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Work Instruction

Title: SFTY-Laboratory Testing in Cases of High risk Highly Infectious Patients		**WI Number** SFOWI-1234 **Revision:** 3
Department: Administration Point-of-Care Testing Safety/Chemical Hygiene **Area:** 2425 Geary Blvd SFO Hospital Lab	***Approved & Released Work Instruction***	**Implementation Date:** 03/25/2019
Type of Document: Work Instruction		**Review Period -** 340 **Days**

1.0 Purpose

To assess laboratory testing readiness for patients with suspected high risk infections requiring isolation precautions.
To define two different lab testing strategies to meet the needs of patients with suspected high risk infections. **1. Portable laboratory in a box** provides the basic and minimum level of POCT testing at the patient's negative pressure room or nearby negative pressure testing area. **2. Limited scope testing** strategy has additional testing capability for complete blood counts (CBC) and liver function tests (LFT), but requires dedicated bench top analyzers located in a contained, negative pressure testing area. The selection of lab testing strategies will depend on the availability of testing equipment, space, and the desired laboratory tests.

2.0 Scope

Laboratory Director, Infectious Disease Providers, POCT testing personnel (RN, RCP, MD) and laboratory personnel (pathologists and laboratory staff)

3.0 Definition of Terms

3.1	High Risk Infections are defined as follows: Infectious agents that require immediate notification to the State laboratories: **BSL4 Level Pathogens** ● **Smallpox (Variola)** ● **Viral Hemorrhagic Fever agents, e.g., Crimean-Congo, Ebola, Lassa, and Marburg viruses** ** BSL4 (maximum containment laboratory) required for organisms that pose a high risk of transmission of life-threatening disease and for which no vaccines or antibiotics are available* **BSL2 Level Pathogens** ● **Anthrax** ● **Botulism** ● **Brucellosis** ● **Influenza, novel strains** ● **Plague** ● **Tularemia**

4.0 Policy

- Laboratory testing of specimens from patients suspected of high risk BSL4 pathogen infection is performed on Point of Care Testing (POCT) devices inside the patient's negative pressure isolation room, or nearby in a contained negative pressure testing area.
- Testing of specimens from patients suspected of high risk BSL4 pathogen infection must not be performed on analyzers in the medical center laboratory.
- Testing is kept to a minimum to only those essential for diagnosis and monitoring purposes.
- Persons performing POCT testing must wear appropriate PPE. Refer to CDC's PPE poster under section 6.1

4.1	**Preparation and Assessment**

	4.1.1	A biological risk assessment performed in conjunction with medical leaders from Infectious Disease, Infection Prevention, Emergency medicine and the Laboratory Medical Director should be conducted and agreed upon at the earliest possible stage of implementation. In addition

		to assessment of PPE requirements to protect skin, eyes, and mucous membranes, the assessment should include a thorough review of space availability in negative pressure rooms, the availability of the POCT laboratory equipment, trained personnel,and the desired essential medical tests.
	4.1.2	**POCT Testing Location(s)** In patient's negative pressure room Yes No In nearby dedicated negative pressure testing area Yes No Comments: _____ _____
	4.1.3	**Availability of required PPE:** Impermeable gown with back closure Yes No Gloves of all sizes Yes No Eye and splash protection Yes No Shoe covers Yes No N-95 Mask and fitting Yes No PAPR training and use Yes No Comments: _____ _____
	4.1.4	**Staff training:** POCT testing personnel have been identified Yes No POCT testing personnel have been trained on the medical center's Infection Control policy Yes No POCT testing personnel have been trained on the proper use of PPE listed under section 4.1.3 for the performance of point of care tests. Yes No POCT testing personnel have been trained on the proper use of POCT testing devices. Yes No POCT Testing personnel have been trained on the preparation and inactivation of blood smear. Yes No POCT testing personnel have been trained on the proper disposal of specimens, contaminated supplies and materials.

		Yes No
	4.1.5	**Transportation of highly infectious specimens for external testing** The laboratory has a plan in place to package and ship highly infectious specimens for external testing (HFV diagnostic test at the CDC and/or blood culture at Regional Laboratory). Yes No Laboratory staff has been trained on the proper packaging of Category A infectious material. Yes No Scheduled training date(s) _____ The laboratory has set up an account with the designated courier (World Courier) for the transportation of Category A infectious materials. Yes No

4.2	In order to minimize transportation risk and staff exposure, POCT testing shall be performed near the patient bedside in a negative pressure room or nearby in a contained negative pressure testing area. There are two different lab testing strategies described in the following sections to meet the testing needs described above. **1. Portable laboratory in a box** provides the basic and minimum level of POCT testing at the patient's negative pressure room or nearby negative pressure testing area. **2. Limited scope testing** strategy has additional testing capability for complete blood counts (CBC) and liver function tests (LFT), but requires dedicated bench top analyzers located in a contained, negative pressure testing area. The selection of lab testing strategies will depend on the availability of testing equipment, space and the desired laboratory tests.

