



LumiraDx SARS-CoV-2 Antigen Test Initial Training and Competency

Date: _____ Site: _____ Operator Name: _____ JHED: _____

Competency Category	Performance Indicator	Assessment Tool	Criteria Met	Criteria Not Met	Remedial Action
			Trainer v		
eLearning	New testing personnel up-to-date on eLearning quiz <i>prior</i> to initial training (Completion Date: _____)	Exam			
Reagent Stability and Storage	Maintains a working knowledge of Test and QC Kits, and Instrument Storage: - Records open dates on Test Kits, as well as open and expiration dates on QC Kits. - Knows consumables expire at Manufacturer's Expiration Date. - Does not use expired Test or QC kits.	Exam			
QC Performance	Adheres to QC policies and procedures, including labeling of Buffer vials and Test Strips, and PPE requirements. - Runs appropriate QC at defined frequency (minimum weekly each instrument, training, annually). - Demonstrates proper instrument programming and testing technique, correctly documents QC results.	Direct observation Exam			
Specimen Collection	Adheres to procedure for collecting swabs and performing extraction steps in buffer vial. - Properly labels buffer vial with two patient identifiers or patient label. - Understands requirement to keep all prepared vials until results are finalized, then discard in biohazard bin.	Direct observation Exam			
Routine Patient Testing	Adheres to Patient Testing procedure, as outlined in POCTW045. - Understands proper instrument programming and testing technique, correctly documents patient results.	Direct observation			
Limitations of Procedure	Interprets and evaluates test results in regards to test limitations.	Direct observation Exam			
Documentation of Results	Interprets, evaluates, and records test results appropriately. - Correctly completes Patient Result Log. - Uses Epic code POC101217 to result all patient results in Epic.	Direct observation Review of records			
Problem Solving Skills	Understands interpretation and corrective action for Invalid Test Results. Knows POCT Office Contact Information (5-2645 M-F; POCT Consult on CORUS; POCTGroup email). Knows location of Troubleshooting Guide for Instrument error codes.	Exam Direct Observation			
Safety	Wears proper PPE at all stages of testing (<i>double gloves, gown, N95 mask/face shield, or PAPR</i>)(<i>gloves, surgical mask</i>). Discards all testing materials in biohazard waste containers as indicated in POCTW045. Instrument and testing area is disinfected as directed in the policy after each test.	Direct observation Exam			
Procedure review	Acknowledges ongoing competency requirements (annual successful completion of QC and pass eLearning quiz). Locates and reads the current version of the SOP (<i>POCTW045</i>).	Operator Acknowledgment			

Date	Operator Initials	Master Kit <i>(information on box)</i>		Instrument ID	QC Level	Lot Number	Interpretation <i>(Circle)</i>	Results Acceptable <i>(Y/N)</i>	Comments
		Lot #	Exp Date						
					Negative		<i>Positive (Pos)</i> <i>Negative (Neg)</i>	Yes No	
					Positive		<i>Positive (Pos)</i> <i>Negative (Neg)</i>	Yes No	

I have reviewed this checklist with new operator and observed completion of QC. POCC/Trainer Initials signify this operator:

Is competent to perform patient testing with the LumiraDx SARS-CoV-2 Antigen Test _____

Requires retraining before performing patient testing using the LumiraDx SARS-CoV-2 Antigen Test _____

Operator signature: _____

Date: _____

Trainer signature: _____

Date: _____