

Site name:	KRM HEALTHCARE
Address:	436/437, Laxmi Plaza, Laxmi Industrial estate, Andheri (West)
City	MUMBAI
State	MAHARASTRA
Province-Postal code	400068
Contact Name	KUMUDINI RAWOOL
Contact Number	7066236631

Calibration Certificate

Date	10/08/2023	Instrument Model	SpeedBio S8	Instrument Serial Number	IA2D00007572
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We certify that the SpeedBio instrument specified above and installed in your lab is calibrated and the performance was found satisfactory.

High Pressure Pump Flow Rate Reference: Service Manual: Section

Measured with (Device manufacturer and model)	Device Serial Number	Device Calibration date (dd mmmm , yyyy)
Measuring Cylinder-139.523.01A	11.20/2123	20/12/2022
Specified Range@ Flow Rate	Measured Value	
1.435- 1.537 ml/Minute	1.478	

Column Holder temperature Reference: Service Manual:

Measured with (Device manufacturer and model)	Device Serial Number	Device Calibration date (dd mmmm , yyyy)
MECO 108B+TRMS	23650307	10/08/2023
Specified Range @ 35°C	Measured Value	
35-39°C	38.1°C	

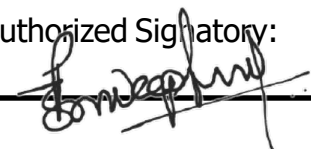
Detector log value Reference: Service Manual: Field Bulletin

Measured with	Specified Range	Measured Value
Instrument Service Software	2500-3500	3100

The next calibration is due on	09 August,2024	(dd mmmm , yyyy)
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For SpeedBio India Pvt Limited

Authorized Signatory:





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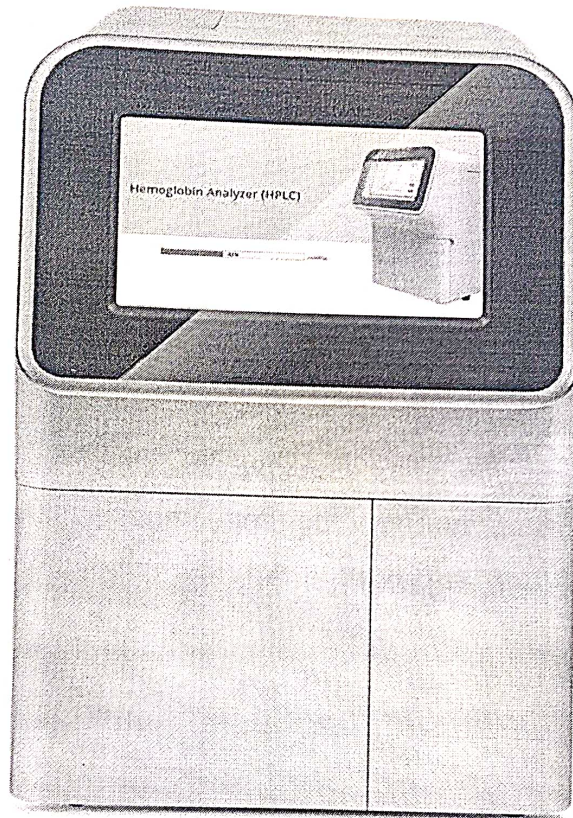
INSTALLATION QUALIFICATION		
CSR No. SIPL22-23/0074		Date: 10/08/2023
Customer Name: KRM HEALTHCARE		
Address: 436/437, Laxmi Plaza, Laxmi Industrial Estate, Andheri(WEST)		
City: Mumbai	State: Maharashtra	ZIP Code: 400068
Contact Person: KUMUDINI RAWOOL		
Email ID: info@krmhealthcare.com		
Make: SPEEDBIO	Model: SPEEDBIO S8	Serial No: IA2D00007572
Location of Installation: Lab	Date: 10/08/2023	Time: 17:30PM
Events: (Date & Time) 10/08/2023	Start of Time: 11:00AM	End of Time: 04:30PM
Visiting Card/ Sticker Pated on Machine: Yes/No		
DETAILS OF PARTICIPANT WHO ATTENDED TRAINING		
Name of Participant:	Designation:	Contact No:
KUMUDINI RAWOOL	LAB INCHARGE	7066236831
AJAY JUNJUT	SR. TECHNICIAN	9167469420
BHOOMIKA RANVA	JR. TECHNICIAN	8433520241
DIVYA BOMBLE	JR. TECHNICIAN	8879178957
TEJAL NAYAK	JR. TECHNICIAN	8356955900
FREEZA RENTIA	JR. TECHNICIAN	9324247934
KATISHMA MOTE	JR. TECHNICIAN	9372120841
KETAN GUJAT	JR. TECHNICIAN	7700069381
AASHISH KALAMBATE	JR. TECHNICIAN	8459602076
Certify that we have received the machine and accessories as per the invoice and agreement the machine is installed and working satisfactory. Operators training conducted and we are satisfied with the performance of the Machine		Name of Service Engineer/Application Specialist: Bhuvnesh Sharma/Harsh tiwari
Lab Incharge/Lab Head:  Seal & Signature: 		Signature:  Date: -10/08/2023 Place: Mumbai (Maharashtra) 



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SpeedBio S8 Hemoglobin Analyzer

Performance verification report



Laboratory Name:- : SPECTRUM DIAGNOSTICS PVT.LTD.

