





TRANSASIA

EM- 200

SR. NO 2002692

FULLY AUTOMATIC BIOCHEMISTRY ANALYZER

IQ,OQ AND PQ

For

**SKYLARK DIAGNOSTIC CENTRE
GOREGAON , MUMBAI.**

**Marketed by:
Transasia Bio-Medicals Ltd.,
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI - 400 072**



Installation Qualification for EM200, Sr. No.:- 2002692

Customer Name : Skylark Diagnostic Centre

Address : Sarthak, 1st floor,
Opp. Udipi Vihar Hotel,
Arey Road,
Goregaon East
Mumbai- 400063

Instrument Name : EM-200

Serial Number : 2002692

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

Found the System to have been delivered in satisfactory condition and no external physical damaged observed on the same. Package was kept in Good Condition as per the directional indicators like not tilt, indicating the System has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

External Requirements for Installation:

1. Input voltage of 220V-240V / 50Hz or 60Hz.
2. Recommended Operating Temperature is 15-30 °C, with Relative Humidity 30-85% and Atmospheric Pressure 70-106 kPa.



Installation Qualification for EM-200, Sr. No.:- 2002692

Customer Name : Skylark Diagnostic Centre.
Address : Sarthak, 1st floor,
Opp. Udipi Vihar Hotel,
Aarey Road,
Goregaon East
Mumbai- 400063
Contact Person : Dr. Swati Datar
Instrument Model : EM-200
Serial Number : 2002692
Date of Installation : 25-10-2023

The instrument was installed and was found to be working satisfactorily. Preliminary Customer Training was provided and standardization of the parameters was done. The results were found to be within the expected range and System found to be working satisfactorily.

TBM, Technical Services Department
Mumbai

Name : Mr. Abhijit Tillu

Designation : Service Engineer


Signature : 



CUSTOMER : Skylark Diagnostics Centre

Contact Person : Dr. Swati Datar

Designation : Lab Director

Signature : 
Dr. Swati Datar
MBBS (Mum) M.D. Path. (Mum)
Consultant Pathologist
Registration No. 084058
084053



Installation Qualifications for EM-200, Sr. No.:- 2002692

Carried out all the Installation Procedures as per the Installation Procedure. (Done)

Carried out all the necessary checks and alignments. (Done)

Carried out all the necessary system checks and tests. (Done)

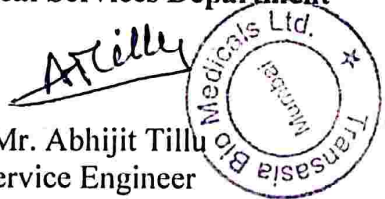
Carried out Priming and Cleaning Operations. (Done)

Checked the results by running the controls and found OK. (Done)

Handed over the Instrument for Operators Training & Qualifications. (Done)

For TBM, Technical Services Department

Name : Mr. Abhijit Tillu
Designation : Service Engineer





Installation Certificate for EM-200, Sr. No.:- 2002692

This is to certify that the instrument EM-200 Sr. No:- 2002692 is successfully Installed and Commissioned at Skylark Diagnostic Centre, Goregaon, Mumbai and the Installation Protocol has been successfully completed for the above instrument.

Date of Installation : 25-10-2023

TBM, Technical Services Department

Atella



Name : Mr. Abhijit Tillu
Designation : Service Engineer

- Patient Entry(F2)
- Test Parameter(F3)
- Profiles / Calc(F4)
- Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Maintenance(F12)
- Settings
- Hibernate
- Shut Down
- Help (F1)

Arm / Stirrer

Arm
 Stirrer

Current State :
Next Possible Action of Assembly

DCF
Dummy Run
Initialize
Execute

Calibration

Clock Wise
 Anti-Clock Wise

Accept Cancel Default
Save Calib Calibration Menu

Sample Tray

Initialize Pulse Barcode Scan

Rotate To Position 1

ASP Barcode Scanner Beam Inner On Off

Reagent Tray

Initialize Pulse Barcode Scan

Rotate To Position 01-1

RGT Barcode Scanner Beam On Off

RCT Tray

Initialize Pulse Rotate To 39

Syringe

Initialize Aspirate 375 µl
Dispense 0 µl

CRU Unit

Initialize Run Check Down

CRU Biohazard Suct'n Pump	On	Off
CRU Water Dispense Valve	On	Off
CRU Detergent Disp Pump	On	Off
CRU Overflow Suct'n Valve	On	Off

Valve And Pump

Arm Trough Valve	On	Off
Arm Probe Clean Valve	On	Off
Stirrer Trough Valve	On	Off

RGT 8.0 P P
RCT Coils 37.0 P P

Read Stop

Communication

Select Com Port COM3 Check

Misc Commands

S.N. ERROR MESSAGE EC

Emergency Stop

Patient Entry (F2)
 Add Parameter (F3)
 Profiles / Calc (F4)
 Calibration (F5)
 Consumables (F6)
 Status Monitor (F7)
 Search (F8)
 Reports (F9)
 Master
 Utility (F11)
 Service Check
 Settings
 Hibernate
 Shut Down
 Help (F1)

Maintenance **Cell Blank** **Maintenance Log**

SPAN

MANUAL SPAN AUTO SPAN Cuv : 01 Gain Value OK Out of Range

Wavelength	340	405	505	546	578	600	660	700
Gain	621	477	483	488	574	566	678	448

START

WASH

WASH MAINTENANCE COMMANDS

CUVETTE RINSE
 WATER SAVE
 AUTO WASH
 PROBE WASH
 PRIME WASH

START

DEAD VOLUME CALIBRATION

SELECT CONTAINER TYPE

Sample TUBE (10 ml) Pos.3
 Sample CUP (2 ml) Pos.2
 Sample TUBE (5.7 ml) Pos.1
 Sample STD CUP (500 µl) Pos.1-1
 Reagent Inner Pos.1
 Reagent Outer Pos.2
 Reagent 5ml Adaptor Pos.3

CALIBRATE
DEFAULT
STOP

AUTO MAINTENANCE

START-UP SHUTDOWN **START**

MAINTENANCE ERRORS

S.N.	ERROR MESSAGE	EC

Select Wavelength :

GRAPH

Present Absorbance Range 0.0524 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0693	11	0.0693	21	0.0659	31	0.0588	41	0.0704
2	0.0780	12	0.0632	22	0.0717	32	0.0739	42	0.0724
3	0.0966	13	0.0725	23	0.0559	33	0.0862	43	0.0942
4	0.1083	14	0.0781	24	0.0630	34	0.0747	44	0.0670
5	0.0717	15	0.0625	25	0.0673	35	0.0647	45	0.0668
6	0.0666	16	0.0685	26	0.0653	36	0.0630		
7	0.0600	17	0.0702	27	0.0621	37	0.0756		
8	0.0623	18	0.0628	28	0.0674	38	0.0651		
9	0.0606	19	0.0574	29	0.0582	39	0.0863		
10	0.0673	20	0.0594	30	0.0643	40	0.0736		

Previous Absorbance Range 0.0525 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0722	11	0.0722	21	0.0685	31	0.0613	41	0.0731
2	0.0814	12	0.0660	22	0.0740	32	0.0770	42	0.0748
3	0.0990	13	0.0752	23	0.0584	33	0.0887	43	0.0966
4	0.1109	14	0.0807	24	0.0654	34	0.0770	44	0.0694
5	0.0744	15	0.0654	25	0.0705	35	0.0673	45	0.0695
6	0.0694	16	0.0718	26	0.0675	36	0.0651		
7	0.0626	17	0.0729	27	0.0644	37	0.0778		
8	0.0654	18	0.0647	28	0.0699	38	0.0678		
9	0.0636	19	0.0607	29	0.0607	39	0.0884		
10	0.0706	20	0.0620	30	0.0669	40	0.0765		

Indication :

Navigation buttons: Home, Back, Forward, Print, EXPORT

- atient Entry(F2)
- ist Parameter(F3)
- profiles / Calc(F4)
- C/Calibration(F5)
- onsumables(F6)
- tatus Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Settings
- Hibernate
- Shut Down
- Help (F1)

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- Patient Entry(F2)
- Test Parameter(F3)
- Profiles / Calc(F4)
- Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Settings
- Hibernate
- Shut Down
- Help (F1)

