Installation Qualifications for XP-100

Carried out all the Installation Procedures as per the Installation Procedure & Checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Carried out Priming and Cleaning Operations

Checked the counts by running the samples and found OK.

Performed all due maintenance activities.

Handed over the Instrument for Operators Training & Qualifications

For TBM, Technical Services Department

Name : Anubhav Sharma

Designation : Dy.R.S.M.(Service)

Date: 17/11/17

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, Delhi

Name: Anubhav Sharma

Designation: Service Engineer

Customer Authorization: Dr.Dass Path Lab

Name: Dr. R.Srivastava

Designation: Consultant Pathologist

Company Representative Name & Sign

Date: 1/11/12

Customer Name & Sign

Date:

TRANSASIA

SYSMEX XP-100
AUTOMATED HEMATOLOGY ANALYZER

INSTALLATION QUALIFICATION

For

DR.DASS PATH LAB

NEW DELHI

Marketed by:
Transasia Bio-Medicals Ltd.,
(ISO 9002 CERTIFIED)
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

Installation Certificate for XP-100

This is to certify that the XP-100 Instrument Serial No.B3614 is successfully installed and Commissioned at TBM, Delhi and the Installation Protocol / checklist has been successfully completed for the above instrument.

TBM, Technical Services Department

Name : Anubhav Sharma

Designation : Dy.R.S.M.(Service)

Date : 11/11/12

c. Performance Testing

Test 1

Test Name: Precision Testing

Purpose: To comply with specification and find out deviation if any. If required to apply correction

Method: To run normal sample 10 times consecutively and identify SD, CV and to establish that it lies as per the manufacturer's specs. To omit first run and to consider rest 10 runs and to calculate SD & CV

c. Accuracy Testing

Test 1

Test Name:

Purpose: Ability to Process Samples

Method: To run e-check control five times

Acceptance Criteria: Each of the results obtained above should be within the range as specified in the control chart.

Validation Team:

Name : Naveen Kr.Jain

Designation : Application Specialist

Signature :

Date : 1/11/17

TRANSASIA

SYSMEX XP-100
AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

For

PUSHPAWATI SINGHANIA HOSPITAL AND REASERCH INSTITUTE

NEW DELHI

Marketed by:
Transasia Bio-Medicals Ltd.,
(ISO 9002 CERTIFIED)
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

Instrument Setup

1. Assembled the instrument accessories.
2. Removed the rubber caps of the reagent connection nipples.
3. Connected all the reagent tubes and waste collection unit.
4. Mounted the printer paper.
5. Placed the control adapter at the sample position

Operational Inspection

1. Performed Solenoid Valves, Motors and Syringes test and found OK.
2. Checked Pressure and Vacuum status and found OK.
3. Checked counts and found OK.

TBM, Technical Services Department

Name : Anubhav Sharma

Designation : Dy.R.S.M.(Service)

Anubhav

Date: 01/11/12

Quality Control mode

Preparing QC for sampling:

1. Remove the QC sample from the refrigerator. Allow to equilibrate to room temperature (18 to 30°C) for at least 20 minutes, before use.
2. Place the vial between the palms and roll it back and forth at least 10 times.
3. Turn the vial upside down and roll the vial between the palms a further 10 times.
4. Repeat the steps 2 and 3 for at least 3 minutes.
5. Visually inspect the bottom of the vial to check if mixing has been optimal and confirm that there is no pellet of cells adhering to bottom of the vial.
6. In case the cell clumps are observed, repeat the step 3 until the cells are optimally Suspended.
7. In case of slight delay, roll the QC vial 3 to 4 times before the sampling process.
8. Upon completion of the QC aspiration, cap the vial and replace it immediately in the refrigerator.

QC mode operation for XP-100

QC mode selection.

1. Be sure the status display is 'Ready'.
2. Select [Quality control] form the [Setting] menu.
3. Select Quality Control method i.e. Xbar or LJ and data output method i.e IP, GP etc.
4. Press [Save] to store the setting.

To enter the Target value and the range for the QC sample:
Select the QC file: The analyzer can store up to 6 QC files.