Date: 10/08/2023

SpeedBio India Private Limited

Corporate Office: 512, City Centre Mall, Sector 12, Dwarka, Delhi-110075 India

Regd. Office: 2nd Floor, Plot No. 21, Khasra No. 33/8, Amberhai Extn., Sector 19, Dwarka, Delhi-110075 India



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Catalogue

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1. Operational Qualification

This scheme is mainly formulated with reference to the relevant requirements of CNAS- CL02 : 2012 《 Accreditation criteria for quality and competence of medical laboratories 》 (ISO15189: 2012, IDT). It is applicable to the performance verification of HbA1c test items of glycosylated hemoglobin analyzer. This scheme evaluates HbA1c test items from two aspects: measurement precision and methodological comparison.

1.1 Instrument information

Instrument to be evaluated	Instrument model	Instrument serial number	Evaluated items
Glycosylated hemoglobin analyzer	S8	IA2D00007572	HbA1c

1.2 Experimental requirements

- (1) The operator shall be familiar with the instrument operation, evaluation scheme, parameter setting, data statistics and other work before conducting the formal evaluation process;
- (2) Before testing. Adjust the instrument as required, use supporting reagents and calibrators to calibrate the instrument;

Environmental conditions

Laboratory environment	Temperature		Humidity		Voltage	
	Specified range	10-30°C	Specified range	≤70%	Specified range	100-240V

1.3 Supporting reagents and consumables

Serial Number	Name	Reagent lot number	Expiration date	QC passed(Y/N)
1	A/B/C/L eluent	H8SX230450	27/02/2025	Y
2	Calibrators	H8SX230037	02/03/2024	Y
3	Control materials	H8SX230037	02/03/2024	Y
4	Chromatographic Column	PS518022M	23/11/2024	Y

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2. Performance Qualification

Intra batch precision

Refer to the requirements on intra batch precision in YYT 1246-2014(Article 3.3 of the pharmaceutical industry standard for glycosylated hemoglobin analyzer) to formulate the intra batch precision verification method and form the manufacturer's internal standard.

1.1 Experimental scheme: select fresh anticoagulant whole blood samples in t

1.2

1.3 he range of 4.0 ~ 7.5% and 9.1 ~ 15.0% respectively, repeat test for 20 times, calculate SD and CV respectively.

1.4 Judgment standard: $CV \leq 3.0\%$ (required by industry standards).

1.5 Test data and result verification conclusion

Table 2 Intra batch precision results

Date of tests	10-08-2023	
Serial number	Sample 1 (mg / L)	Sample 2 (mg / L)
1	5.3	8.6
2	5.3	8.7
3	5.3	8.7
4	5.3	8.7
5	5.3	8.7
6	5.3	8.7
7	5.3	8.7
8	5.3	8.7
9	5.3	8.6
10	5.3	8.7
11	5.3	8.7
12	5.3	8.7
13	5.3	8.7
14	5.3	8.7
15	5.3	8.7
16	5.3	8.7
17	5.4	8.7
18	5.4	8.6
19	5.4	8.6
20	5.3	8.6
Average value	5.3	8.7
SD value	0.04	0.04
CV value	5.30	8.7

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2. Precision between batches

Refer to the experimental requirements for daytime precision in WST 461-2015 (Glycosylated hemoglobin test standard article 6.2.2 of health industry standard) and NCCLS EP5-A2 (Experimental requirements for daytime precision in the precision performance evaluation of quantitative measurement methods).

2.1 Experimental scheme : use two levels of quality control materials (high and low values) respectively, test them four times a day for 3 working days. Calculate the average value, standard deviation and coefficient of variation based on 20 results within 3 working days.