Maintenance Cell Blank Maintenance Log
GRAPH

Select Wavelength : 405

Present Absorbance Range 0.0314 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0687	11	0.0689	21	0.0687	31	0.0624	41	0.0758
2	0.0765	12	0.0662	22	0.0726	32	0.0737	42	0.0781
3	0.0938	13	0.0740	23	0.0628	33	0.0847	43	0.0938
4	0.0935	14	0.0794	24	0.0655	34	0.0744	44	0.0689
5	0.0723	15	0.0661	25	0.0708	35	0.0694	45	0.0697
6	0.0699	16	0.0709	26	0.0715	36	0.0656		
7	0.0668	17	0.0716	27	0.0663	37	0.0754		
8	0.0664	18	0.0666	28	0.0722	38	0.0689		
9	0.0638	19	0.0633	29	0.0633	39	0.0763		
10	0.0687	20	0.0643	30	0.0665	40	0.0762		

Previous Absorbance Range 0.0314 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0714	11	0.0714	21	0.0712	31	0.0647	41	0.0781
2	0.0794	12	0.0687	22	0.0747	32	0.0765	42	0.0801
3	0.0961	13	0.0766	23	0.0650	33	0.0868	43	0.0960
4	0.0960	14	0.0817	24	0.0675	34	0.0765	44	0.0709
5	0.0746	15	0.0687	25	0.0737	35	0.0716	45	0.0718
6	0.0723	16	0.0738	26	0.0733	36	0.0673		
7	0.0689	17	0.0742	27	0.0685	37	0.0772		
8	0.0691	18	0.0684	28	0.0743	38	0.0713		
9	0.0664	19	0.0662	29	0.0655	39	0.0800		
10	0.0716	20	0.0667	30	0.0687	40	0.0787		

Indication : Select wavelength to view absorbance data.

←
→
↺
↻
EXPORT

Maintenance Cell Blank Maintenance Log

Select Wavelength : 505

GRAPH

Present Absorbance Range 0.0268 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0700	11	0.0679	21	0.0682	31	0.0636	41	0.0770
2	0.0746	12	0.0671	22	0.0736	32	0.0729	42	0.0798
3	0.0873	13	0.0744	23	0.0675	33	0.0808	43	0.0904
4	0.0830	14	0.0785	24	0.0681	34	0.0724	44	0.0717
5	0.0726	15	0.0686	25	0.0721	35	0.0719	45	0.0706
6	0.0718	16	0.0719	26	0.0741	36	0.0653		
7	0.0702	17	0.0724	27	0.0678	37	0.0723		
8	0.0688	18	0.0685	28	0.0747	38	0.0708		
9	0.0657	19	0.0673	29	0.0660	39	0.0753		
10	0.0688	20	0.0665	30	0.0671	40	0.0774		

Previous Absorbance Range 0.0268 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0717	11	0.0695	21	0.0699	31	0.0650	41	0.0786
2	0.0765	12	0.0687	22	0.0750	32	0.0747	42	0.0809
3	0.0888	13	0.0760	23	0.0688	33	0.0820	43	0.0918
4	0.0845	14	0.0802	24	0.0692	34	0.0735	44	0.0727
5	0.0740	15	0.0704	25	0.0740	35	0.0732	45	0.0718
6	0.0732	16	0.0739	26	0.0750	36	0.0663		
7	0.0713	17	0.0741	27	0.0692	37	0.0734		
8	0.0706	18	0.0692	28	0.0760	38	0.0723		
9	0.0674	19	0.0693	29	0.0674	39	0.0761		
10	0.0708	20	0.0680	30	0.0685	40	0.0790		

Indication : Select wavelength to view absorbance data.

Navigation buttons: Home, Back, Forward, Refresh, EXPORT

- Ident Entry(F2)
- Print Parameter(F3)
- Profiles / Calc(F4)
- Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Settings
- Hibernate
- Shut Down
- Help (F1)

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Select Wavelength : GRAPH

Present Absorbance Range 0.0239 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0684	11	0.0639	21	0.0667	31	0.0621	41	0.0737
2	0.0699	12	0.0663	22	0.0712	32	0.0713	42	0.0767
3	0.0832	13	0.0724	23	0.0651	33	0.0742	43	0.0860
4	0.0782	14	0.0737	24	0.0673	34	0.0683	44	0.0698
5	0.0698	15	0.0664	25	0.0705	35	0.0676	45	0.0659
6	0.0708	16	0.0676	26	0.0697	36	0.0631		
7	0.0683	17	0.0685	27	0.0661	37	0.0683		
8	0.0659	18	0.0645	28	0.0710	38	0.0690		
9	0.0629	19	0.0661	29	0.0642	39	0.0726		
10	0.0656	20	0.0652	30	0.0651	40	0.0732		

Previous Absorbance Range 0.0242 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0718	11	0.0670	21	0.0700	31	0.0649	41	0.0768
2	0.0735	12	0.0694	22	0.0745	32	0.0745	42	0.0794
3	0.0864	13	0.0754	23	0.0677	33	0.0769	43	0.0891
4	0.0815	14	0.0768	24	0.0698	34	0.0712	44	0.0722
5	0.0730	15	0.0696	25	0.0736	35	0.0706	45	0.0686
6	0.0738	16	0.0713	26	0.0719	36	0.0656		
7	0.0710	17	0.0719	27	0.0692	37	0.0710		
8	0.0693	18	0.0667	28	0.0741	38	0.0718		
9	0.0663	19	0.0695	29	0.0673	39	0.0747		
10	0.0692	20	0.0683	30	0.0679	40	0.0765		

Indication :

- ⌨ Patient Entry(F2)
- ⊕ Add Parameter(F3)
- 📁 Profiles / Calc(F4)
- 🔧 C/Calibration(F5)
- 📦 Consumables(F6)
- 📊 Status Monitor(F7)
- 🔍 Search(F8)
- 📄 Reports(F9)
- 👤 Master
- 🔧 Utility(F11)
- 🛑 Service Check
- ⚙ Settings
- 🛌 Hibernate
- 🛑 Shut Down
- 🆘 Help (F1)

- atient Entry(F2)
- st Parameter(F3)
- rofiles / Calc(F4)
- C/Calibration(F5)
- onsumables(F6)
- tatus Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Settings
- Hibernate
- Shut Down

GRAPH

Select Wavelength : 578

Present Absorbance Range 0.0210 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0690	11	0.0652	21	0.0677	31	0.0637	41	0.0730
2	0.0704	12	0.0675	22	0.0724	32	0.0723	42	0.0764
3	0.0823	13	0.0725	23	0.0653	33	0.0739	43	0.0847
4	0.0763	14	0.0735	24	0.0674	34	0.0684	44	0.0702
5	0.0704	15	0.0671	25	0.0707	35	0.0675	45	0.0664
6	0.0717	16	0.0674	26	0.0694	36	0.0641		
7	0.0684	17	0.0687	27	0.0678	37	0.0691		
8	0.0668	18	0.0653	28	0.0717	38	0.0690		
9	0.0641	19	0.0667	29	0.0642	39	0.0727		
10	0.0667	20	0.0662	30	0.0654	40	0.0728		

Previous Absorbance Range 0.0215 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0718	11	0.0678	21	0.0707	31	0.0660	41	0.0761
2	0.0734	12	0.0704	22	0.0751	32	0.0752	42	0.0790
3	0.0852	13	0.0753	23	0.0675	33	0.0764	43	0.0875
4	0.0794	14	0.0764	24	0.0692	34	0.0710	44	0.0721
5	0.0731	15	0.0696	25	0.0734	35	0.0702	45	0.0690
6	0.0743	16	0.0708	26	0.0711	36	0.0662		
7	0.0707	17	0.0717	27	0.0706	37	0.0712		
8	0.0699	18	0.0670	28	0.0744	38	0.0714		
9	0.0671	19	0.0697	29	0.0671	39	0.0745		
10	0.0702	20	0.0689	30	0.0678	40	0.0758		

Indication : Select wavelength to view absorbance data.

