



ISO 9001 : 2015
RQ91/3144

S.M. ENTERPRISES 26

(Calibration and Testing of Electrical, Electronic & Precision Instruments.)

Years of Services

Office/Cal. Lab : Plot No. 12, "Ganesh Niwas", Sanjeevaiah Nagar, Co-operative Society, Besides Tadbund Hanuman Temple, Sikh Village, Secunderabad - 500 009. T.S. INDIA ☎ : (040) 27840697, 48541008
Cell : 9848020798, 9948291008, 9948292008, 9948293008, 9948294008 Email : msudheer_98@yahoo.com, msudheer_98@smentp.org, SME_003@YAHOO.IN, url : www.smentp.org

CALIBRATION CERTIFICATE

CALIBRATION ON 20/11/2021		CALIBRATION DUE 19/11/2022	
1. Calibration Report Ref. No. & Date :		SME/PA/PH/DF/CAL-02/2021; Dt:20/11/2021	
2. Requested by : (Name and address of the organization)		M/s. Pace Hospitals, Hi-tech City, Hydreabad T S	
3. Instrument under calibration		HEMOTOLOGY ANALYZER	
4. Make / Model		MIDRAY / BC-5140	
5. Instrument ID No.		PHM/BME/LAB/HAM/01	
6. Instrument SI No		TP-99000471	
7. Location		4th Floor	
8. Department:		LAB	
9. Environmental Conditions		Temperature : 28 +/- 2°C; R.H: 65 +/- 5 %	
10. Test parameter & condition		Electrical Vs Electrical	
11. Standards Instruments used for Calibration		Master Digital Multi meter	
12. Traceability Certificate Ref. No.		ETL/1046/21/C/F/394;Dt:07/10/2021;DueDt:07/10/2022	
TEST RESULTS			
A)	Power Supply	Acceptable Limits As Per Spec	Actual Value
1)	Voltage min	100 VAC min	115 VAC
2)	Voltage max	240 VAC max	245 VAC
B	Frequency		
1)	Frequency	50Hz / 60 Hz	55 Hz
C	Operating Environment		
1)	Temperature	10 to 30 °C	25°C
2)	Humidity	20% to 85%	85%
		70 to 106kpa	90kpa
PLEASE NOTE: THE INSTRUMENT ERROR FOUND TO BE WITHIN THE SPECIFIED ACCURACY LIM AND THIS CERTIFICATE VALID FOR PERIOD OF ONE YEAR FROM THE DATE OF ISSUE.			
CALIBRATED BY S.M. Enterprises 		VERIFIED BY M/s. Pace Hospitals,	
QA INCHARGE			



GSTIN : 36AFVPS4924F1ZW

Service Tax No.: AFVPS4924FST001

PAN No.: AFVPS4924F

NABL APPROVED LAB (CC-2471) / Approved Laboratory of ISO 9001-2015

TEST EQUIPT. / STANDARDS USED ARE TRACEABLE TO NATIONAL STANDARDS



CALIBRATION CERTIFICATE

Customer Name	Pace Hospitals		
Department	Laboratory		
Address	Beside Avasa Hotel, Near Hitech City Metro Station, Hyderabad		
	Date of Calibration	02/10/2021	
Instrument	BC 5140	Next Calibration Date	01/Mar/2022
Serial No	TP-99000471	Calibrator Lot Number	PLUS0333
	Calibrator Expiry date	2021-11-10	

	Parameter	Target	Range	Mean of Measured Values	New Factor	Old Factor
<u>Calibration Values</u>	WBC x 10 ⁹ /L	8.93	8.73-9.13	8.93	99.1	100
	RBC x 10 ¹² /L	4.49	4.40-4.57	4.49	99.8	100
	HGB g/L	13.4	13.2-13.6	13.4	100	100
	MCV fl	92.0	90.0-94.0	92.0	99.6	100
	PLT x 10 ⁹ /L	259	246-271	259	100	100

This is to certify that the BC5140.....H.E.M. - 5 Part.....Analyzer Sr. No: TP-99000471.....9-Jan-2020.....installed at Pace Hospitals, Hyderabad has been calibrated using the CBC-5D CAL standard reference material.....CBC-CAL-PLUS.....Calibrator. Traceability of.....R.S.D. Systems - CBC.....Calibrator material from the manufacturer is attached along with this certificate.


