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# The Validation Protocol for the Quantitation of HbA1c on D10 Analyzer DJ4F013414

**Protocol**  
**Prepared by:**  
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**Bio-Rad Laboratories**

  
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**Sign & Date**

**Protocol**  
**Reviewed by**

**NU HOSPITAL**  
**SHIMOGA**

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



## PERFORMANCE QUALIFICATIONS

THIS IS TO CERTIFY THAT THE **BIORAD D10** HEAMOGLOBIN ANALYZER BEARING SERIAL. No. **DJ4F013414** INSTALLED AT **NU HOSPITAL, SHIMOGA** PERFORMANCE HAS BEEN CHEKCED BY PERFORMING THE FOLLOWING PROCEDURES ON 09-10-2020.

### 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 of Lot N0	RUN 1	RUN 2	RUN 3	RUN 4	RUN 5	RUN 6	RUN 7	RUN 8	RUN 9	RUN 10
33991	5.1	5.0	5.1	5.0	5.0	5.1	5.1	5.0	5.1	5.1

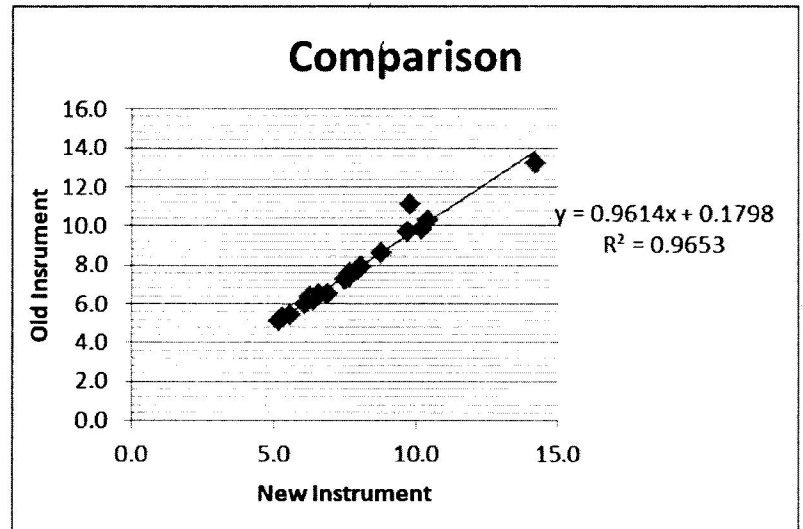
Contr of Lot N0	RUN 11	RUN 12	RUN 13	RUN 14	RUN 15	RUN 16	RUN 17	RUN 18	RUN 19	RUN 20	Avera ge	SD	CV%
33991	5.0	5.0	5.2	5.1	5.1	5.1	5.1	5.2	5.1	5.0	5.1	0.06	1.25%

Contr of Lot N0	RUN 1	RUN 2	RUN 3	RUN 4	RUN 5	RUN 6	RUN 7	RUN 8	RUN 9	RUN 10
33992	10.0	9.7	9.9	9.8	9.9	9.7	9.7	10.1	9.7	9.9

Contr of Lot N0	RUN 11	RUN 12	RUN 13	RUN 14	RUN 15	RUN 16	RUN 17	RUN 18	RUN 19	RUN 20	Avera ge	SD	CV%
33992	9.8	9.8	9.9	9.7	9.9	9.9	9.7	9.8	9.8	9.7	9.8	0.11	1.17%

#### 4. COMPARISON STUDY:

Sample ID	Old Instrument	New Instrument
518795	5.2	5.1
518758	5.3	5.3
518922	7.7	7.4
518377	14.2	13.2
518754	8.0	7.8
518549	6.3	6.4
518584	9.8	11.1
518434	6.1	6.0
518963	10.2	9.8
518829	9.7	9.7
518483	6.9	6.5
519035	6.6	6.5
518438	5.6	5.4
518573	7.5	7.3
518823	8.8	8.6
518627	7.7	7.6
519027	10.4	10.3
518911	6.4	6.2
518791	8.1	7.9



#### Linear Regression Statistics

No. of Samples	19
Slope	0.9614
Y-Intercept	0.1798
Correlation (r)	0.9653

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