1. Press [QC] button at 'Ready' status.
2. Press display column of file number to be used.
3. Press [Setting] button the first QC file setting will appear.
4. To enter Lot ID press [Lot ID] column and press [Expiration] column to enter expiration date.
5. Press (→) button to move to second setting screen.
6. Input TARGET and LIMIT for each parameter.
7. Set the entered values by pressing [Save] and then [OK].

The details entered above in dialog box can also be entered using handheld barcode.

To Perform the QC analysis under L-J quality control setting.
Up to 60 data points can be stored for each parameter in each of the QC file.

1. Press [QC] button on main screen.
2. Select the display column of analysing file .
3. Mix the control properly and then feed to analyzer for aspiration of QC. Be sure the staus displays 'Ready'.
4. Hold the QC vial as long as the "aspirating" message is displayed. When the buzzer sounds two times and analyzing is displayed, remove the QC vial.
5. The analysis results are displayed under the Data column.
6. Press [OK] to confirm. The data is accepted and the point is entered in the QC chart.

Deletion of QC chart: This is meant to clear the old data from the QC file.

1. Select the [Out/Del] button in quality control chart.
2. Press [Current] button next to [Delete].
3. Press [OK] button to delete the data.

Routine analysis of Samples

Installation training for hematology analyzers

Pre-installation checks:

1. The instrument has to be placed in an environment as per the recommendations provided in the operator's manual.
a. The instrument should be placed at an ambient temperature of 15° to 30°C, with relative humidity range of 30% to 85%.
b. Instrument should be placed in a dust free environment, away from direct sunlight.
c. Instrument should not be placed close to instruments which can cause electrical interferences such as refrigerator or centrifuge.
d. Instrument should be placed on firm base. Provide at least 50cm distance between the wall and the rear of the hematology analyzer, as per the recommendation.

2. It is mandatory to ascertain that the power supply is as per the recommendations. It is essential that proper grounding has been achieved and is in line with the acceptable norms for the installation of the hematology analyzer. Do not forget to coordinate with the Technical service personnel for this. The training should be carried out only after these aspects have been certified by the TBM-Technical service personnel.

3. Check the storage of the reagents. Ascertain that the reagents are stored in a cool, dry place away from extreme temperatures. They should be placed in dust free environment.

4. Ascertain that reagent ports are connected properly, to the specific reagents. See to it that these reagent bottles / containers are covered sufficiently, to prevent the contamination with dust.

Sampling requirement:

Improper specimen collection and processing may influence the outcome of analytical results. The evacuated blood collection system is preferred over the needle and syringe since it is a safer method to use and provides a better quality blood specimen.

The whole blood sample should be collected in K2/K3 – EDTA only.
Dipotassium EDTA is now the recommended anticoagulant for hematology by the International Council for Standardization in Haematology (ICSH) and the NCCLS.

During the blood collection, recommended collection volume for that container has to be achieved. The results may not be appropriate if the recommended collection volume has not been adhered to.

Upon the completion of the blood collection, the mixing process has to be performed.
The mixing process is very critical and determines the appropriateness of the analysis report.
The thorough mixing by gentle inversions (by 180°) should be done.
Proper mixing of the whole blood specimen ensures that EDTA is dispersed throughout the sample. Blood collection tubes with EDTA should be mixed for up to 10 inversion cycles. They should again be gently inverted for further 2 minutes (10 to 15 cycles) prior to analysis. This procedure ensures that the whole blood being aspirated has been optimized for sample analysis.
Tubes should be checked for proper blood fill volumes and appropriate action should be taken based on hospital protocol if tubes are under-filled.
Whole blood specimens should be mixed adequately by end-to-end inversion just prior to analysis. Blood counts from acceptable venipuncture specimens should be performed within six hours of collection.

Consumable List

Consumables such as Cell clean, Cell Pack , Stromatolyser were supplied along with instrument.

Currently a sufficient stock of the same is being maintained Yes ☐ No ☐

C. List of Manuals, Certificates and Drawings

Transasia provides the following with the instrument.