EXPORT

Help (F1)

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Select Wavelength :

GRAPH

Present Absorbance Range 0.0212 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0700	11	0.0649	21	0.0674	31	0.0637	41	0.0728
2	0.0713	12	0.0671	22	0.0730	32	0.0723	42	0.0765
3	0.0812	13	0.0719	23	0.0660	33	0.0736	43	0.0847
4	0.0753	14	0.0734	24	0.0684	34	0.0681	44	0.0714
5	0.0713	15	0.0674	25	0.0708	35	0.0682	45	0.0668
6	0.0729	16	0.0685	26	0.0696	36	0.0635		
7	0.0688	17	0.0697	27	0.0685	37	0.0671		
8	0.0679	18	0.0660	28	0.0726	38	0.0692		
9	0.0652	19	0.0675	29	0.0649	39	0.0717		
10	0.0671	20	0.0667	30	0.0654	40	0.0730		

Previous Absorbance Range 0.0220 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0705	11	0.0654	21	0.0681	31	0.0636	41	0.0736
2	0.0720	12	0.0677	22	0.0733	32	0.0729	42	0.0768
3	0.0820	13	0.0724	23	0.0662	33	0.0740	43	0.0853
4	0.0765	14	0.0743	24	0.0679	34	0.0688	44	0.0709
5	0.0718	15	0.0676	25	0.0711	35	0.0686	45	0.0670
6	0.0732	16	0.0699	26	0.0689	36	0.0633		
7	0.0688	17	0.0704	27	0.0688	37	0.0670		
8	0.0687	18	0.0655	28	0.0731	38	0.0693		
9	0.0660	19	0.0682	29	0.0653	39	0.0712		
10	0.0684	20	0.0673	30	0.0654	40	0.0739		

Indication :

Navigation buttons: Left arrow, Home, Right arrow, and EXPORT button.

- Patient Entry(F2)
- Test Parameter(F3)
- Profiles / Calc(F4)
- Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Settings
- Hibernate
- Shut Down
- Help (F1)

Maintenance Cell Blank Maintenance Log

Select Wavelength :

GRAPH

Present Absorbance Range 0.0215 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0686	11	0.0604	21	0.0623	31	0.0593	41	0.0693
2	0.0683	12	0.0627	22	0.0686	32	0.0681	42	0.0734
3	0.0741	13	0.0659	23	0.0647	33	0.0687	43	0.0799
4	0.0710	14	0.0696	24	0.0669	34	0.0637	44	0.0681
5	0.0684	15	0.0663	25	0.0674	35	0.0662	45	0.0633
6	0.0707	16	0.0674	26	0.0667	36	0.0584		
7	0.0664	17	0.0680	27	0.0648	37	0.0607		
8	0.0658	18	0.0641	28	0.0703	38	0.0663		
9	0.0630	19	0.0659	29	0.0630	39	0.0670		
10	0.0639	20	0.0639	30	0.0616	40	0.0696		

Previous Absorbance Range 0.0221 Abs. below : 0.02 Abs. above : 0.2

No.	1 To 10	No.	11 To 20	No.	21 To 30	No.	31 To 40	No.	41 To 45
1	0.0716	11	0.0637	21	0.0657	31	0.0615	41	0.0728
2	0.0712	12	0.0659	22	0.0711	32	0.0713	42	0.0763
3	0.0775	13	0.0686	23	0.0675	33	0.0716	43	0.0830
4	0.0750	14	0.0732	24	0.0689	34	0.0671	44	0.0703
5	0.0714	15	0.0691	25	0.0703	35	0.0693	45	0.0665
6	0.0736	16	0.0713	26	0.0686	36	0.0609		
7	0.0691	17	0.0711	27	0.0676	37	0.0631		
8	0.0695	18	0.0662	28	0.0736	38	0.0689		
9	0.0665	19	0.0694	29	0.0660	39	0.0691		
10	0.0677	20	0.0670	30	0.0643	40	0.0733		

Indication :

Navigation buttons: Left arrow, Home, Right arrow, and EXPORT button.

- Patient Entry(F2)
- Parameter(F3)
- Files / Calc(F4)
- Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Settings
- Hibernate
- Shut Down
- Help (F1)



Operations Qualifications for EM-200, Sr. No.:- 2002692

1. Verified all the Mechanical Movements : (Done)
2. Verified Hydraulics. : (Done)
3. Verified Electrical Systems : (Done)
4. Verified with Controls : (Done)

TBM, Technical Services Department



Name : Mr. Abhijit Tillu

Designation : Service Engineer

Date : 25-10-2023



Operational Qualification:

System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any, have been addressed.

The System is ready for specific usage.

Protocol Performed By: TBM, Mumbai

Name: Mr. Abhijit Tillu

Designation: Service Engineer

Customer Authorization : Skylark Diagnostic Centre

Name: Dr. Swati Datar

Designation: Lab Director


Company Representative Name & Sign




Mr. Abhijit Tillu

Date: 25-10-2023

Customer Name & Sign


Dr. Swati Datar
MBBS (Mum) Consultant Pathologist
Registration No. 084058
084053

Date: 25-10-2023



Performance Qualifications for EM-200, Sr. No.:- 2002692

1. **CONTROLS:** - Run QC of all the parameters, found within acceptable limit
2. **PRECISION CHECK:** - Run the precision of three the parameters, calculate mean, and SD, found within range.

System Certification:

Study data has determined that the System described in this document either meets the necessary criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The System is ready for specific usage.

Protocol Performed By: Mr. Vikrant Pandurang Bargude

Name : Mr. Vikrant Pandurang Bargude

Designation : Senior Application Specialist

PERFORMANCE QUALIFICATION DONE BY

Name : Dr. Swati Datar

Designation : Lab Director





TRANSASIA BIOMEDICALS LIMITED			
PERFORMANCE QUALIFICATION			
Customer Name: SKYLARK DIAGNOSTIC CENTRE	Model: EM -200 _____	Serial Number:	2002692
			TRANSASIA® Bio-Medicals Ltd.

ANNEXURE-A

TABLE OF CONTENTS

Sr.No.	Title	Page. No.
1.	Approval	1
2.	Objectives	2
3.	Pre-Requisites	2
4.	Test Plan	2
5.	Acceptance Criteria	2
6.	Summary	2

1. APPROVAL:

1.1 Prepared By:

Name	Designation	Signature	Date
Mr. Vikrant Pandurang Bargude	Seniors Application Specialist	<i>Bargude</i>	25-10-2023

1.2 Checked By:

Name	Designation	Signature	Date
Dr. Swati Datar	Lab Director	<i>Datar</i>	25-10-2023

1.3 Approved By:

Name	Designation	Signature	Date
Dr. Swati Datar	Lab Director	<i>Datar</i>	25-10-2023



TRANSASIA BIOMEDICALS LIMITED PERFORMANCE QUALIFICATION

TRANSASIA®
Bio-Medicals Ltd.

Customer Name: SKYLARK DIAGNOSTIC
CENTRE

Model:
EM -200 _____

Serial
Number:

2002692

2. OBJECTIVE:

The objective of this protocol is to establish documented evidence for the Performance Qualification of Fully Automated Biochemistry Analyzer and to Ensure that the results obtained are within the pre-determined Acceptance Criteria.

3. PRE-REQUISITES:

Following Pre-requisites are required before the execution of Performance Qualification.

- Completion of Installation Qualification (IQ) prior to PQ.
- Completion of Operational Qualification (OQ) prior to PQ.

4. TEST PLAN:

Following any of 3 available test parameters precision shall be performed (N=20 for each parameter each level) on Mono-Level &/or Bi-Level controls and check the CV% during the Performance Qualification of Fully Automated Biochemistry Analyzer.

Sr.No.	Test Parameter
1.	ALBUMIN
2.	SGPT
3.	UREA
4.	GLUCOSE
5.	ALKALINE PHOSPHATASE
6.	HDL
7.	CREATININE

5. ACCEPTANCE CRITERIA:

Acceptance criteria are based on the precision studies conducted as per *CLSI Guideline EP 05-A3*.

6. SUMMARY:



UNMATCHED SERVICE
SINCE 1979...

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

Customer Name: SKYLARK DIAGNOSTIC
CENTRE

Model:
EM -200 _____

Serial
Number:

2002692

TRANSASIA®
Bio-Medicals Ltd.

