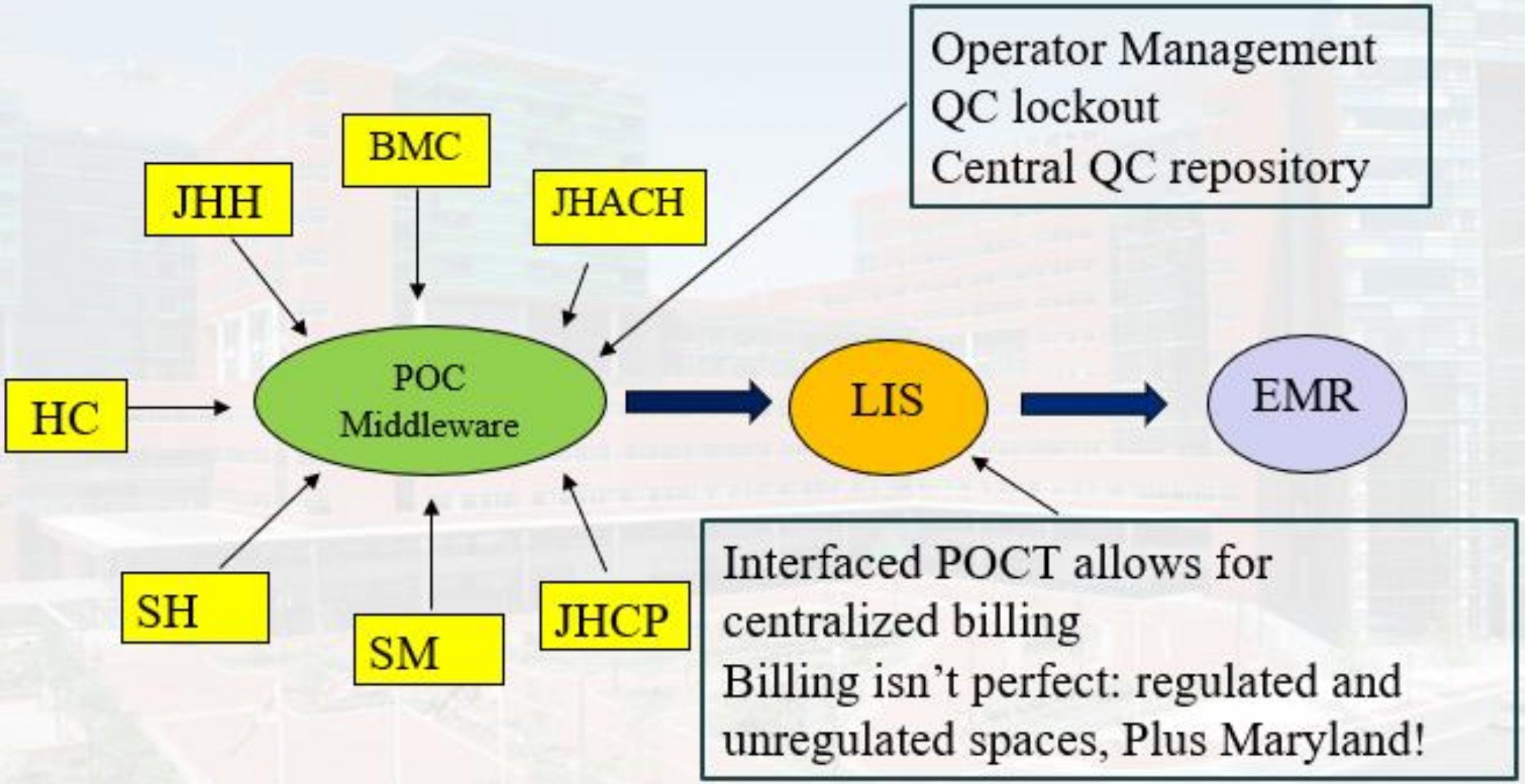
Single IT Interface



Slide credit: Leandra Soto, CLS(ASCP)

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Adding New POCT

- Decision is based off of information provided on the new test request form, as well as central laboratory reports, if needed.
- The POC Committee may want to meet with the requestor to go over this information and determine the best course of action.