1. Instruction For Use
2. User's Guide

D. Change Control Procedure

The instrument will not be altered, enhanced, modified or substituted for another system until a formal Change Control Authorization is approved from Transasia Bio-Medicals Ltd. and Ganesh Diagnostics and Imaging Centre (lab name).

E. Maintenance

The instrument listed within this document will be placed under the control of the purchasing institution with respect to proper maintenance procedures as detailed in the operations manual chapter 9

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period Transasia offers several levels of Maintenance Agreements and Performance Testing services to assist you in maintaining GLP/GMP compliance. Contacting your local representative and requesting the additional Service Agreement can supply additional information.

Validation Team:

Name : Naveen Kr.Jain

Designation : Sr. Application Specialist

Signature :

Date : 1/11/12

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Certificate of Training

This is to certify that Mr.Suraj Singh **working in Dr.Dass Path Lab New Delhi** has undergone training on the operation and user maintenance of the instrument fully Hematology analyzer **Sysmex XP-100.**

For Transasia Bio-Medicals Ltd.,

Authorized Signatory

Erba® Mannheim

COMMENTS:

VII. System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By: Transasia Representative

Name : Naveen Kr.Jain

Title : PERFORMANCE QUALIFICATION Signature:

Company: TRANSASIA BIO-MEDICALS LTD. Date: 11/11/12

Customer Authorizations: Dr.Dass Path Lab

Name : Dr R.Srivastava

Title : PERFORMANCE QUALIFICATION Signature:

Designation: Consultant Pathologist Date :

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6. PRECISION STUDY PERFORMED ON THE ANALYZER USING A BLOOD SAMPLE (ORIGINALS ATTACHED)

SMP NO	WBC	RBC	HGB	HCT	PLT
1	7.3	5.60	14.4	45.4	294
2	7.2	5.70	14.5	45.9	307
3	7.1	5.60	14.5	45.1	301
4	7.2	5.60	14.6	45.2	298
5	7.10	5.60	14.4	45.5	299
6	7.1	5.60	14.6	45.5	300
7	7.2	5.60	14.5	45.3	296
8	7.1	5.60	14.5	45.2	295
9	7.3	5.70	14.6	45.7	290
10	7.20	5.65	14.5	45.3	289
Mean	7.18	5.63	14.51	45.41	296.90
SD	0.079	0.042	0.074	0.247	5.343
CV%	**1.099**	**0.755**	**0.509**	**0.544**	**1.799**
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

Amit Puri

Technical Service Department
Transasia Bio-Medicals Ltd

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7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
1	7.00	4.31	11.8	32.30	263
2	6.90	4.34	11.7	32.50	261
3	6.80	4.32	11.7	32.30	264
4	7.00	4.37	11.7	32.70	271
5	7.00	4.31	11.7	32.10	273
MEAN	**6.94**	**4.330**	**11.72**	**32.38**	**266.4**
Acceptable Limits	6.54 - 7.12	4.242 - 4.415	11.64 - 11.88	31.82 - 33.26	249.1 - 275.3
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

8. (Traceability System) :

The traceability system of Sysmex Hematology analyzers are shown in attached sheet.

Amit Suri

Technical Service Department
Transasia Bio-Medicals Ltd

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6. PRECISION STUDY PERFORMED ON THE ANALYZER USING A BLOOD SAMPLE (ORIGINALS ATTACHED)

SMP NO	WBC	RBC	HGB	HCT	PLT
2	10.7	4.22	11.2	34.9	227
3	10.7	4.20	11.1	34.7	210
4	10.7	4.28	11.1	35.2	215
5	10.6	4.24	11.2	35.0	210
6	10.60	4.34	11.1	36.6	208
7	10.6	4.43	11.3	36.6	203
8	10.4	4.24	11.1	35.1	217
9	10.6	4.27	11.1	35.3	220
10	10.5	4.22	11.1	34.9	215
11	10.50	4.29	11.2	35.5	202
Mean	10.59	4.27	11.15	35.38	212.70
SD	0.099	0.069	0.071	0.681	7.689
CV%	**0.939**	**1.610**	**0.634**	**1.925**	**3.615**
Acceptable CV%	*Within 3.5%*	*Within 2.0%*	*Within 1.5%*	*Within 2.0%*	*Within 6.0%*
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

