Boston Area Consolidated Laboratory, Department of Pathology and Laboratory Medicine Point of Care Testing, ICON 20 hCH, Quantitative Urine Preganancy

Employee:	Location <u>:</u>					
Initial:	Re-assessment:					
Mathada of Malidation.						
Methods of Validation: (O) Observation	(PR) Peer Review	(W) Written Assessment	(D) Demonstr	ration	(V) Verbal	
<u></u>	(i i i i i i i i i i i i i i i i i i i	(iii) iiiiidaa iiidaa aa	(2) 20		(1) 10.00.	
When multiple assessme	nt methods are acceptable	INDICATE the assessment method of va	lidation (more than	one method n	nay be used); write your in	itials and date.
Successful performance o	f routine patient test perfo	rmance, verified by direct observation by	supervisor or quali	ified designee	OPRWDV	′
including: Patient preparation, identification, specimen collection, handling, processing and testing					Initial & Date	
Monitoring the recording and reporting of test results, including as applicable, reporting critical results					□ O □ PR □ W □ D □ V	′
					Initial & Date	
Review of immediate test results, QC, proficiency test and maintenance/cleaning records, as applicable					☐ O ☐ PR ☐ W ☐ D ☐ V Initial & Date	′
Successful performance of instrument maintenance/cleaning and function check as applicable, verified by direct observation						,
uccessiui perioriliance o	instrument maintenance/	cleaning and function check as applicable	, verified by difect t	observation	Initial & Date	
Assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency					□ O □ PR □ W □ D □ V	1
testing samples					Initial & Date	
Assessment of problem-solving skills					□ O □ PR □ W □ D □ V	,
· 					Initial & Date	
roficiency Test; purpose	and handling				□ O □ PR □ W □ D □ V	′
			ı. ı \ \ ı		Initial & Date	,
Documentation that I am knowledgeable about the contents of the procedure manuals (including changes) relevant to the					☐ O ☐ PR ☐ W ☐ D ☐ V Initial & Date	′
cope of testing activities.						
	clude Corrective Action Pla	n below			☐ Yes or ☐No	
Observer/Assessor Signation	ure and date					
Rating Official (Supervisor) signature and date						
·						
Employee signature and date						
Corrective Action Plan						
Retraining Needed?	□YES	□NO				
If YES complete t						
Date of Retraining:		Date of Reassessment:	Initials o	Initials of reassessing observer:		
Employee's initials:						
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