TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	6/1/2016
Department:	Mgmt, QA	**Due Date:**	6/13/2016
		Implementation:	**6/14/2016**

DESCRIPTION OF PROCEDURE

Name of procedure:

Laboratory-Developed (LDT) and Modified Tests GEC.QA244, SGAH.QA932, WAH.QA923 v0

Description of change(s):

New SOP to define process for laboratory-developed tests (LDT) and modified FDA-cleared/approved tests implemented by the laboratory.

Note: the test list attached in SS is site-specific

This SOP will be implemented on June 14, 2016

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training

Non-Technical SOP

Title	**Laboratory-Developed (LDT) and Modified Tests**
Prepared by	Leslie Barrett Date: 5/13/2016
Owner	Cynthia Bowman-Gholston Date: 5/13/2016

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

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1. PURPOSE

This procedure specifies the process for laboratory-developed tests (LDT) and modified FDA-cleared/approved tests implemented by the laboratory.

2. SCOPE

This procedure applies to the implementation of laboratory-developed tests (LDT) and any modification of FDA-cleared/approved tests.

3. RESPONSIBILITY

The technical supervisor is responsible for ensuring compliance with this procedure.

4. DEFINITIONS

Laboratory-developed test (LDT) – The FDA defines a Laboratory Developed Test (LDT) as an *in vitro* diagnostic test that is manufactured by and used within a single laboratory (i.e. a laboratory with a single CLIA certificate). LDTs are also sometimes called in-house developed tests, or "home brew" tests.
The CLIA requirements are based on the test complexity; the more complex the test is to perform, the more stringent the requirements. **LDTs are considered high complexity tests**. Therefore, the laboratory must meet all applicable CLIA requirements for high complexity testing.
Note: When a laboratory develops a test system such as an LDT in-house without receiving FDA clearance or approval, CLIA prohibits the release of any test results prior to the laboratory establishing certain performance characteristics relating to analytical validity for the use of that test system in the laboratory's own environment, *see* 42 CFR 493.1253(b)(2) (establishment of performance specifications). This analytical validation is limited, however, to the specific conditions, staff, equipment and patient population of the particular laboratory, so the findings of these laboratory-specific analytical validation are not meaningful outside of the laboratory that did the analysis. Furthermore, the

laboratory's analytical validation of LDTs is reviewed during its routine biennial survey – after the laboratory has already started testing.

Modification of manufacturer's instructions – Any change to the manufacturer's supplied ingredients or modifications to the assay as set forth in the manufacturer's labeling and instructions, including specimen type, stability, instrumentation, or procedure that could affect its performance specifications for sensitivity, specificity, accuracy, or precision or any change to the stated purpose of the test, its approved test population, or any claims related to interpretation of the results.

5. PROCEDURE

A. Method Performance Specifications

1. All tests methods must be validated prior to implementation in accordance with the procedures "Laboratory Method Validation Protocol" and "Process and Equipment Validation Protocol."

    a. For quantitative modified FDA-cleared/approved tests and LDTs, a minimum of 20 samples across the AMR must be tested. For qualitative tests, a minimum of 20 samples, including positive, negative, and low-positive samples should be used; equivocal samples should not be used.

    b. Modified FDA-cleared/approved tests and LDTs in use prior to July 31, 2016 that have limited validation studies recorded, may utilize ongoing acceptable test performance data as supporting documentation.

    c. The sample size requirement does not apply to manual microscopy or conventional microbiology cultures.

    d. All LDT clinical claims made by the laboratory must be validated. This requirement also applies to any clinical claim not included in manufacturer instructions for FDA-cleared/approved tests.

2. A listing of LDT and modified-FDA tests is maintained on the College of American Pathologists (CAP) form. This document must be available during CAP inspections. Refer to appendix A.

3. New test methods and modifications to existing test methods that are classified as an LDT or modified-FDA test will be added to the test list in appendix A.

B. Reporting

LDT results are reported with the following comment:

"This test was developed and its performance characteristics determined by *<insert laboratory/company name>*. It has not been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high-

complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research."

Note: The report comment does not apply to traditional methods, such as manual microscopy, convention microbiologic cultures, and manual and immunology tests.

6. RELATED DOCUMENTS

Laboratory Method Validation Protocol, QA procedure
Process and Equipment Validation Protocol, QA procedure

7. REFERENCES

All Common checklist, College of American Pathologists, Laboratory Accreditation Program, Northfield, IL 60093, www.cap.org

What is CMS' authority regarding Laboratory Developed Tests (LDTs) and how does it differ from FDA's authority? https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/ldt-and-clia_faqs.pdf, 10.22.2013

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9. ADDENDA AND APPENDICES

A. Laboratory-Developed & Modified FDA-Cleared/Approved Test List (see Attachment pane in SmartSolve)

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Laboratory-Developed & Modified FDA-Cleared/Approved Test List

List all laboratory-developed tests (LDTs) and modified FDA-cleared or approved tests below and present to the inspector during the on-site inspection. This form may be used to assist in compliance with the All Common Checklist requirement COM.40200.