Test Name	Glucose		SGPT		HDL	
	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2
Mean	100	198	39	91	46.3	64.1
SD	0.83	1.56	1.27	1.30	0.96	0.32
CV%	0.84	0.79	3.23	1.43	2.07	0.50
Acceptable Criteria (Max.value)	<3	<3	<5	<5	<5	<5
Status	PASS	PASS	PASS	PASS	PASS	PASS

Traceability: Instrument Raw Data from Test Statistics Menu.

Note: This report is effective from the date of approval.

Annexure-B

Instrument Raw Data from Test Statistics Menu to be attached as printout attachments in Annexure-B.

Result Reprint

Report Type : Controls 25-OCT-2023

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	S022358	ERBA NORM	SGPTD	42 U/L		21016	25-Oct-2023 11:12:54	40.530	2.700	32.43 - 48.63
2	S022358	ERBA NORM	GOTHL	37 U/L		21017	25-Oct-2023 11:13:11	36.310	2.420	29.05 - 43.57
3	S022358	ERBA NORM	ALPU	106 U/L	-1SD	21018	25-Oct-2023 11:13:29	117.520	7.830	94.03 - 141.01
4	S022358	ERBA NORM	UREA	35 mg/dL		21019	25-Oct-2023 11:13:47	34.310	1.720	29.15 - 39.47
5	S022358	ERBA NORM	CRENZ	1.1 mg/dL		21020	25-Oct-2023 11:14:05	1.100	0.060	0.92 - 1.28
6	S022358	ERBA NORM	GLU	95 mg/dL		21021	25-Oct-2023 11:14:24	92.720	4.640	78.8 - 106.64
7	S022358	ERBA NORM	TRIG	116 mg/dL		21022	25-Oct-2023 11:14:42	112.220	5.610	95.39 - 129.05
8	S022358	ERBA NORM	CHOL	152 mg/dL	+1SD	21023	25-Oct-2023 11:15:00	143.810	7.190	122.24 - 165.38
9	S022358	ERBA NORM	HDLC	43.8 mg/dL		21024	25-Oct-2023 11:15:18	45.370	3.020	36.31 - 54.43
10	S022358	ERBA NORM	UA	5.6 mg/dL		21025	25-Oct-2023 11:15:36	5.740	0.290	4.87 - 6.61
11	S022358	ERBA NORM	CA	8.9 mg/dL		21026	25-Oct-2023 11:15:54	8.970	0.450	7.62 - 10.32
12	S022358	ERBA NORM	ALBD	3.5 g/dL		21027	25-Oct-2023 11:16:12	3.460	0.170	2.95 - 3.97
13	S022358	ERBA NORM	PRO	6.10 g/dL	+1SD	21028	25-Oct-2023 11:16:30	5.560	0.370	4.45 - 6.67

Test Statistics

Test	GLU	Report Type	Patients
Date From	25-Oct-2023	Date To	25-Oct-2023

Sample ID	PRECISION 1	Patient Name	Age	Result Date	Curve #	Used Calibration
Sr#	Result Unit	Flag				
1	100 mg/dL	-		25-Oct-2023 14:25:42	20027	15-Sep-2022 14:13:36
2	99 mg/dL	-		25-Oct-2023 14:25:24	20026	15-Sep-2022 14:13:36
3	99 mg/dL	-		25-Oct-2023 14:25:06	20025	15-Sep-2022 14:13:36
4	99 mg/dL	-		25-Oct-2023 14:24:48	20024	15-Sep-2022 14:13:36
5	99 mg/dL	-		25-Oct-2023 14:24:30	20023	15-Sep-2022 14:13:36
6	100 mg/dL	-		25-Oct-2023 14:24:12	20022	15-Sep-2022 14:13:36
7	100 mg/dL	-		25-Oct-2023 14:23:54	20021	15-Sep-2022 14:13:36
8	100 mg/dL	-		25-Oct-2023 14:23:35	20020	15-Sep-2022 14:13:36
9	99 mg/dL	-		25-Oct-2023 14:23:17	20019	15-Sep-2022 14:13:36
10	100 mg/dL	-		25-Oct-2023 14:22:59	20018	15-Sep-2022 14:13:36
11	100 mg/dL	-		25-Oct-2023 14:22:41	20017	15-Sep-2022 14:13:36
12	100 mg/dL	-		25-Oct-2023 14:22:23	20016	15-Sep-2022 14:13:36
13	101 mg/dL	-		25-Oct-2023 14:22:05	20015	15-Sep-2022 14:13:36
14	101 mg/dL	-		25-Oct-2023 14:21:47	20014	15-Sep-2022 14:13:36
15	100 mg/dL	-		25-Oct-2023 14:21:29	20013	15-Sep-2022 14:13:36
16	101 mg/dL	-		25-Oct-2023 14:21:11	20012	15-Sep-2022 14:13:36
17	100 mg/dL	-		25-Oct-2023 14:20:53	20011	15-Sep-2022 14:13:36
18	98 mg/dL	-		25-Oct-2023 14:20:35	20010	15-Sep-2022 14:13:36
19	101 mg/dL	-		25-Oct-2023 14:20:17	20009	15-Sep-2022 14:13:36
20	99 mg/dL	-		25-Oct-2023 14:19:59	20008	15-Sep-2022 14:13:36



Test Statistics

Test	GLU	Report Type	Patients
Date From	25-Oct-2023	Date To	25-Oct-2023

Computed Ranges And Statistical Values

Reference Range	20
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	20

Str# From 1 To 20

N	20
Mean	100
SD	0.83
%CV	0.84
Range	3

[Handwritten signature]

Test Statistics

Test	GLU	<i>Report Type</i>	<i>Patients</i>
Date From	25-Oct-2023	Date To	25-Oct-2023

Sample ID	PRECISION 2			Patient Name	Age
Sr#	Result	Unit	Flag	Result Date	Curve # Used Calibration
1	196	mg/dL	H	25-Oct-2023 14:31:43	20047 15-Sep-2022 14:13:36
2	196	mg/dL	H	25-Oct-2023 14:31:25	20046 15-Sep-2022 14:13:36
3	199	mg/dL	H	25-Oct-2023 14:31:07	20045 15-Sep-2022 14:13:36
4	195	mg/dL	H	25-Oct-2023 14:30:49	20044 15-Sep-2022 14:13:36
5	198	mg/dL	H	25-Oct-2023 14:30:30	20043 15-Sep-2022 14:13:36
6	198	mg/dL	H	25-Oct-2023 14:30:12	20042 15-Sep-2022 14:13:36
7	198	mg/dL	H	25-Oct-2023 14:29:54	20041 15-Sep-2022 14:13:36
8	197	mg/dL	H	25-Oct-2023 14:29:37	20040 15-Sep-2022 14:13:36
9	198	mg/dL	H	25-Oct-2023 14:29:18	20039 15-Sep-2022 14:13:36
10	199	mg/dL	H	25-Oct-2023 14:29:00	20038 15-Sep-2022 14:13:36
11	198	mg/dL	H	25-Oct-2023 14:28:42	20037 15-Sep-2022 14:13:36
12	199	mg/dL	H	25-Oct-2023 14:28:24	20036 15-Sep-2022 14:13:36
13	198	mg/dL	H	25-Oct-2023 14:28:06	20035 15-Sep-2022 14:13:36
14	199	mg/dL	H	25-Oct-2023 14:27:48	20034 15-Sep-2022 14:13:36
15	201	mg/dL	H	25-Oct-2023 14:27:30	20033 15-Sep-2022 14:13:36
16	200	mg/dL	H	25-Oct-2023 14:27:12	20032 15-Sep-2022 14:13:36
17	200	mg/dL	H	25-Oct-2023 14:26:54	20031 15-Sep-2022 14:13:36
18	200	mg/dL	H	25-Oct-2023 14:26:36	20030 15-Sep-2022 14:13:36
19	200	mg/dL	H	25-Oct-2023 14:26:18	20029 15-Sep-2022 14:13:36
20	197	mg/dL	H	25-Oct-2023 14:26:00	20028 15-Sep-2022 14:13:36



Test Statistics

Test	GLU	Report Type	Patients
Date From	25-Oct-2023	Date To	25-Oct-2023

Computed Ranges And Statistical Values

Reference Range	0
Above Reference Range	20
Below Reference Range	0
Default Range	0
Total Test(s)	20