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7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
2	7.10	4.13	12.0	32.20	252
3	7.00	4.14	11.9	32.20	262
4	7.00	4.13	12.0	32.10	256
5	6.90	4.18	12.0	32.50	254
6	6.90	4.14	11.9	32.30	271
MEAN	**6.98**	**4.144**	**11.96**	**32.26**	**259.0**
Acceptable Limits	6.75 - 7.36	4.104 - 4.271	11.83 - 12.07	31.92 - 33.37	245.4 - 271.2
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

8. (Traceability System) :

The traceability system of Sysmex Hematology analyzers are shown in attached sheet.

Amol Kakatkar

Technical Service Department
Transasia Bio-Medicals Ltd

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5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3 x 10^3/Ul or Less
RBC	0.00	0.02 x 10^6/uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10 x 10^3/uL or Less

Amol Rahatgaonkar

Technical Service Department
Transasia Bio-Medicals Ltd

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5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3 x 10^3/Ul or Less
RBC	0.00	0.02 x 10^6/uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10 x 10^3/uL or Less

Technical Service Department
Transasia Bio-Medicals Ltd

2. Set cell clean to the sample probe and press start switch.
3. Remove the cell clean only after the buzzer for the completion of aspiration has been sounded.
4. The shutdown process will now be executed automatically. This would take around 7 minutes.
5. When shutdown is completed, analyzer displays the message "Turn off the power supply".

Whole Blood Mode (WB mode):

1) Be sure the status display on screen is 'Ready'.

2) Select the mode of analysis as WB mode, by pressing [WB] on screen (it will turn red in color).

3) Enter the sample ID, it can be entered in 2 ways :
   a. By numerical key dialog box.
   b. By handheld barcode.
   Sample ID up to 15 characters can be entered. Make sure Sample ID is correct and press [Ent.].

4) Mix the sample sufficiently.

5) Remove the plug while taking care not to allow blood scatter.

6) Set the tube to the sample probe, and in that condition, press the start switch.

7) The buzzer sounds two times - "beep, beep" - and when the color LCD screen displays "Analyzing," remove the tube.

After that, the unit executes automatic analysis and displays the result on the LCD screen. Then the unit turns to the Ready status, becoming ready for analysis of the next samples.

Pre-Diluted (PD) Mode:

Dilute samples to the ratio of 1:26 using CELLPACK dispensed beforehand in clean containers. 20 mL of blood is diluted in 500 mL of CELLPACK.

8) Be sure the status display on screen is 'Ready'.

9) Press [PD] button on screen to change the Mode. The PD button turns yellow.

10) Enter the sample ID, it can be entered in 2 ways :
   c. By numerical key dialog box.
   d. By handheld barcode.
   Sample ID up to 15 characters can be entered. Make sure Sample ID is correct and press [Ent.].

11) To run samples be sure status display on screen is 'Ready'.

12) Mix the diluted sample, remove plug taking care not to allow blood scatter.

13) Set the tube to sample probe and press Start Switch.

14) The buzzer sounds two times - "beep, beep" - and when the color LCD screen displays "Analyzing," remove the tube.

After that, the unit executes automatic analysis and displays the result on the LCD screen. Then the unit turns to the Ready status, becoming ready for analysis of the next samples.

SHUTDOWN Procedure:

Perform shutdown after completion of the days work. When the instrument is used continuously, shutdown has to be executed every 24 hours.

1. Press (SHUTDOWN) key in the ready status. The shut down screen appears.

Test 2

Test Name:

1. Tests for checking the performance of the instruments during analysis
2. Tests for checking long term performance of the instrument

Purpose:

The purpose of the above checks is to ensure the reliability of the results being obtained.

Method:

1. During Sample analysis:

To run control samples each time the instrument is used for sample analysis and verification of the results of the controls to be within the reference range to be established by performance of the precision experiments.

