

ANALYZER CALIBRATION CERTIFICATE

CALIBRATION PROTOCOL

The purpose of this calibration protocol is to define the qualifications and the acceptance standard in order to verify the normal operation and function of the AUTOChem Xpert auto chemistry analyzer in the laboratory. Trained knowledgeable personnel from GENWORKS Health Pvt. Ltd. along with the department personnel will perform and review analyzer calibration protocol as mentioned by the manufacturer. The satisfactory outcome of this procedure assures that the system functions according to the parameters.

EQUIPMENT INFORMATION:-

Instrument Name	:	AUTO CHEMISTRY ANALYZER
Model/Type	:	AUTOChem XPert
Serial No	:	AES2K2KH04116YA
Installation Date	:	13/09/2022
Calibration Done On	:	15/09/2023
Next Calibration Due On	:	14/09/2024

Laboratory/Hospital Name : MEDRAY CLINICS PVT.LTD
No.962,12th Main Road, Opp.Lakme Salon
Doopannahalli, Indiranagr, Bangalore,
Karnataka - 560008.

Supported By : Genworks Health Pvt Ltd,
Survey No 525/1 & 538/1,
V.S Mani Nagar, Madhavaram,
Chennai-600060

CALIBRATION AND MAINTAINANCE PROCEDURES

MAINTAINANCE:

- Instrument was checked for cleanliness.
- Cuvettes were manually cleaned and performed wash cells(All) operation in maintenance.
- Wash unit working was checked whether it is dispensing and aspirating Xpert wash and water in the perfect sequence manually.
- Cleaned sample reagent and mixing probes manually with alcohol and then with distilled water also performed probe wash(Detergent) in the maintenance.
- Performed sample reagent and mixer probes horizontal and vertical movement.
- Air Purge was performed to remove any air bubbles present in the syringes.
- Instrument mechanism operation check was done and found instrument working in satisfied operation conditions.

CALIBRATION:

- Input supply and lamp voltage for the machine was found adequate using the multimeter.
- Cell blank values are measured in the maintenance screen and reports are attached.
- Cuvette temperature are readings are indicated in the Software
- Reagent compartments cooling temperature is indicated in LED display behind the machine.
- Detectors performance were checked by checking the temperature control voltage.
- All parameters Calibration and both level Quality control was done and results found satisfactory

This is to certify that this Analyzer has been inspected and calibrated for following parameters

TEST PARAMETER	TARGET VALUE & RANGE	OBTAINED VALUE
INPUT VOLTAGE	230-240V AC	234V AC
CELL BLANK VAULE	20000- 60000 for all wavelengths	
Cuvette TEMP	37 degree +/- 0.3	37.1 degree
REAGENT COMPARTMENT COOLING CHECK	4 to 14 degrees centigrade	8.2 degree
TEMP CONTROL UNIT	24 +/- 0.2V	
6V LAMP SUPPLY	6 +/- 0.2V	
24V MAIN BOARD SUPPLY	24 +/- 0.3V	

The results are obtained as per specifications & tolerance ranges. Routine chemistry parameters precision study was carried out. The CV's obtained are in acceptable range (< 3.0% CV). Calibrations of routine tests were also done & the results of controls & samples found satisfactory.

Calibration Reports:-

The controls results are obtained as per specifications & tolerance ranges. Verified the calibration & controls results according to the specific limits and considered the satisfactory results herewith certificate that AUTOChem Xpert Analyzer operates correctly according to the instrument specifications.

Calibration details of Standard used :

Multimeter Make. : Fluke
Serial No : **40640066WS**

Traceability Certificate : HI Tech calibration Services
Certificate # : HT\CC\201107-16\001 &
CR\PCAL\51278 Validity : 19-July-2024

Calibration details of Standard used :

Temperature Sensor Make : PT-100
Instrument ID : **WI-CALT-TS02**

Traceability Certificate : Northlab (INDIA) PVT.LTD
Certificate # : 0261221-T04 & CC24571400002920F
Validity : 02-DEC-2024

Report Sign Off:

Calibration Done By: Mr.Suresh G J

Designation: Circle Manager

Date & Sign: 15.09.2023



For
Mr. Suresh G. J.
(Circle Manager)

Note: Supportive date to be attached along with this certificate.