2.2 Requirement: $CV \leq 3.0\%$

2.3 Results

Table3 Precision between batches

Test time	Quality Control 1	Quality Control 2
DAY-1 (10/08/2023)	5.3	8.6
	5.3	8.7
	5.3	8.7
	5.3	8.7
DAY-2 (11/08/2023) Morning	5.3	8.7
	5.3	8.7
	5.3	8.7
	5.3	8.7
DAY-2 (11/08/2023) Evening	5.3	8.6
	5.3	8.7
	5.3	8.7
	5.3	8.7
DAY-3 (12/08/2023) Morning	5.3	8.7
	5.3	8.7
	5.3	8.7
	5.3	8.7
DAY-3 (12/08/2023) Evening	5.4	8.7
	5.4	8.6
	5.4	8.6
	5.3	8.6
		8.7
Average value	5.3	0.04
SD value	0.04	8.7

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CV value
5.30
0.46

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3. Methodology comparison

Refer to the accuracy requirements in YYT 1246-2014(Article 3.2 of the pharmaceutical industry standard for glycosylated hemoglobin analyzer) to formulate the comparison method between instruments and form the manufacturer's internal standard.

3.1 Experimental scheme: Select 10 patients, collect anticoagulant whole blood on the same day and at the same time, test each sample twice and take the mean value.

Use the comparison instrument to test each sample twice and take the mean value. Take the mean value tested by the comparison instrument as the standard, the relative deviation shall be within $\pm 8.0\%$.

3.2 Test results and verification conclusions:

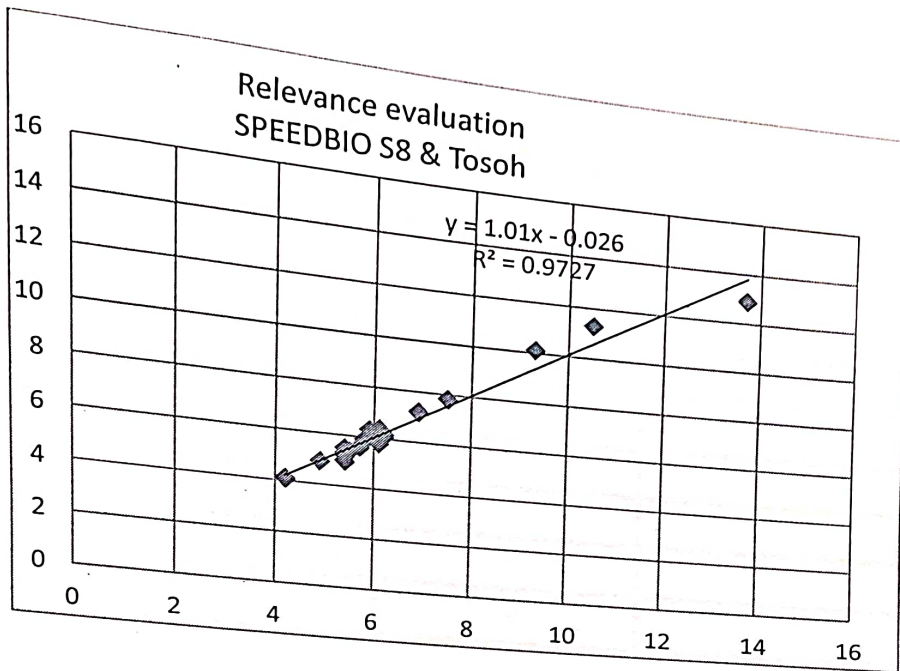
Table 5 Comparison results between instruments

Sample Number	SPEEDBIO S8	SPEEDBIO S9	Relative Deviation
	Test Result	Test Result	
1	5.3	5.2	-1.92
2	5.7	5.6	-1.79
3	6.2	6.3	1.59
4	5.8	5.7	-1.75
5	8.5	8.6	1.16
6	5.8	5.9	1.69
7	6.5	6.6	1.52
8	5.5	5.5	0.00
9	5.9	5.9	0.00
10	5.9	5.9	0.00
Allowable Deviation	The relative deviation within $\pm 8.0\%$.		
Conclusion	The relative deviation of 10 samples meets the requirements, and the accuracy verification has Passed.		

Graph 2 Relevance evaluation

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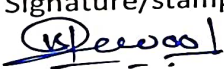




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3. System performance judgment

Through the above experimental analysis, the performance evaluation results are summarized as below:

Evaluation Items	Evaluation conclusion	
	Qualified	Unqualified
Environment and status	√	
Intra batch precision	√	
Precision between batches	√	
Methodological comparison	√	

As shown in the above table, the precision and methodological comparison results of SpeedBio S8 hemoglobin analyzer meet the standards of quality requirements (Quality requirements of accreditation criteria for quality and competence of medical laboratories). The verification is qualified.

FOR CUSTOMER (Name & Signature with stamp)	FOR SPEEDBIO INDIA PVT LTD (Name & Signature with stamp)
Name of Lab Manager/Lab Head: Kumudini Bhikeji Ramool	Name of Service Engineer/Application Specialist: Bhuvnesh Sharma/Harsh tiwari
Signature/stamp:  	Signature/stamp:   
Date: 11-8-2023	Place: Mumbai (Maharashtra) Date:-12/08/2023

SpeedBio India Private Limited