4.2.1	**Option 1: Portable Laboratory in a Box - Basic and Minimum scope** The "Portable Lab Box" contains POCT devices and supplies for minimum level of testing: Electrolytes, Hemoglobin, Hematocrit, Glucose, Creatinine, Blood Gas, urinalysis, urine pregnancy , Malaria, WBC and Platelet estimates. Lactate, Troponin, PT/INR are available but are not considered essential analytes. Diagnosis of HFV is performed by the CDC. Validated testing instrumentation and materials shall be maintained by the laboratory and supplied to the patient area within 1 hour from request. A list of supplies can be found on the "Lab in a Box" Checklist of the reference document

	"NCAL Laboratories: Ebola Preparedness Toolkit". Refer to section 7.0.

4.2.2 **Option 1: Portable Lab Equipment Assessment**

Assessment Date: _____

Test Category	Circle iSTAT cartridges or device currently in use	If none, enter follow up action plan**
Hemoglobin & HCT (iSTAT)	CG8 or EG7 or CHEM8	
Coagulation (iSTAT)	PT/INR	
Chemistry (iSTAT)	CHEM8, CG8 or EG7 or CG4 (Lactate), Troponin	
Urinalysis	Roche or Siemens urinalysis dipsticks	
Urine Pregnancy	Urine Pregnancy Kit (OSOM or equivalent)	
Malaria Testing	BinaxNow and/or smear	
Blood Cultures, if required after consultation	Blood Cultures Bottles x2 Package blood culture bottles according to Category A requirements and transport by World Courier to Regional Laboratory for testing	
Diagnosis of Hemorrhagic Fever Virus (HFV)	Contact CDPH and CDC prior to specimen collection. If instructed, follow CDC guidelines to complete paperwork and collect specimen in plastic EDTA tube. Package specimen according to Category A requirements and transport by World	

	Courier to CDC for testing	

Test Category	Circle Test Method	If none, enter follow up action plan**
WBC counts	Competent lab personnel to perform slide estimation, or HemoCue WBC System	
Platelet counts	Competent lab personnel to perform slide estimation	

A Portable Laboratory Box has been assembled with validated testing devices, cartridges, reagents and all necessary tubes and supplies (Refer to page 25 on NCAL Laboratories: Ebola Preparedness Toolkit)

Yes or **In Progress** (Circle your answer)

Date Portable Lab Box is ready for deployment_____

** Implementation of any new test or test cartridges requires resources, method validation, enrollment in proficiency testing when applicable, procedure development, staff training and competency assessment. Validation, maintenance, calibration, quality control, reagent management and twice yearly correlation between iSTAT cartridges and main laboratory analyzers shall fall under POCT supervision.

4.2.3	**Option 2: Limited Scope Testing - Stationary equipment for POCT** **Limited scope testing** strategy has additional testing capability for complete blood counts (CBC) and liver function tests (LFT), but requires dedicated bench top analyzers located in a contained, negative pressure testing area. Testing will not be performed on laboratory analyzers in the medical center laboratory.

4.2.4	**Option 2: Limited Scope - Stationary Lab Testing Assessment** Assessment Date: _____ **Availability of Testing Location:**

Dedicated negative pressure testing area has been identified Yes No

If Yes, List the specific testing location: _____

Availability of testing equipment:

Test Category	Circle Test Method	If none, enter follow up action plan**, if any
CBC	Coulter Ac.T2 or pocH 100i	
Chemistry & Liver Function Tests ALP, ALT, AMY, Tbil	Piccolo Xpress	

4.2.5 Stationary Lab Preparation and Maintenance

** Implementation of any new test analyzer requires resources, method validation, enrollment in proficiency testing when applicable, procedure development, staff training and competency assessment.

Validation, maintenance, calibration, quality control, reagent management and twice yearly correlation between these dedicated instruments and main laboratory analyzers shall fall under POCT supervision.

5.0 Documentation and Records

5.1 Based on the assessment conducted under section 4.2.2 and 4.2.4, the laboratory director in conjunction with Infection Prevention and Emergency Medicine has selected the following option(s) (Circle the selection(s))

Option 1 : Portable Lab in a Box - Basic and Minimum level of POCT testing

Option 2: Limited Scope Testing - Stationary Lab

Laboratory Director's Signature:

_____Date _____

Infection Prevention _____ (Add Title)

_____Date_____

Emergency Medicine _____ (Add Title)

	_____Date _____

6.0 Related Documents

6.1	CDC PPE Poster

7.0 References

1.	NCAL Laboratories: Ebola Preparedness Toolkit. JSchapiro, September 2014

Associated Documents:

External Documents

NCAL Laboratories Ebola Preparedness Toolkit Sept 2014.pdf CDC PPE poster.pdf

Associated Quality System Documents - None

Document Revision History:

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Document Author: Richard Chui/CA/KAIPERM	

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1	N/A	Adopted from Regional Template.	10/14/2014
2	N/A	Change of Director	7/6/2016
3	Approver	Change of Lab Director	3/25/2019

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Approvals:

First Approver's Signature

Name: Elizabeth M Hosfield/CA/KAIPERM Mar 25, 2019 12:29:39 PM PDT - Approved by: Elizabeth M Hosfield/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

Document History Section