Laboratory Name: Germantown Emergency Center **CAP Number:** **7196153**

Test Name	Laboratory Section/ Department	Type of Test Mark column with an "x"		Date Implemented	Date Retired	Comments
		LDT	Modified Test			
Cell count, body & synovial fluid, manual method	Core lab	X		8/2006		
Cell count & differential, CSF	Core lab	X		8/2006		
Gram stain, manual method	Core lab	X		8/2006		
Wet Prep	Core lab	X		8/2006		
Stool for WBCs	Core lab	X		8/2006		

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Laboratory-Developed & Modified FDA-Cleared/Approved Test List

List all laboratory-developed tests (LDTs) and modified FDA-cleared or approved tests below and present to the inspector during the on-site inspection. This form may be used to assist in compliance with the All Common Checklist requirement COM.40200.

Laboratory Name: Shady Grove Medical Center **CAP Number:** **7185322**

Test Name	Laboratory Section/ Department	Type of Test Mark column with an "x"		Date Implemented	Date Retired	Comments
		LDT	Modified Test			
APT	Chemistry	X		Prior to 11/2003		
Creatinine, body fluid	Chemistry		X	12/8/15		
Urine Amphetamine/ Methamphetamine Screen	Chemistry		X	7/17/12		Removed pH testing per communication from manufacturer.
Urine Barbiturates Screen	Chemistry		X	7/17/12		
Urine Benzodiazepines Screen	Chemistry		X	7/17/12		
Urine Cannabinoids Screen	Chemistry		X	7/17/12		
Urine Cocaine Metabolite Screen	Chemistry		X	7/17/12		
Urine Opiates Screen	Chemistry		X	7/17/12		
Urine Phencyclidine Screen	Chemistry		X	7/17/12		
Cell count, body & synovial fluid	Hematology	X		Prior to 11/2003		
Cell count & differential, CSF	Hematology	X		Prior to 11/2003		

Test Name	Laboratory Section/ Department	Type of Test Mark column with an "x"		Date Implemented	Date Retired	Comments
		LDT	Modified Test			
Gram stain, manual method	Microbiology	X		Prior to 11/2003		
Malaria	Microbiology	X		Prior to 11/2003		
Urine Culture screen	Microbiology	X		9/1/15		
Wet Prep	Microbiology	X		Prior to 11/2003		
Stool for WBCs	Urinalysis	X		Prior to 11/2003		

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Laboratory-Developed & Modified FDA-Cleared/Approved Test List

List all laboratory-developed tests (LDTs) and modified FDA-cleared or approved tests below and present to the inspector during the on-site inspection. This form may be used to assist in compliance with the All Common Checklist requirement COM.40200.

Laboratory Name: Washington Adventist Hospital **CAP Number:** **7185324**

Test Name	Laboratory Section/ Department	Type of Test Mark column with an "x"		Date Implemented	Date Retired	Comments
		LDT	Modified Test			
Creatinine, body fluid	Chemistry		X	12/8/15		
Urine Amphetamine/ Methamphetamine Screen	Chemistry		X	7/17/12		Removed pH testing per communication from manufacturer.
Urine Barbiturates Screen	Chemistry		X	7/17/12		
Urine Benzodiazepines Screen	Chemistry		X	7/17/12		
Urine Cannabinoids Screen	Chemistry		X	7/17/12		
Urine Cocaine Metabolite Screen	Chemistry		X	7/17/12		
Urine Opiates Screen	Chemistry		X	7/17/12		
Urine Phencyclidine Screen	Chemistry		X	7/17/12		
Cell count, body & synovial fluid, manual method	Hematology	X		Prior to 11/2003		
Cell count & differential, CSF	Hematology	X		Prior to 11/2003		
Gram stain, manual method	Microbiology	X		Prior to 11/2003		

Test Name	Laboratory Section/ Department	Type of Test Mark column with an “x”		Date Implemented	Date Retired	Comments
		LDT	Modified Test			
Malaria	Microbiology	X		Prior to 11/2003		
Urine Culture screen	Microbiology	X		9/1/15		
Wet Prep	Microbiology	X		Prior to 11/2003		
Stool for WBCs	Urinalysis	X		Prior to 11/2003		