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Point-of-Care Testing
New Test Request Form
(One test request per form)

Date: _____ Department/Unit Requesting Test: _____

Requester's Name: _____ Title: _____

Telephone number / e-mail address: _____

TEST PROCEDURE: _____

Instrument/Kit Name: _____ Manufacturer: _____

A. Test site address/location: _____

☐ Inpatients only ☐ Outpatients only ☐ Inpatients and Outpatients

B. Days/Hours of operation: _____ Frequency of test performance: _____

C. CLIA Test Complexity: ☐ Waived ☐ Moderately Complex ☐ Highly Complex ☐ Provider Performed Microscopy

D. Are there current CLIA/State licenses for testing for this site? Yes ☐ No ☐

IF YES	IF NO
Current CLIA #	Name of facility to be listed on the License:
Maryland State License #	Email for facility contact:
Date changes are to occur:	Fed Tax ID Number:
Current test menu:	Type of facility: a. Ambulatory Surgery ☐ d. Mobile Lab ☐ b. Health Fair ☐ e. Independent ☐ c. Physician office ☐
	Type of ownership a. Private Nonprofit ☐ c. Proprietary ☐ b. Other Nonprofit ☐
	Does the director serve as director to other laboratories Yes ☐ No ☐ If YES, list CLIA #'s:
	Director Must submit the following with application: a. For MD - Medical Diploma, Board Certification and Medical License b. For PhD – Diploma, Board Certification and CV

E. Is this service currently available through the central laboratory? ☐ Yes ☐ No

F. What is the desired turnaround time for this test if performed in the central laboratory? _____

G. Briefly explain why the current central laboratory services do not fulfill your needs?

_____

_____

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Point-of-Care Testing
New Test Request Form
(One test request per form)

H. If this test were made available at the point-of-care, how soon would the results be utilized for clinical decision making?

_____

I. Would patient treatment/management decisions be based solely on the point-of-care test results? ☐ Yes ☐ No
Explain: _____

_____

J. Estimate the number of point-of-care tests to be performed: ____/day ____/week ____/month

K. What level(s) of staff would be performing this test and how many would need to be trained?

_____

L. Briefly describe what the patient care benefits/outcomes and potential cost savings would be with implementing this point-of-care test. (Please provide evidence, preferably peer-reviewed, of the test's clinical utility)

_____

_____

_____

M. Are funds approved to support the costs associated with this new test request? ☐ Yes ☐ No

Costs associated with POCT, in addition to the cost of a tests device or kit, may include annual fees for connectivity, quality control, reagents, test validation, training/competency assessment, proficiency testing, oversight, etc.

Description of Charge for Each Test System	Total Cost	Frequency
Laboratory Proficiency Testing		
Depending on amount of tests performed and level of complexity. Total cost to be determined once New Test Request is completed. Proficiency Test Kits	$250 - $450	Annual
Instrument, Reagent, Control Costs		
Instruments, reagents and controls costs will be itemized upon request	$50 - $10,000	Varied
Quality Oversight Fees		
Depending on amount of tests performed and level of complexity. Total cost to be determined once New Test Request is completed.	$200 -$750	Annual
Connectivity Fees		
Instrumentation that requires connectivity instrument type		Annual

N. Please provide cost center/budget number designated for Point-of-Care Testing costs: _____

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Point-of-Care Testing
New Test Request Form
(One test request per form)

O. Signatures Required:

Medical Director Signature/ Date: _____

PRINT NAME: _____

Finance Administrator's Signature/ Date: _____

PRINT NAME: _____

Testing Personnel Manager's Signature/Date: _____

PRINT NAME: _____

Date POCT Received: _____

Director Date: _____ Approve Disapprove

Signature Director, POCT Program: _____

Date Submitted to CQI for Billing/Licensing: _____ Needs Yes $_____ No

Revision 3/2023

Timeframe

- May take several months to implement a new POC device.
- Dependent on:
  - Size of facility
  - Current workload
  - Number of POCC's
  - Complexity of test
  - Number of testing personnel
  - New test, or previously established test

Future Initiative: breakdown our current turn-around time for projects

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Past – Little to No Interface

- Manually recording results in patient charts
- By “sneakernet” system, we would download instruments once a month to keep data
- Transcription errors

Create Your Own Master Project List

- MS Excel, MS Project
- Weekly, Ongoing Updates
- Shared on File share site
- Presented to Lab leadership monthly

Master Project List - Enterprise

JHH CAP inspection March 16-17
[redacted] Upgrade March 17
[redacted] FREEZE March 10th

