JOHNS HOPKINS
MEDICINE

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

Research Studies:
Point-of-Care Test Requests

Please provide the following information and return to:

The Johns Hopkins Medical Laboratories
Department of Pathology
Point-of-Care Testing Program Office

Mailing Address: CMSC SB-207
600 North Wolfe Street
Baltimore, MD 21287

Fax Number: 410-502-2232

E-mail Address: POCT Group

Name of Study: _____

Principle Investigator's Name: _____ Telephone Number: _____

Study Coordinator's Name: _____ Telephone Number: _____

Approximate Length of Study: _____

Study Location: _____

Please submit copies of your IRB approval and Study Protocol.

Please complete the following Point-of-Care Testing New Test Request Form for each point-of-care test that you wish to perform, i.e., each requested test requires a separate form.

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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 ◯ PPM ◯

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 ◯ b. Health Fair ◯ c. Physician office ◯ d. Mobile Lab ◯ e. Independent ◯
	Type of ownership a. Private Nonprofit ◯ b. Other Nonprofit ◯ c. Proprietary ◯
	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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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
Telcor Connectivity Fees		
Instrumentation that requires connectivity $385 per instrument type (if 2 instrument types, $385 x 2)	$385	Annual

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

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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 Telcor: Yes: ◯ $_____ No ◯

Revision 10/2019