



D-10 Installation, Operational and Performance Qualification Report

Date (dd mmmm, yyyy)	11 December, 2023	Serial Number	DJ22I05801	Work Order	01735880
Customer	Lupin Diagnostics - Hyderabad				
Software version	4.30-2	Firmware version	4.30-2	Service Activity	I.Q.-O.Q. - P.Q.
Engineer	ARCS Prasad/Nayeem	Assay	A1c	Cartridge lot #	R00345AP
Buffer A lot#	AA30158	Buffer B lot #	AA30159	Wash lot #	AA30118
Checks		Lowest	Highest	Minimum	Maximum
HP Pump Pressure stable: Variances less than \pm (5% +0.2kg/cm ²) for 2 minutes		29.2	30.1	26.2	33.1
					Unit
					Kg/cm ²
					✓ = Pass
External waste bottles fluidic and electronic connections in working order					✓
Preventive Maintenance Schedule is current					✓
Check for absence of crystallization or signs of leakage at the, HP Pumps, Transducer, Injector valve and Cartridge Holder					✓
Pinch valves tubing not clamped and positioned correctly					✓
Needle is straight and clean					✓
Verify all tubing behind the HPLC tray is routed correctly and not pinched between the HPLC tray and the chassis.					✓
Verify the HPLC tray is secured in place					✓
All covers secure					✓
All "System-Checks" pass					✓
LIS connection operational (optional)					✓
Computer network and connection operational (optional)					✓
BRiCare operational (optional)					✓
Network printer operational (optional)					✓

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A1c Assay Testing Results are shown below **Work Order**

A calibration is required for the following reasons: If a HP pump or the Detector have been serviced, or the cartridge has been replaced or the instrument has been producing poor quality control results prior to the service call. 01735880

A1c Calibration Required of any assay that reports A1c Results			Lot number:	S20287	New Slope	1.20	New Intercept	-0.33
Low Level A1c Target Value	Actual Low Level A1c Value	Low level A1c Retention time	Low level Ao Retention time	High Level A1c Target Value	Actual High Level A1c Value	High Level A1c Retention time	High Level Ao Retention time	
5.4	5.4	0.84	1.37	10.3	10.3	0.80	1.37	

A1c Quality Control Required of any assay that reports A1c Results						Lot number	2300HA
	Target A1c values		Actual A1c Value	A1c Retention Time	Ao Retention Time	Baseline Stable	Total Area
	Minimum	Maximum					
QC Low	4.5	6.8	4.9	0.81	1.37	✓	3,177,505
QC Mid-Range (Liquicheck Only)							
QC High	8.8	13.2	10.4	0.80	1.37	✓	2,707,662

A1c Primary Tube Samples: A1c and Dual Kit Short Assays require 10 primary tube samples

	Sample identification	A1c Result value	A1c Retention Time	Ao Retention time	Baseline Stable	Total area
1	BI01269209	5.5	0.82	1.39	✓	2,633,271
2	BI01269713	5.9	0.84	1.39	✓	2,302,593
3	BI01270350	6.9	0.83	1.39	✓	2,068,140
4	BI01271343	6.8	0.84	1.40	✓	1,330,833
5	BI01271347	5.6	0.83	1.39	✓	2,555,247
6	BI01271350	6.6	0.84	1.40	✓	1,452,307
7	BI01271353	6.1	0.84	1.40	✓	1,307,299
8	BI01271372	7.5	0.83	1.40	✓	1,657,687
9	BI01271545	5.2	0.84	1.40	✓	137,462
10	BI01272122	4.9	0.84	1.30	✓	2,135,276

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β-thalassemia Assay Testing Results are not reported on this instrument

A calibration is required for the following reasons: If a HP pump or the Detector have been serviced, or the cartridge has been replaced, or the instrument has been producing poor quality control results prior to the service call.

Hb F and A2 Calibration (Perform, if necessary, on systems running Dual kit Extended Assay)

Lot number:	NA	New Hb F Slope		New Hb F Intercept		New A2 Slope		New A2 Intercept	
Low Level Hb F Target Value	Actual Low Level Hb F Value	Hb F Retention time	Low Level Hb A2 Target Value	Actual Low Level Hb A2 Value	Hb A2 Retention time	Total Area			
High Level Hb F Target Value	Actual High Level Hb F Value	Hb F Retention time	High Level Hb A2 Target Value	Actual HighLevel Hb A2 Value	Hb A2 Retention time	Total Area			


Hb F and A2 Quality Control				Required on systems running Dual Kit Extended Assay				Lot number	NA	
	Target Hb F values		Actual Hb F Value	HB F Retention Time	Target A2 values		Actual Hb A2 Value	Hb A2 Retention Time	Baseline Stable	Total Area
	Minimum	Maximum			Minimum	Maximum				
Low QC										
High QC										

F / A1c / A2 Primary Tube Samples: 5 Primary tube samples are required on systems running Dual kit Extended Assay

	Sample identification	Hb F Result value	Hb F Retention Time	Hb A1c Result value	Hb A1c Retention Time	Hb A2 Result value	Hb A2 Retention time	Baseline Stable	Total area
1	NA								
2	NA								
3	NA								
4	NA								
5	NA								

Comments

If necessary, add the chromatograms :

Work Order number	Bio-Rad Representative Printed Name	Bio-Rad Representative Signature
01735880	ARCS Prasad/Nayeem	

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