Sr# From 1 To 20

N	20
Mean	198
SD	1.58
%CV	0.79
Range	6



Test Statistics

Test	SGPTD	Report Type	Patients
Date From	25-Oct-2023	Date To	25-Oct-2023

Sample ID	PRECISION 3		Patient Name	Age		
Sr#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	40	U/L	-	25-Oct-2023 13:41:29	19947	09-Sep-2023 14:57:25
2	40	U/L	-	25-Oct-2023 13:41:11	19946	09-Sep-2023 14:57:25
3	41	U/L	-	25-Oct-2023 13:40:53	19945	09-Sep-2023 14:57:25
4	40	U/L	-	25-Oct-2023 13:40:35	19944	09-Sep-2023 14:57:25
5	41	U/L	-	25-Oct-2023 13:40:16	19943	09-Sep-2023 14:57:25
6	41	U/L	-	25-Oct-2023 13:39:58	19942	09-Sep-2023 14:57:25
7	40	U/L	-	25-Oct-2023 13:39:40	19941	09-Sep-2023 14:57:25
8	41	U/L	-	25-Oct-2023 13:39:22	19940	09-Sep-2023 14:57:25
9	39	U/L	-	25-Oct-2023 13:39:04	19939	09-Sep-2023 14:57:25
10	40	U/L	-	25-Oct-2023 13:38:46	19938	09-Sep-2023 14:57:25
11	41	U/L	-	25-Oct-2023 13:38:28	19937	09-Sep-2023 14:57:25
12	39	U/L	-	25-Oct-2023 13:38:10	19936	09-Sep-2023 14:57:25
13	38	U/L	-	25-Oct-2023 13:37:52	19935	09-Sep-2023 14:57:25
14	39	U/L	-	25-Oct-2023 13:37:34	19934	09-Sep-2023 14:57:25
15	38	U/L	-	25-Oct-2023 13:37:16	19933	09-Sep-2023 14:57:25
16	38	U/L	-	25-Oct-2023 13:36:58	19932	09-Sep-2023 14:57:25
17	37	U/L	-	25-Oct-2023 13:36:40	19931	09-Sep-2023 14:57:25
18	39	U/L	-	25-Oct-2023 13:36:22	19930	09-Sep-2023 14:57:25
19	38	U/L	-	25-Oct-2023 13:36:04	19929	09-Sep-2023 14:57:25
20	38	U/L	-	25-Oct-2023 13:35:46	19928	09-Sep-2023 14:57:25



Test Statistics

Test	SGPTD	Report Type	Patients
Date From	25-Oct-2023	Date To	25-Oct-2023

Computed Ranges And Statistical Values

Reference Range	20
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	20

Sr# From 1 To 20

N	20
Mean	39
SD	1.27
%CV	3.23
Range	4



Test Statistics

Test	SGPTD	Report Type	Patients
Date From	25-Oct-2023	Date To	25-Oct-2023

Sample ID	PRECISION 4		Patient Name	Age		
Sr#	Result	Unit	Flag	Result Date	Curve #	Used Calibration
1	91	U/L	H	25-Oct-2023 13:47:30	19967	09-Sep-2023 14:57:25
2	90	U/L	H	25-Oct-2023 13:47:12	19966	09-Sep-2023 14:57:25
3	90	U/L	H	25-Oct-2023 13:46:54	19965	09-Sep-2023 14:57:25
4	87	U/L	H	25-Oct-2023 13:46:36	19964	09-Sep-2023 14:57:25
5	92	U/L	H	25-Oct-2023 13:46:18	19963	09-Sep-2023 14:57:25
6	91	U/L	H	25-Oct-2023 13:45:59	19962	09-Sep-2023 14:57:25
7	92	U/L	H	25-Oct-2023 13:45:41	19961	09-Sep-2023 14:57:25
8	91	U/L	H	25-Oct-2023 13:45:23	19960	09-Sep-2023 14:57:25
9	92	U/L	H	25-Oct-2023 13:45:05	19959	09-Sep-2023 14:57:25
10	92	U/L	H	25-Oct-2023 13:44:47	19958	09-Sep-2023 14:57:25
11	91	U/L	H	25-Oct-2023 13:44:29	19957	09-Sep-2023 14:57:25
12	92	U/L	H	25-Oct-2023 13:44:11	19956	09-Sep-2023 14:57:25
13	92	U/L	H	25-Oct-2023 13:43:53	19955	09-Sep-2023 14:57:25
14	91	U/L	H	25-Oct-2023 13:43:35	19954	09-Sep-2023 14:57:25
15	92	U/L	H	25-Oct-2023 13:43:17	19953	09-Sep-2023 14:57:25
16	91	U/L	H	25-Oct-2023 13:42:59	19952	09-Sep-2023 14:57:25
17	92	U/L	H	25-Oct-2023 13:42:41	19951	09-Sep-2023 14:57:25
18	91	U/L	H	25-Oct-2023 13:42:23	19950	09-Sep-2023 14:57:25
19	93	U/L	H	25-Oct-2023 13:42:05	19949	09-Sep-2023 14:57:25
20	93	U/L	H	25-Oct-2023 13:41:47	19948	09-Sep-2023 14:57:25



Test Statistics

Test	SGPTD	Report Type	Patients
Date From	25-Oct-2023	Date To	25-Oct-2023

Computed Ranges And Statistical Values

Reference Range	0
Above Reference Range	20
Below Reference Range	0
Default Range	0
Total Test(s)	20

Sr# From 1 To 20

N	20
Mean	91
SD	1.30
%CV	1.43
Range	6



Test Statistics

Test	HDLC	Report Type	Patients
Date From	25-Oct-2023	Date To	25-Oct-2023

Sample ID	PRECISION5		Patient Name	Age	Result Date	Curve #	Used Calibration
Sr#	Result	Unit	Flag				
1	45.2	mg/dL	-		25-Oct-2023 13:53:31	19987	02-May-2023 13:10:29
2	46.0	mg/dL	-		25-Oct-2023 13:53:13	19986	02-May-2023 13:10:29
3	45.4	mg/dL	-		25-Oct-2023 13:52:55	19985	02-May-2023 13:10:29
4	46.0	mg/dL	-		25-Oct-2023 13:52:37	19984	02-May-2023 13:10:29
5	46.0	mg/dL	-		25-Oct-2023 13:52:19	19983	02-May-2023 13:10:29
6	46.0	mg/dL	-		25-Oct-2023 13:52:01	19982	02-May-2023 13:10:29
7	46.5	mg/dL	-		25-Oct-2023 13:51:42	19981	02-May-2023 13:10:29
8	46.8	mg/dL	-		25-Oct-2023 13:51:24	19980	02-May-2023 13:10:29
9	46.2	mg/dL	-		25-Oct-2023 13:51:06	19979	02-May-2023 13:10:29
10	47.2	mg/dL	-		25-Oct-2023 13:50:48	19978	02-May-2023 13:10:29
11	46.9	mg/dL	-		25-Oct-2023 13:50:30	19977	02-May-2023 13:10:29
12	48.4	mg/dL	-		25-Oct-2023 13:50:12	19976	02-May-2023 13:10:29
13	47.6	mg/dL	-		25-Oct-2023 13:49:54	19975	02-May-2023 13:10:29
14	47.7	mg/dL	-		25-Oct-2023 13:49:36	19974	02-May-2023 13:10:29
15	47.4	mg/dL	-		25-Oct-2023 13:49:18	19973	02-May-2023 13:10:29
16	45.1	mg/dL	-		25-Oct-2023 13:49:00	19972	02-May-2023 13:10:29
17	45.3	mg/dL	-		25-Oct-2023 13:48:42	19971	02-May-2023 13:10:29
18	45.2	mg/dL	-		25-Oct-2023 13:48:24	19970	02-May-2023 13:10:29
19	45.9	mg/dL	-		25-Oct-2023 13:48:06	19969	02-May-2023 13:10:29
20	45.6	mg/dL	-		25-Oct-2023 13:47:48	19968	02-May-2023 13:10:29

Test Statistics

Test	HDLC	<i>Report Type</i>	<i>Patients</i>
Date From	25-Oct-2023	Date To	25-Oct-2023

Computed Ranges And Statistical Values

Reference Range	20
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	20

Sr# From 1 To 20

N	20
Mean	46.3
SD	0.96
%CV	2.07
Range	3.3



Test Statistics

Test	HDLC	<i>Report Type</i>	<i>Patients</i>
Date From	25-Oct-2023	Date To	25-Oct-2023