Bharath Bhattula



Engineer- Customer Service

AGAPPE DIAGNOSTICS LTD. | ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

CORPORATE OFFICE / REAGENT PLANT
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MUMBAI [REGISTERED OFFICE]

DELHI OFFICE

BANGALORE OFFICE



Installation and Validation Report

AGAPPE

1. Instrumental Qualification:

1.1 Dealer and Customer Information:

Dealer		Customer	
Name: Agappe Diagnostics Ltd	Name:	Pace Hospitals	
Contact Person: Bharath Battula	Contact person:	U. Anusri	
Telephone No:	Telephone No:	91014706552	

1.2 Instrument Information:

Type of Instrument:			
Serial No.:	TP-99000471	Installation Date:	09/01/2020

1.3 Transport Damage:

Package Damaged:	Yes	No <input checked="" type="checkbox"/>
Machine(Or Accessory) Damaged:	Yes	No <input checked="" type="checkbox"/>
If yes, please specify:		
Please return the damaged parts, including a malfunction report.		

1.4 Initial Check:

Parts missing? (Check against the packing list)		No	Yes <input checked="" type="checkbox"/>
		Yes → Please specify:	
Part number:	Part description:		
Part number:	Part description:		
Part number:	Part description:		
Part number:	Part description:		

ADL/KO/SER/0010/21-22

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YOUR BEST PARTNER IN DIAGNOSTICS

1.5 Installation:

Perform the next steps:

- Install the PC (Computer, Monitor, Printer, Keyboard and Mouse)
- Install the Software (the software version: _____) *yes*
- Connect the PC, Analyzer, Monitor, Keyboard and Mouse.
- Remove the fixed plate.
- Install the Probe
- Connect the Fluidic Tubing and Prepare the Waste Liquid Tank
- Load the Wash Buffer and the Waste Cuvette Boxes
- Prepare the Cuvette Boxes and the Substrate Tubing Wash Solution

2. Operational Qualification:

Serial Number: <i>TP-99000471</i>	
Power Up PC, and Exit to Desktop.	
Power Up the analyzer, and run software from start menu.	
Set the Atmosphere Pressure and Run "Fluidic Prime".	
Confirm the Mechanical Position	
Set the Initial Maintenance Record	
Load the Reagents and Import the Items Parameters	
Confirm the Basic Performance Testing	
Remarks: _____	
Technical acceptance: <i>yes</i>	
Date: _____	
<i>[Signature]</i> Service Engineer	<i>[Signature]</i> Customer
Name: Bharath Battula	Name: Pace Hospitals

AGAPPE DIAGNOSTICS LTD.

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24229MH1998PLC115413

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3. Performance Qualification:

Clinical Performance Validation				
Run Calibrations <i>yes</i>				
Run QC <i>yes</i>				
Test Items	QC range level 1	Test result	QC range level 2	Test result
H.B	5.3 - 6.1	5.8	15.4 - 17.0	16.6
P.B.C	1.95 - 2.31	2.09	4.79 - 5.39	5.11
W.B.C	2.75 - 3.75	3.47	14.59 - 19.5	17.89
PLT	31 - 71	51	455 - 575	535
HCT	16.3 - 19.3	17.9	48.7 - 53.5	52.3
MCV	78.7 - 88.4	85.7	95.4 - 105.4	102
MCH	24.3 - 29.3	27.9	29.3 - 34.3	32.6
MCHC	290 - 350	326	287 - 347	318
Remarks:				
Technical acceptance <i>yes</i>				
Date:	<i>9/11/2020</i>		<i>(d/m/y)</i>	
Service Engineer <i>[Signature]</i>			Pace Hospitals <i>[Signature]</i>	
Name:	Bharath Battula		Name:	<i>[Signature]</i>



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