

Instrument Installation Acceptance Statement

Account Name: Vishwaraj Hospital, Rajbaug, Pune-Solapur Road, Loni Kalbhor,

City: Pune-412201 State: Maharashtra

Instrument Installed: Dimension EXL 200 S/N: DE271193
S/N: _____
S/N: _____

Install Completion Date: 19th July 2019

Customer:

I understand and state that the installation of the Dade Behring instrument(s) has/have been completed to my satisfaction, including training of laboratory personnel on the operation and maintenance of this instrument(s).

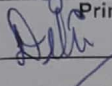
I also state that the instrument(s) is/are (1) operating in accordance with manufacturing specification and (2) the instrument(s) and consumable(s) performance has/have been validated according to Dade Behring's protocol.

Customer's Name: Dr. Aniruddha Garud
Print Name

Customer Signature:  Date: 20/07/2019

Dade Behring CAS:

CAS's Name: Mr. Nitin Deshmukh
Print Name

CAS Signature:  Date: 19/07/2019

RightFax (302-631-7259) a copy of this Customer Acceptance Statement within 2-3 business days of completing the installation to the Installation Coordinator in Glasgow, DE.

THIS PAGE FOR INTERNAL USE ONLY

Voltages:

Wall Receptacle	Power OFF	Power ON	Power ON
G-H	_____ V (0-1V)	_____ (90-110V)	_____ (198-264V)
	_____ V (0-1V)	_____ (110-125V)	
H-N	_____ V (0-1V)	_____ (90-110V)	_____ (198-264V)
	_____ V (0-1V)	_____ (110-125V)	
G-N	_____ V (0-1V)	_____ (Max 0.5)	_____ (< 2V)
	_____ V (0-1V)	_____ (< 2 V)	

Gaps:

Syringe

(Glass to plunger)	Observed	Adjusted	Specification
Sample Metering	<u>OK</u>	<u>OK</u>	(.005" - .010")
Sample Flush	<u>OK</u>	<u>OK</u>	(.005" - .010")
Reagent 1 Metering	<u>OK</u>	<u>OK</u>	(.005" - .010")
Reagent 1 Flush	<u>OK</u>	<u>OK</u>	(.005" - .010")
Reagent 2 Metering	<u>OK</u>	<u>OK</u>	(.005" - .010")
Reagent 2 Flush	<u>OK</u>	<u>OK</u>	(.005" - .010")
Reagent 3 Flush	<u>OK</u>	<u>OK</u>	(.005" - .010")
IF HM Instrument Chemistry Wash	<u>OK</u>	<u>OK</u>	(.005" - .010")

Cuvette Manufacture Solenoids

	Observed	Adjusted	Specification
Top Seal	<u>OK</u>	<u>OK</u>	(.010" *)
Cuvette Form	_____	_____	(0.020" - 0.045"**)
U-Seal	_____	_____	(0.020" ± 0.010"*)
Capstan	_____	_____	(.005" ± 0.010"*)

* Cuvette solenoid gaps are in the energized state with film installed.

** Solenoid gap is determined with solenoid de-energized and by manually pushing the solenoid shaft/armature forward until able to feel airflow with compressor and top seal (cuvette air valve) turned on.) The gap when solenoid is energized is likely to be ~~less~~.

NOTE: Any adjustments made must be recorded on the Installation Rating Form.

Operators

Topic: Sample Processing

Key **Other**

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Activity	Reference
Process patient sample using sample cup, primary tube (include barcoded tube if used)	Operator's Guide, <i>Sample Processing and Test Reports</i>
Process multiple fluid types, including urine assays	Operator's Guide, <i>Sample Processing and Test Reports</i>
Enter manual dilution factor	Operator's Guide, <i>Sample Processing and Test Reports</i>
Respond to system need; use ALT N to review needs screen	Operator's Guide, <i>Sample Processing and Test Reports</i>
Add and remove reagent cartridges	Operator's Guide, <i>Sample Processing and Test Reports</i>
Use ALT S to determine segment status and to delete segments	Operator's Guide, <i>Sample Processing and Test Reports</i>
Process short sample: • use ALT I to respond to Insufficient Sample message • use SSC • use sample cup • use tube fill guide before processing	Operator's Guide, <i>Sample Processing and Test Reports</i>
Review use of sample status key, F2	Operator's Guide, <i>Sample Processing and Test Reports</i>
Edit samples, including adding and deleting tests, rerunning tests and deleting samples	Operator's Guide, <i>Sample Processing and Test Reports</i>
Use CTL Help and ALT R in response to reagent management icon	Operator's Guide, <i>Sample Processing and Test Reports</i>
Perform manual query, if used	Operator's Guide, <i>Sample Processing and Test Reports</i>
Review use of these keys: Pause Exit/Shift Exit Reset Backspace/Backslash Run Up Arrow/Down Arrow Alarm Pg Up/Pg Down CTL Stop	Operator's Guide, <i>System Overview</i>
Review Help functions/keys: Help, ALT Help, CTL Help, Shift Help	Operator's Guide, <i>Appendix</i>
Review these key combinations: ALT I, ALT P, ALT O	Operator's Guide, <i>Appendix</i>
Review interpreting test report messages	Operator's Guide, <i>Appendix</i>

Operators

Topic: Customization (continued)

Key	Other	Activity	Reference
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Configuring QC Alerts	Operator's Guide,
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Defining QC Ranges	Operator's Guide
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Defining QC Products	Operator's Guide,
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Editing QC Products	Operator's Guide,
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Defining QC Panels	Operator's Guide,
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Defining Calibration Products	Operator's Guide,
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Configuring Calibration Alert	Operator's Guide
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Setting up Calibration Auto Acceptance	Operator's Guide,
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Grouping Calibration Alerts	Operator's Guide,
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Setting Up Calibrations Manually	Operator's Guide
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Grouping QC Alerts	Operator's Guide,
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Retrieving Calibration History	Operator's Guide,
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Storing Laboratory Data	Operator's Guide,