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :7 Sample ID:ALANOUD Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:22-12-2023 13:53:05

No.	Test Name	Result	Hint	Unit	Reference range
1	[CREA-J1]CRE	0.83		mg/dl	0.40~1.50

Checker:admin Examiner: BANGALORE Report Date:22-12-2023 15:08:26

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :8 Sample ID:ALANOUD Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:22-12-2023 13:53:05

No.	Test Name	Result	Hint	Unit	Reference range
1	[CREA-J1]CRE	1.32		mg/dl	0.40~1.50

Checker:admin Examiner: BANGALORE Report Date:22-12-2023 15:08:26

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :9 Sample ID:ALANOUD Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:22-12-2023 13:53:05

No.	Test Name	Result	Hint	Unit	Reference range
1	[CREA-J1]CRE	1.38		mg/dl	0.40~1.50

Checker:admin Examiner: BANGALORE Report Date:22-12-2023 15:08:26

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :10 Sample ID:ALANOUD Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:22-12-2023 13:53:05

No.	Test Name	Result	Hint	Unit	Reference range
1	[CREA-J1]CRE	0.89		mg/dl	0.40~1.50

Checker:admin Examiner: BANGALORE Report Date:22-12-2023 15:08:26

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :11 Sample ID:ALANOUD Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:22-12-2023 13:53:05

No.	Test Name	Result	Hint	Unit	Reference range
1	[CREA-J1]CRE	0.76		mg/dl	0.40~1.50

Checker:admin Examiner: BANGALORE Report Date:22-12-2023 15:08:26

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :12 Sample ID:ALANOUD Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:22-12-2023 13:53:05

No.	Test Name	Result	Hint	Unit	Reference range
1	[CREA-J1]CRE	0.77		mg/dl	0.40~1.50

Checker:admin Examiner: BANGALORE Report Date:22-12-2023 15:08:26

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :13 Sample ID:ALANOUD Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:22-12-2023 13:53:05

No.	Test Name	Result	Hint	Unit	Reference range
1	[CREA-J1]CRE	0.80		mg/dl	0.40~1.50

Checker:admin Examiner: BANGALORE Report Date:22-12-2023 15:08:26

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :14 Sample ID:ALANOUD Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:22-12-2023 13:53:05

No.	Test Name	Result	Hint	Unit	Reference range
1	[CREA-J1]CRE	0.80		mg/dl	0.40~1.50

Checker:admin Examiner: BANGALORE Report Date:22-12-2023 15:08:26

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :15 Sample ID:ALANOUD Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:22-12-2023 13:53:05

No.	Test Name	Result	Hint	Unit	Reference range
1	[CREA-J1]CRE	0.82		mg/dl	0.40~1.50

Checker:admin Examiner: BANGALORE Report Date:22-12-2023 15:08:26

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :16 Sample ID:ALANOUD Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:22-12-2023 13:53:05

No.	Test Name	Result	Hint	Unit	Reference range
1	[CREA-J1]CRE	0.81		mg/dl	0.40~1.50

Checker:admin Examiner: BANGALORE Report Date:22-12-2023 15:08:26

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :2 Sample ID:MD ABDUL MOMIN Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:19-12-2023 12:31:30

No.	Test Name	Result	Hint	Unit	Reference range
1	[GLU3]GLUCOSE	109.4		mg/dl	70.0~140.0

Checker:admin Examiner: BANGALORE Report Date:19-12-2023 13:14:39

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :3 Sample ID:MD ABDUL MOMIN Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:19-12-2023 12:31:30