Sample ID	PRECISION6		Patient Name	Age
Sr#	Result	Unit	Flag	Result Date
				Curve #
				Used Calibration
1	64.3	mg/dL	-	25-Oct-2023 13:59:31
2	63.8	mg/dL	-	25-Oct-2023 13:59:13
3	64.4	mg/dL	-	25-Oct-2023 13:58:56
4	64.0	mg/dL	-	25-Oct-2023 13:58:37
5	64.3	mg/dL	-	25-Oct-2023 13:58:19
6	64.3	mg/dL	-	25-Oct-2023 13:58:01
7	64.2	mg/dL	-	25-Oct-2023 13:57:43
8	63.9	mg/dL	-	25-Oct-2023 13:57:25
9	63.8	mg/dL	-	25-Oct-2023 13:57:07
10	64.5	mg/dL	-	25-Oct-2023 13:56:49
11	64.0	mg/dL	-	25-Oct-2023 13:56:31
12	64.6	mg/dL	-	25-Oct-2023 13:56:13
13	64.1	mg/dL	-	25-Oct-2023 13:55:55
14	63.8	mg/dL	-	25-Oct-2023 13:55:37
15	64.5	mg/dL	-	25-Oct-2023 13:55:19
16	63.7	mg/dL	-	25-Oct-2023 13:55:01
17	64.4	mg/dL	-	25-Oct-2023 13:54:43
18	63.6	mg/dL	-	25-Oct-2023 13:54:25
19	63.7	mg/dL	-	25-Oct-2023 13:54:07
20	63.7	mg/dL	-	25-Oct-2023 13:53:49



Test Statistics

Test	HDLC	Report Type	Patients
Date From	25-Oct-2023	Date To	25-Oct-2023

Computed Ranges And Statistical Values

Reference Range	20
Above Reference Range	0
Below Reference Range	0
Default Range	0
Total Test(s)	20

Sr# From 1 To 20

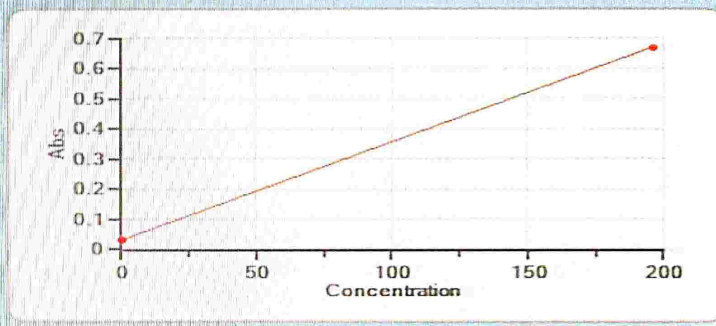
N	20
Mean	64.1
SD	0.32
%CV	0.50
Range	1.0



Test : **GLU** Revision : <A-200-GLU-1 20.08.2013> Curve Type : **Linear**

Last Calibration Date : **14-Feb-2024 12:57:20** Calibration Expiry Limit : **0** Days Acceptable Limit (%) : **15**

Pos	Consumable	LotNo.	Conc	Abs	Factor
	DW BLAN...	001	0.000	0.0324	0.0000
	MULTICA...	23010...	196.000	0.6698	307.4992



Calibration Date : **14-Feb-2024 12:57:20**

R1 Lot-Bottle No : **B082322-332#4935**

Set Latest Calibration

Copy Calibration

Prev **Next** **Selective Calibration**

Only Successful Lot calibrations
Current Calibration

Tests

<<	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTHL	GOTHL	ALPU	BIT	>>
	BIDD	ALBD	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

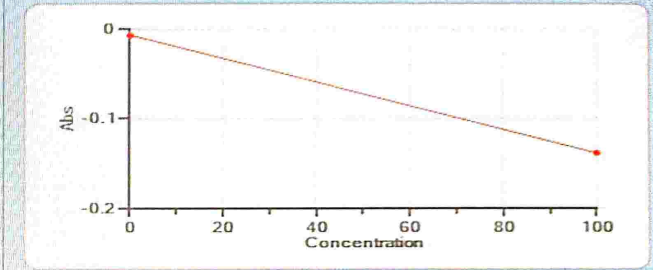
Indication : **Successful Calibration**

Navigation buttons: **←** **↶** **↷** **→** **PRINT** **SAVE** **CLEAR** **EDIT** **DELETE**

Test : UREA Revision : <A-200-UREA-2 01.03.2016> Curve Type : Linear

Last Calibration Date : 20-Mar-2024 14:44:39 Calibration Expiry Limit : 0 Days Acceptable Limit (%) : 15

Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
I-1	DW BLAN...	001	0.000	-0.0061	0.0000
I-2	MULTICA...	23010...	100.000	-0.1392	-751.5972



Calibration Date : 20-Mar-2024 14:44:39
 R1 Lot-Bottle No : S082321-333#1541
 R2 Lot-Bottle No : S082321-333#0107

Set Latest Calibration
Copy Calibration

Prev **Next** **Selective Calibration**

Only Successful Lot calibrations
Current Calibration

Tests

<<	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTHL	GOTHL	ALPU	BIT	>>
	BIDD	ALB	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : Successful Calibration

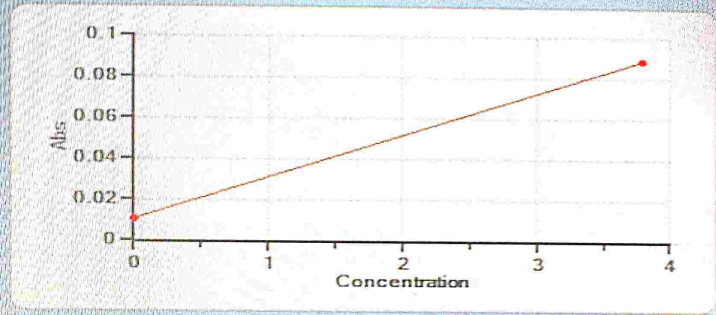
PRINT **SAVE** **CLEAR** **EDIT** **DELETE**

- Patient Entry(F2)
- Test Parameter(F3)
- Profiles / Calc(F4)
- QC/Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Maintenance(F12)
- Settings
- Shut Down

Test : **CRENZ** Revision : <A-200-CRENZ-1 01.08.2014> Curve Type : Linear

Last Calibration Date : 06-Mar-2024 11:30:53 Calibration Expiry Limit : 0 Days Acceptable Limit (%) : 15

Pos	Consumable	LotNo.	Conc	Abs	Factor
	DW BLAN...	001	0.000	0.0108	0.0000
	MULTICA...	23010...	3.790	0.0887	48.6521



Calibration Date : 06-Mar-2024 11:30:53
 R1 Lot-Bottle No : S082307-332#5107
 R2 Lot-Bottle No : S082307-332#7423

Set Latest Calibration
Copy Calibration

Prev **Next** **Selective Calibration**

Only Successful Lot calibrations
Current Calibration

Tests

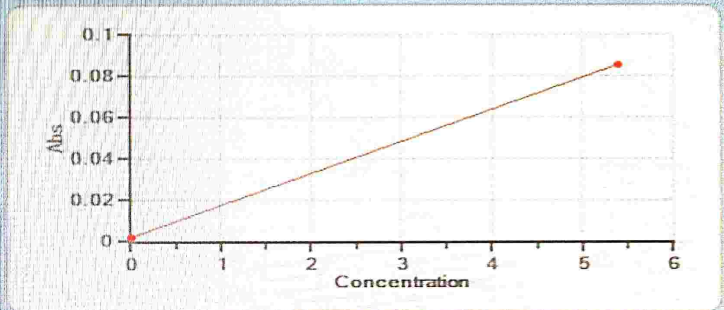
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	BIDD	ALBD	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : Successful Calibration

PRINT **SAVE** **CLEAR** **EDIT** **DELETE**

Test : **UA** Revision : <A-200-UA-1 01.06.2015> Curve Type : **Linear**
 Last Calibration Date : **06-Nov-2023 13:47:04** Calibration Expiry Limit : **0** Days Acceptable Limit (%) : **15**