Location or DEP/MPI ID	Interface Needed	Status	NOTES/JIRA/Updates	Address:	Need JACK Installed	Current Jack is Active	Next Step/Responsible Party	Submitted for PO	Submitted for CQI Reimbursements	Priority
JHM - Correction for after [redacted] software upgrade issue	n/a	completed	[redacted] - POC- the result component POC QC Performed? no longer has hard stop	n/a	n/a		1/6/22: Patrice will reach out to her TS and Nicole to find out what options we have for a correction of the issue created by an [redacted] pgrade 1/13/22: [redacted] currently has the fix under development - from SLG 1/20/22: need a dowtime for deployment - looking at the one in March to deploy			
JHM Temp corrected Result display	n/a	in progress	After the addition of measured and temp corrected panels for standardization, results are not displaying in the correct order on the Result review tree	n/a	n/a	n/a	2/24/22: Patrice trying to get in a meeting to resolve this 3/3/22: Patrice has a scheduled meeting for 3/9 to present to joint design to move temp corrected analytes to the top of the			
Suburban	[redacted]	in progress	Suburban is adding [redacted] instruments	Suburban hospital	?	?	1/7/21; Julia's update- [redacted] troubleshooting is priority at this time. We will try for July go live. More details to follow in coming weeks. 1/28/21: no further updates.	no		2

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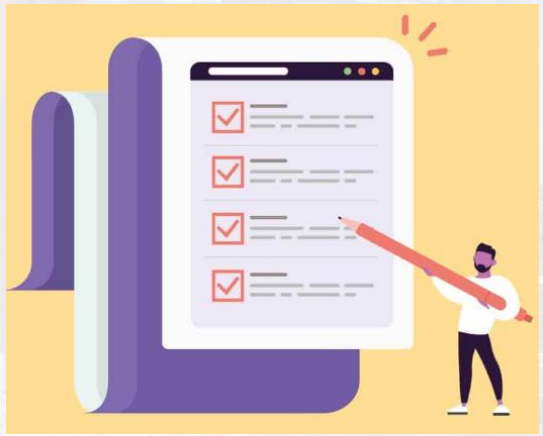
Master Project List Components

- Single Row for each project
- Project Assignee and location
- Notes – running list of notes for each meeting



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More Details on the Master Project List

- Add all required IT steps (connectivity, IP address, Jacks, etc.)
- Status
- Priority! 1- high to 4- low

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New Test Start-Up Project Plan

JHH POCT New Test Start-up Project Plan

Project Name: Project Assignee: Start date: Completion date:

Site Address/Location:

Proposed test system/device:

_____ Waived
_____ Research
_____ Training modules exist
_____ Moderately Complex
_____ Clinical
_____ Device approved

Contact:

CLIA/State License #'s (if existing):

Cost Center:

Category	Item	Who	Progress Notes	Goal date	Completion date
Submission	New test request (and IRB submission if research)				
	New test request approved				
	CLIA application submission (or updates to existing)				
	Establish lab director				
	Submit approved request to CQI				

Category	Item
Submission	New test request (and IRB submission if research)
	New test request approved
	CLIA application submission (or updates to existing)
	Establish lab director
	Submit approved request to CQI
Procedures	Write testing procedure/obtain approval
	Write ancillary procedures/obtain approval
	Create training/competency materials
Supplies	Send cost estimates and SAP numbers
	Order device
	Site orders ancillary supplies (i.e. refrigerator, thermometer, timer)
	Validate new device/correlate with Core lab
Connectivity	Obtain DEP information
	Identify/activate jacks
	Submit Telcor invoice
	Submit IT work request
	Establish Telcor connection
	Set up device/Test connectivity
Training	Identify trainer
	Send links to My Learning

Categories

- Submission of all forms
- Procedures
- Suppies
- Connectivity
- Training

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Training	Identify trainer
	Send links to My Learning Modules, training and procedures
	Train/observe trainer
	Set up log book/Org chart
	Trainer trains operators/Se up operators in Telcor
Regulatory	Order PT, if needed
	Obtain signatures on delegation documents
	Obtain LD signatures on procedures, if needed
Final Inspection	Final inspection

Categories

- Training
- Regulatory
- Final Inspection

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Quality Indicators

- Patient ID errors
- Tracking completion of Annual Competency Assessment
- Use of “fake patient ID or 911 Barcodes”
- Unit Audit Scores
- Errors running MICRO samples in POCT lab
- Labeling reagents
- Storage of reagents