Operators

Topic: Problem Resolution

Key	Other	Activity	Reference
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Review response to alarm ON/OFF	Operator's Guide, <i>Introducing</i> ,
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Review response to error messages using ALT M	Operator's Guide, <i>Introducing</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Review using Reset key to clear error messages	Operator's Guide, <i>Introducing</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Review active and resident error logs; including More Info and See Minor functions	Operator's Guide, <i>Troubleshooting</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Review troubleshooting, emphasizing system check troubleshooting guidelines	Operator's Guide, <i>Troubleshooting</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Review icons and using CTL Help to respond to icons	Operator's Guide, <i>Appendix</i>

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CALIBRATION CERTIFICATE

This is to certify that Dimension EXL 200, Equipment ID: 1042762920 & serial number DE271193 installed at Maers Vishwaraj Hospital has been **successfully calibrated on January 6, 2022**. Please find below, results of calibration performed on the instrument.

Please find below, results of calibration performed on the instrument.

Photometric Calibration Data are as follows:

Parameter	Result	Acceptable Ranges
Photometer Dark Calibration		
Reference	9266.29 Hz	8500 – 11000 Hz
Sample Outer ON	9448.72 Hz	8500 – 11000 Hz
Sample Outer OFF	9444.90 Hz	8500 – 11000 Hz

Lamp Calibration		
Low Calib Level	52.4%	NA
High Calib Level	58.2%	NA
Photometer Arm Alignment	-5%	-2 to -9

Filters	Offset (mAU)	System Check Results	Range
293 nm	292	0.44	+/- 2.5
340 nm	323	0.29	+/- 1.5
383 nm	336	0.24	+/- 1.5
405 nm	325	0.18	+/- 1.5
452 nm	322	0.24	+/- 1.5
510 nm	300	0.27	+/- 1.5
540 nm	309	0.37	+/- 1.5
577 nm	307	0.34	+/- 1.5
600 nm	302	0.23	+/- 1.5
700 nm	306	0.26	+/- 1.5

Siemens Healthcare Private Limited

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 Vikhroli (E), Mumbai - 400 079 Email: hc_contact.india@siemens-healthineers.com
 www.siemens.co.in

System Check Results – CHK Lot No: BB2075

Parameters			Range	
	Mean	SD	Mean	SD
Reagent 1	398.00	1.65	392+/-15	< 3.8
Reagent 2	399.53	1.89	392 +/-15	< 3.8
Sampler	39.80	0.24	39.0 +/-2	< 0.8

Temperature			
Cuvette		37.0°C	37.0°C +/- 0.2
Regent Tray		4.2°C	2°C to 8°C
HM		43.0°C	43.0°C +/- 1.0

The instrument is working satisfactorily, subsequent to Calibration of the above parameters, and the next PM is due on July 2022

Next Calibration is due in the month of July 2022

Note: CHK kit is an USFDA approved kit used in performing the system check in all Dimension systems. The carton value is a predetermined value for which the limits are defined in system check screen and operator guide of Dimension.

Siemens Healthcare Private Limited

Jagannath Choudhary
Regional Customer Care Manager – West & West Central



CALIBRATION REPORT

To.

DATE- 01/04/21

**Maharashtra Academy of Engineering and Educational Research,
Vishwaraj Hospital, Pune**

Dear Sir,

As desired by you please find enclosed herewith the Calibration report

1. Instrument: Bio-chemistry Analyzer ERBA CHEM-7 S.N- S1709178
2. Range of the instrument: Optical density Linear form 0-2.5
3. Date of Calibration – 01st Apr 2021
4. Next Calibration Due- 31st Mar 2022

Quality Control Results-

Test Type	Test Results	Range
End Point (GLU)	95.8	80.2-108.2
Fix Time (URE)	33.11	29.85-37.85
Kinetic (SGPT)	41.6	37.5-52.5

Thanking you and assuring of our prompt attention at all times.

Yours faithfully,

For **TRANSASIA BIO-MEDICALS LTD.**


Swapnil Kamarikar
Service Engineer



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Handwritten mark resembling a stylized 'T' or '7' above some faint, illegible text.



Calibration Certificate

Date 01st Apr 2021

To,
Maharashtra Academy of Engineering and Educational Research,
Vishwaraj Hospital, Pune.

Dear Sir,
As desired by you please find enclosed herewith Technical calibration report
for your Urine Analyzer Model: Laura M Sr. No. 8381160315.

1. Date of Calibration - : 01st Apr 2021
2. Next Calibration date- : 31st Mar 2022

Calibration status:

Ref	R=335	G=336	B=338
LEU	R=335	G=336	B=338
NIT	R=335	G=336	B=338
URO	R=335	G=336	B=338
PRO	R=335	G=336	B=338
pH	R=335	G=336	B=338
BLD	R=335	G=336	B=338
S.G.	R=335	G=336	B=338
KET	R=335	G=336	B=338
BIL	R=335	G=336	B=338
GLU	R=335	G=336	B=338
VTC	R=335	G=336	B=338

Calibration value Range 333+/- 10 (323 -343)

Calibration of instrument is ok.
Thanking you and assuring of our prompt attention at all times.

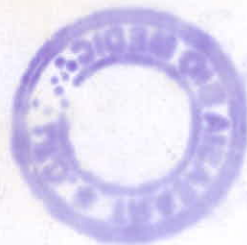
Yours faithfully,

For TRANSASIA BIO-MEDICALS LTD.


Mr. Swapnil Kamarikar
Service Engineer



ARAB



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