



**Bio-Rad**  
**Laboratories (India) Private Limited**  
(A wholly owned subsidiary)

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CIN No.: U32109DL1996PTC078494

# The Validation Protocol for the Quantitation of HbA1c on D10 Analyzer DJ5H029609

Protocol  
Prepared by:  
Vishwa Bharathi H A

Bio-Rad Laboratories



\_\_\_\_\_  
Sign & Date

Protocol  
Reviewed by

KM NU HOSPITAL  
AMBUR

\_\_\_\_\_  
Sign & Date



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## PERFORMANCE QUALIFICATIONS

THIS IS TO CERTIFY THAT THE **BIORAD D10** HEAMOGLOBIN ANALYZER BEARING SERIAL. No. **DJ5H029609** INSTALLED AT **KM NU HOSPITAL, AMBUR** PERFORMANCE HAS BEEN CHECKED BY PERFORMING THE FOLLOWING PROCEDURES ON 14-09-2020.

### 1. CALIBRATION CHECK:

Cal Level No	ACTUAL VALUE	OBTAINED VALUE
HbA1c Cal 1: AA90271	5.3 %	5.3 %
HbA1c Cal2: AA90272	10.1 %	10.1%

### 2. ACCURACY CHECK:

Control Name	Control Range	Mean	Obtained Values
Biorad Low Level	4.5 – 5.7 %	5.1 %	5.2 %
Biorad High Level	8.5 – 10.7 %	9.7 %	9.9 %

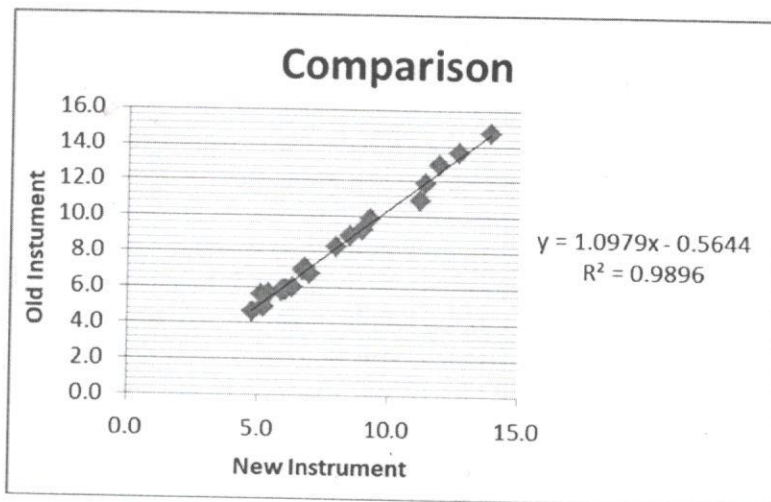
### 3. PRECISION TEST (FOR CONTROLS):

Contr ol Lot N0	RUN 1	RUN 2	RUN 3	RUN 4	RUN 5	Avera ge	SD	CV%
33991	5.3	5.3	5.3	5.3	5.4	5.32	0.04	0.84%

Contr ol Lot N0	RUN 1	RUN 2	RUN3	RUN 4	RUN 5	Aver age	SD	CV
33992	9.0	9.0	9.1	8.9	9.0	9.0	0.07	0.78%

**4. COMPARISON STUDY:**

Sample ID	Old Instrument	New Instrument
527253	9.0	9.3
526929	11.4	11.9
527440	6.1	5.9
527241	11.9	12.9
527124	9.3	9.9
527069	12.7	13.6
527358	5.9	5.8
527180	8.0	8.3
527130	13.9	14.7
527457	4.8	4.6
527127	5.4	5.7
527615	5.2	4.9
527414	11.2	10.9
527230	8.5	8.9
527245	5.1	5.6
527450	6.3	6.0
527391	7.0	6.8
527086	6.7	7.0
527082	6.8	7.1
527375	6.0	5.9



**Linear Regression Statistics**

No. of Samples	20
Slope	1.0979
Y-Intercept	0.5644
Correlation (r)	0.9896

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*(Signature)*  
BIO-RAD LABORATORIES (INDIA) PVT. LTD.  
Sign & Date