Pos	Consumable	LotNo.	Conc	Abs	Factor
	DW BLAN...	001	0.000	0.0022	0.0000
	MULTICA...	23010...	5.390	0.0855	64.6671



Calibration Date : **06-Nov-2023 13:47:04**

R1 Lot-Bottle No : **S062304-322#2883**

R2 Lot-Bottle No : **S062304-322#1887**

Set Latest Calibration

Copy Calibration

Prev **Next** **Selective Calibration**

Only Successful Lot calibrations
Current Calibration

Tests

<<	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTHL	GOTHL	ALPU	BIT	>>
	BIDD	ALBD	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : **Successful Calibration**

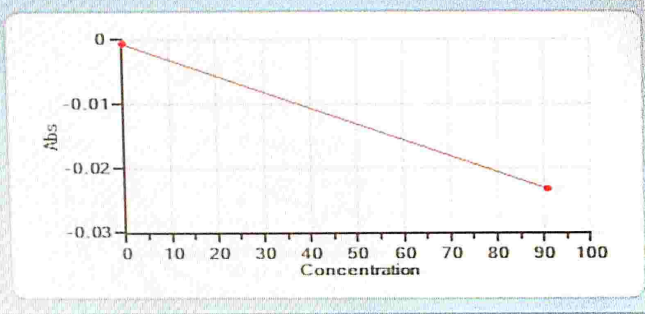
Click to view - Next Record **PRINT** **SAVE** **CLEAR** **EDIT** **DELETE**

Schedule QC / Calibration **Calibration** QC Data Twin Plot QC Graph

Test : **GPTHL** Revision : <A-200-GPTHL-3 01.03.2016> Curve Type : Linear

Last Calibration Date : 09-May-2023 15:43:42 Calibration Expiry Limit : 0 Days Acceptable Limit (%) : 15

Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
	DW BLAN...	001	0.000	-0.0007	0.0000
	MULTICA..	2204083	90.600	-0.0232	-4017.7383



Calibration Date : 09-May-2023 15:43:42

R1 Lot-Bottle No : S032246-212#1044

R2 Lot-Bottle No : S032246-212#1356

Set Latest Calibration
Copy Calibration

Prev **Next** **Selective Calibration**

Only Successful Lot calibrations
Current Calibration

Tests	<<	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTHL	GOTHL	ALPU	BIT	>>
		BIDD	ALBD	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
		AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : Successful Calibration

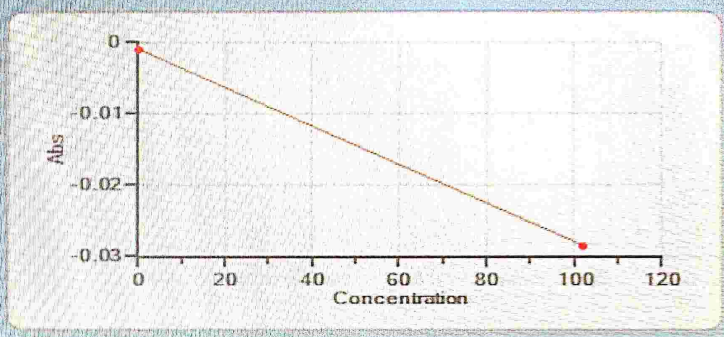
PRINT **SAVE** **CLEAR** **EDIT** **DELETE**

- Print Entry(F2)
- Parameter(F3)
- Files / Calc(F4)
- Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Maintenance(F12)
- Settings
- Shut Down

Test : **GOTHL** Revision : <A-200-GOTHL-4 01.03.2016> Curve Type : Linear

Last Calibration Date : 06-Nov-2023 13:33:31 Calibration Expiry Limit : 0 Days Acceptable Limit (%) : 15

Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
	DW BLAN...	001	0.000	-0.0009	0.0000
	MULTICA...	2204083	102.000	-0.0285	-3688.9695



Calibration Date : 18-Mar-2023 18:44:14

R1 Lot-Bottle No : S122225-250#0340

R2 Lot-Bottle No : S122225-250#0594

Set Latest Calibration
Copy Calibration

Prev Next

Selective Calibration

Only Successful Lot calibrations
Current Calibration

Lot Calibration

Tests

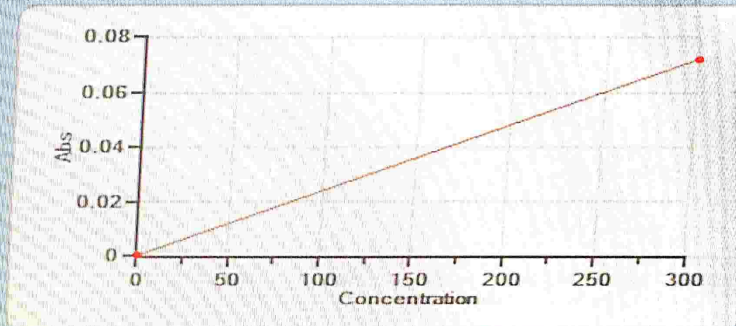
<<	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTHL	GOTHL	ALPU	BIT	>>
	BIDD	ALBD	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : Successful Calibration

← → ↺ ↻ PRINT SAVE CLEAR EDIT DELETE

Test : **ALPU** Revision : <A-200-ALPU-3 01.03.2016> Curve Type : **Linear**
 Last Calibration Date : **06-Nov-2023 13:34:26** Calibration Expiry Limit : **0** Days Acceptable Limit (%) : **15**

Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
	DW BLAN...	001	0.000	0.0003	0.0000
	MULTICA...	23010...	300.000	0.0721	4178.2729



Calibration Date : **06-Nov-2023 13:34:26**
 R1 Lot-Bottle No : **S092302-336#2858**
 R2 Lot-Bottle No : **S092302-336#1970**

Set Latest Calibration

Copy Calibration

Prev **Next**

Selective Calibration

Only Successful Lot calibrations
Current Calibration

Lot Calibration

Tests

<<	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTHL	GOTHL	ALPU	BIT	>>
	BIDD	ALBD	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : **Successful Calibration**

PRINT **SAVE** **CLEAR** **EDIT** **DELETE**

Test : **ALBD** Revision : <A-200-ALBD-1 07/11/2017>

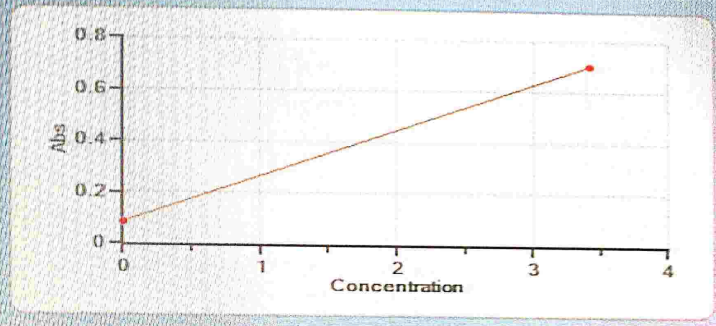
Curve Type : Linear

Last Calibration Date : 20-Mar-2024 14:46:45

Calibration Expiry Limit : 0 Days

Acceptable Limit (%) : 15

Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	DW BLAN...	001	0.000	0.0877	0.0000
I-2	MULTICA...	23010...	3.420	0.7046	5.5438



Calibration Date : 20-Mar-2024 14:46:45

R1 Lot-Bottle No : B052326-319#0617

Set Latest Calibration

Copy Calibration

Prev Next

Selective Calibration

Only Successful Lot calibrations
Current Calibration

Tests

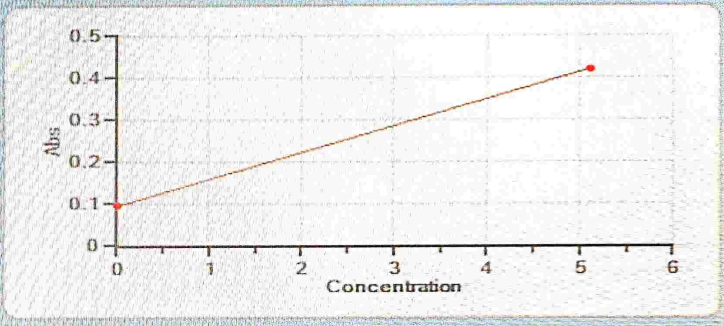
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	BIDD	ALBD	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : Successful Calibration