No.	Test Name	Result	Hint	Unit	Reference range
1	[GLU3]GLUCOSE	101.6		mg/dl	70.0~140.0

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :4	Sample ID:MD ABDUL MOMIN	Bed No. :	Sample Type:Serum
Name:	Gender:Male	Age:	Case No. :
Department:	Doctor:	Diagnosis:	
Remark:			Register Date:19-12-2023 12:31:30

No.	Test Name	Result	Hint	Unit	Reference range
1	[GLU3]GLUCOSE	101.0		mg/dl	70.0~140.0

Checker:admin Examiner: BANGALORE Report Date:19-12-2023 13:14:39

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :5	Sample ID:MD ABDUL MOMIN	Bed No. :	Sample Type:Serum
Name:	Gender:Male	Age:	Case No. :
Department:	Doctor:	Diagnosis:	
Remark:			Register Date:19-12-2023 12:31:30

No.	Test Name	Result	Hint	Unit	Reference range
1	[GLU3]GLUCOSE	101.1		mg/dl	70.0~140.0

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No.:6 Sample ID:MD ABDUL MOMIN Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:19-12-2023 12:31:30

No.	Test Name	Result	Hint	Unit	Reference range
1	[GLU3]GLUCOSE	98.9		mg/dl	70.0~140.0

Checker:admin Examiner: BANGALORE Report Date:19-12-2023 13:14:39

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No.:7 Sample ID:MD ABDUL MOMIN Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:19-12-2023 12:31:30

No.	Test Name	Result	Hint	Unit	Reference range
1	[GLU3]GLUCOSE	99.3		mg/dl	70.0~140.0

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :8 Sample ID:MD ABDUL MOMIN Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:19-12-2023 12:31:30

No.	Test Name	Result	Hint	Unit	Reference range
1	[GLU3]GLUCOSE	100.0		mg/dl	70.0~140.0

Checker:admin Examiner: BANGALORE Report Date:19-12-2023 13:14:39

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :9 Sample ID:MD ABDUL MOMIN Bed No. : Sample Type:Serum
Name: Gender:Male Age: Case No. :
Department: Doctor: Diagnosis:
Remark: Register Date:19-12-2023 12:31:30

No.	Test Name	Result	Hint	Unit	Reference range
1	[GLU3]GLUCOSE	98.7		mg/dl	70.0~140.0

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :10	Sample ID:MD ABDUL MOMIN	Bed No. :	Sample Type:Serum
Name:	Gender:Male	Age:	Case No. :
Department:	Doctor:	Diagnosis:	
Remark:			Register Date:19-12-2023 12:31:30

No.	Test Name	Result	Hint	Unit	Reference range
1	[GLU3]GLUCOSE	100.8		mg/dl	70.0~140.0

Checker:admin	Examiner:	BANGALORE	Report Date:19-12-2023 13:14:39
---------------	-----------	-----------	---------------------------------

MEDRAY DIAGNOSTICS
INDIRANAGAR

Sample No. :11	Sample ID:MD ABDUL MOMIN	Bed No. :	Sample Type:Serum
Name:	Gender:Male	Age:	Case No. :
Department:	Doctor:	Diagnosis:	
Remark:			Register Date:19-12-2023 12:31:30

No.	Test Name	Result	Hint	Unit	Reference range
1	[GLU3]GLUCOSE	100.8		mg/dl	70.0~140.0

Auto Chem Xpert ANALYSER - PRECISION data		
CUSTOMER NAME	Medray Clinics Pvt Ltd	
	Parameters	
S.No	Glucose	Creatinine
1	109.4	0.83
2	101.6	1.32
3	101	1.38
4	101.1	0.89
5	98.9	0.76
6	99.3	0.77
7	100	0.8
8	98.7	0.8
9	100.8	0.82
10	100.8	0.81
Mean	101.16	0.92
SD	3.06	0.23
CV%	3.03	25.15