New for FY24		JHH POCT Quality Report Card	Target	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23
	1							
No	a	Total Number of Providers	(varied)	166				
	b	Number of Providers Who Completed Modules	(varied)	141				
	c	Percentage of Modules Completed	80%	85%				
No	2							
	a	Total Incorrect CSN	N/A	263	250	265	263	200
	b	Total CSN Not Corrected	N/A	23	27	20	26	12
	c	Percent CSN Not Corrected	<9%	9%	11%	8%	10%	6%
No	3							
	a	Total Units Completed	N/A	20	8	17	14	16
	b	Average % Compliance	91%	91%	97%	97%	92%	94%
No	4							
	a	MICRO Samples Processed at POCT	TBD	3	2	5	1	3
No	5							
	a	It Service Tickets Left Unresolved >30 days	0	0	2	0	0	0
No	6							
	a	ED POCT Lab Unit Audit Scores	85%	78%	80%	75%	59%	94%
No	5							
	a	Total Patient Samples	N/A			51,522	58,070	56,332
	b	DT Samples	N/A			4,536	5,789	5,663
	c	DT %	<11			9%	10%	10%

Corrective Action Notes and Comments for Targets not Met Indicate the Month, then add comments.	**Oct:** ED POCT Lab Unit Audit Scores-3 issues occur routinely will address with unit educators. **Aug Unit audit scores**: were recorded as 83%, 2 inspections in iAuditor Software were recorded as JHH when they were Sibley audits. Removing these audits and adding up actual JHH scores (77.8 % 8 = 97%) brought the score within target. **Dec PPM:** working with hospital CQI for compliance. **Feb Percent CSN not corrected:** JHH still has high number of new employees in orientation every other week. Working with Nurse educators to review training workflow to look for opportunities to improve knowledge and skills for new hires. **Feb/Mar:** AED unit audit score - corrective actions to be discussed with Dr. Clarke, last meeting with the AED was in Oct/Nov.

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BMC POCT Dashboard FY24

New for FY24		INDICATOR	Target	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24
	1	**Completion of Provider Performed Microscopy Modules -Biannually**										
No	a	Total Number of Providers	N/A	105					94			
	b	Number of Providers Who Completed Modules	N/A	48					53			
	c	Percentage of Modules Completed	80%	46%					56%			
No	2	**Incorrect CSNs (Patient/Episode not found in QML) and % Not Corrected**										
		Total Incorrect CSN	N/A	30	55	27	76	44	29	84	45	23
		Total CNS Not Corrected	N/A	1	2	1	3	1	1	1	0	1
		Percent CSN Not Corrected	≤3%	3%	4%	4%	4%	2%	3%	1%	0%	4%
No	4	**Unit Audit Average Score**										
	a	Total Units Completed	N/A	16	16	21	11	6	12	19	25	14
	b	Average % Compliance	91%	97%	98%	94%	93%	85%	94%	91%	92%	96%
No	5	**Glucometer Downtime Override Monthly %**										
	a	Total Patient Samples	N/A	20104	20974	19,677	21,321	21,599	20,870	22,560	19,426	20,379
	b	DT Samples	N/A	623	426	580	844	769	350	426	451	466
	c	DT %	TBD	3%	2%	3%	4%	4%	2%	2%	2%	2%

Corrective Action Notes and Comments for Targets not Met Indicate the Month, then add comments.	Aug, Sep, Oct, Mar - incorrect CSN: due to high employee turnover. Nov - Audit score average: of the 6 units audited, 4 were at 78% (failed 1 element). All were at 100% for last audit performed in Sep and all re-audited in Dec and obtained 100%. No follow up necessary.

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Report Card Updated Monthly

- Pull data from middleware
- Run reports on types of patient errors
- Only limit is my knowledge of the middleware

Manage Operator Competency

- Middleware (including manual tests)
- 2 elements of competency – successful QC and passing quiz score
- Auto re-certify
- Monthly operator expiration reports by unit

Future Initiatives

- Dissecting Master Project List
  - Project timelines
  - Turn-around time from request to implementation
- Develop New Test Request Procedure for all POCC

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Department of Pathology

Point of Care Testing

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Thank You !!

Jeanne Mumford, MLS (ASCP)

jmumfor3@jhmi.edu

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