2. Long term Performance

This is to be checked by levey Jennings plots to be updated once in six months

Validation Team:

Name : Naveen Kr.Jain

Designation : Application Specialist

Signature :

Date : 11/11/12

I. Performance Qualification

a. Instrument Identification

		Verified Date
1. Model Name	Sysmex XP-100	01/11/2017
2. Serial Number	B3614	01/11/2017

b. Following is a list of tests to be performed and verified:

Test No.	Test Name	Test Purpose	Verified Date
01	Precision Tests	Establishing Reproducibility	01/11/2017
02	Accuracy Checks	Ability of Sample processing	01/11/2017

Validation Team:

Name : Naveen Kr.Jain

Designation : Sr. Application Specialist

Signature :

Date : 1/11/17

Installation Qualification for XP-100

Customer Name	: Dr.Dass Path Lab.
Address	: A-28 Lower ground floor, Ghanshyam dass jain marg,South Extension Part-2 New Delhi-110049
Instrument Name	: Sysmex XP100
Serial Number	: B3614

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. The Tilt-indicator and the Shock-indicators on the Packaging were found to be in Good Condition, 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.

Installation Procedure & Checklist Attached for records.

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.

Operations Qualifications for Sysmex XP-100 Sr. No.B3614

1. Verified all the reagent connections : Done
2. verified all Solenoid Valve, Motors And Syringes tests : Done
3. Verified Pressure and Vacuum status : Done
4. Verified Blank Counts : Done

Name : Anubhav Sharma

Designation : Dy.R.S.M.(Service)

Date : 1/11/12

Installation Report for

Customer Name : Pushpawati Singhania Hospital and Research Institute

Department : Hematology

Contact Person : Dr. R.Srivastava

Instrument Model : Sysmex XP-100

Serial Number : B3614

Date of Installation: 01-11-2017

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

Protocol Performed By: TBM, Delhi

Name: Anubhav Sharma

Designation: Service Engineer

Customer Authorization: Dr.Dass Path Lab

Name: Dr R.Srivastava

Designation: Consultant Pathologist

Company Representative Name & Sign

Date: 1/11/17

Customer Name & Sign

Date

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SYSMEX XP-100
AUTOMATED HEMATOLOGY ANALYZER

OPERATIONAL QUALIFICATION

For

DR.DASS PATH LAB

NEW DELHI

Marketed by:
Transasia Bio-Medicals Ltd.,
(ISO 9002 CERTIFIED)
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

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TRANSASIA BIOMEDICALS LIMITED INSTALLATION QUALIFICATION				TRANSASIA® Bio-Medicals Ltd.
Instrument Name **EM200**	**Clinical Chemistry Analyzer** **Dr.Dass Path Lab**	**Instrument ID** **B200537**		

11.0 IDENTIFICATION OF STANDARD OPERATING PROCEDURE

SOP No.	Title
Operation	Operation of Bio-Chemistry Random Analyzer
Calibration	Calibration of Parameters
Controls	Checking of Controls for Parameters
Maintenance	Maintenance / Checking of Distilled water, Waste, Wash solution, Cuvette rinse, Sample probe wash and Water save
Cleaning	Cleaning of Instrument surface

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Date: 01/11/2018
Effective Date: 01/11/2018

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XP – 100

2. Serial No.: B3614

3. Calibration Date: 01/11/2018

4. Material used: SCS-1000 (Lot No. 8310 0525, Expiry date: -09-Dec-2018)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for CBC 5 parameters using the measurement standard material (SCS-1000) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

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011 - 25732223 **Fax:** 011-25785451 **Email:** nz1@transasia.co.in **CIN:** U33110MH1985PLC036198

TRANSASIA®

Date: 30/10/2020
Effective Date: 30/10/2020

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XP – 100

2. Serial No.: B3614

3. Calibration Date: 30/10/2020

4. Material used: SCS-1000 (Lot No. 0280 0525, Expiry date: 08-Nov-2020)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for CBC 5 parameters using the measurement standard material (SCS-1000) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

Technical Service Department
Transasia Bio-Medicals Ltd