Test : **PRO** Revision : <A-200-PRO-2 26.09.2013> Curve Type : Linear

Last Calibration Date : 06-Nov-2023 13:51:52 Calibration Expiry Limit : 0 Days Acceptable Limit (%) : 15

Pos	Consumable	LotNo.	Conc	Abs	Factor
	DW BLAN...	001	0.000	0.0950	0.0000
	MULTICA...	23010...	5.100	0.4201	15.6851



Calibration Date : 06-Nov-2023 13:51:52
 R1 Lot-Bottle No : S072390-330#2976

Only Successful Lot calibrations
 Current Calibration

Lot Calibration

Tests

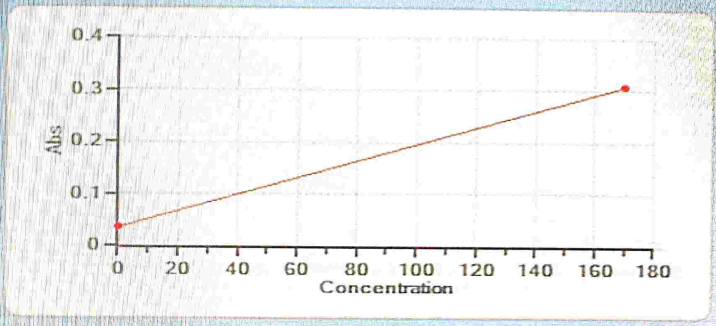
<<	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTH	GOTHL	ALPU	BIT	>>
	BIDD	ALBD	PRO2	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : Successful Calibration

Test : **CHOL** Revision : <A-200-CHOL-1 20.08.2013> Curve Type : Linear

Last Calibration Date : 06-Mar-2024 11:33:36 Calibration Expiry Limit : 0 Days Acceptable Limit (%) : 15

Pos	Consumable	LotNo.	Conc	Abs	Factor
	DW BLAN...	001	0.000	0.0364	0.0000
	MULTICA...	23010...	170.000	0.3087	624.3114



Calibration Date : 06-Mar-2024 11:33:36

R1 Lot-Bottle No : S092350-339#0755

Only Successful Lot calibrations
 Current Calibration

Lot Calibration

Tests

<<	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTHL	GOTHL	ALPU	BIT	>>
	BIDD	ALBD	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : Successful Calibration

Test : **TRIG** Revision : <A-200-TRIG-1 20.08.2013>

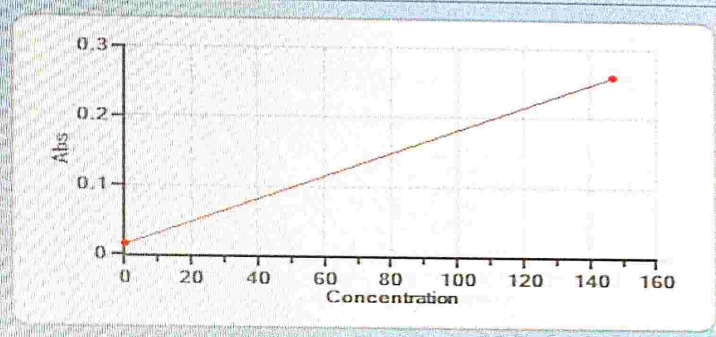
Curve Type : Linear

Last Calibration Date : 06-Nov-2023 13:42:33

Calibration Expiry Limit : 0 Days

Acceptable Limit (%) : 15

Pos	Consumable	LotNo.	Conc	Abs	Factor
1	DW BLAN...	001	0.000	0.0150	0.0000
2	MULTICA...	23010...	147.000	0.2602	599.6328



Calibration Date : 06-Nov-2023 13:42:33

R1 Lot-Bottle No : S042393-320#0119

R2 Lot-Bottle No : S042393-320#0496

Set Latest Calibration

Copy Calibration

Prev Next

Selective Calibration

Only Successful Lot calibrations
Current Calibration

Lot Calibration

Tests

<<	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTHL	GOTHL	ALPU	BIT	>>
	BIDD	ALBD	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

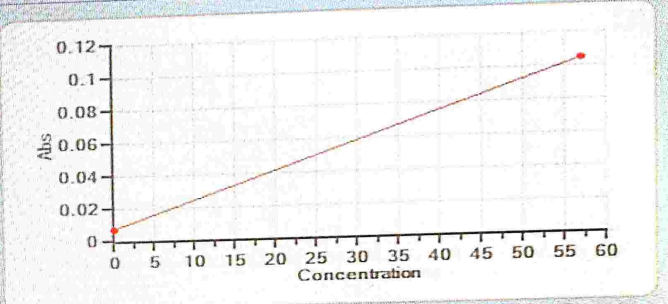
Indication : Successful Calibration

Navigation buttons: Home, Back, Forward, PRINT, SAVE, CLEAR, EDIT, DELETE

- Patient Entry(F2)
- Test Parameter(F3)
- Profiles / Calc(F4)
- Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Maintenance(F12)
- Settings
- Shut Down

Test : HDLC Revision : <A-200-HDLC-1 20.00.2019>
 Last Calibration Date : 02-May-2023 13:10:29 Calibration Expiry Limit : 0 Days Acceptable Limit (%) : 15

Pos	Consumable	LotNo.	Conc	Abs	Factor
DW BLAN...	001	0.000	0.0075	0.0000	
HDL CAL...	S032347	57.000	0.1047	586.1182	



Calibration Date : 02-May-2023 13:10:29
 R1 Lot-Bottle No : S032347-311#2751
 R2 Lot-Bottle No : S032347-311#2497

Set Latest Calibration
Copy Calibration

Prev Next Selective Calibration

Only Successful Lot calibrations

Current Calibration

Tests	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTH	GOTHL	ALPU	BIT	
<<	BIDD	ALBD	PRO	CHOL	TRIG	HDLC	CA	PHOS	GGT	LDH	>>
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : Successful Calibration

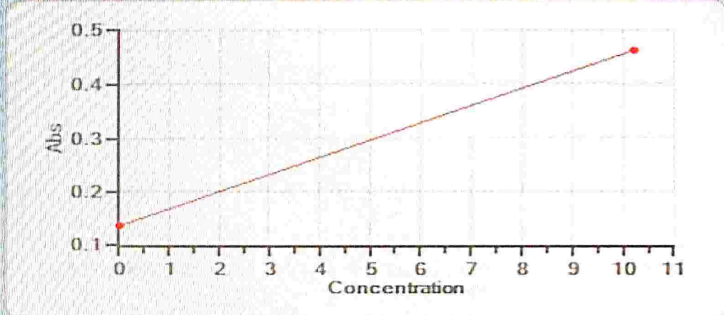
PRINT SAVE CLEAR EDIT DELETE

Help (F1)

Test : CA Revision : <A-200-CA-1 20.08.2013> Curve Type : Linear

Last Calibration Date : 09-Nov-2023 13:45:21 Calibration Expiry Limit : 0 Days Acceptable Limit (%) : 15

Pos	Consumable	LotNo.	Conc	Abs	Factor
	DW BLAN...	001	0.000	0.1371	0.0000
	MULTICA...	23010...	10.200	0.4622	31.3701



Calibration Date : 09-Nov-2023 13:45:21
 R1 Lot-Bottle No : S072394-331#2516

Only Successful Lot calibrations

Current Calibration

Tests

<<	GLU	UREA	CRENZ	UA	SGPTD	SGOTD	GPTHL	GOTHL	ALPU	BIT	>>
	BIDD	ALBD	PRO	CHOL	TRIG	HDLC	FA	PHOS	GGT	LDH	
	AMY	CKNac	ASO1	CRPD	HA1cD	RFD	MPR	ADA	LDL	FE	

Indication : Successful Calibration



Certificate of Training

This is to certify that Dr. Swati Datar,

Ms.Sana Siddique , Ms. Pritika Nalawade, Ms. Rohini Mahajan , Mr. Aditya Jadhav

Ms. Amruta Ghadigaonkar, has undergo Training on the Operation

& User Maintenance of the Instrument- EM 200

Date: 25/ OCT / 2023

Venue:

Scientific Services
Transasia Bio-Medicals Ltd.

Skylark Diagnostic Centre
Goregaon E Mumbai