Health Horizon
DIAGNOSTICS

HEALTH HORIZON DIAGNOSTICS

METROPOLIS HEALTHCARE LTD.
EXTERNAL QUALITY ASSURANCE SERVICE
(MHL EQAS PROGRAM)

CORRECTIVE AND PREVENTIVE ACTION
FOR
UNACCEPTABLE RESULTS OF

SERUM CHLORIDE TEST

SR. NO	LIST OF DOCUMENTS
01	Annexure: 01: Instrument service Report
02	Annexure: 02: Internal Quality Control Data Date of 17/01/2023 & 30/01/2023
03	Annexure: 03: Internal Quality Control BIO-RAD Value Sheet Lot No. 26490, Level 01 :26491 & Level 02: 26492
04	Annexure: 04: Inter-Lab Comparison (ILC) Report
05	Annexure: 05: MOU with NABL Accredited Lab for Outsource Investigation

HHD-QSP/009/00

Health Horizon DIAGNOSTICS	FORMAT OF EXTERNAL QUALITY CONTROL/ PROFICIENCY TESTING (PT) SAMPLES: CORRECTIVE AND PREVENTIVE ACTION FOR UNACCEPTABLE RESULTS	
	ANNEXURE-01	HEALTH HORIZON DIAGNOSTICS

Type of Evaluation: External Quality Control / Proficiency Testing (PT) Sample ☑

Other ☐ **(Specify):** —

Evaluation Date: 25/01/2023

Investigation: **Hematology** ☐ **Biochemistry** ☑ **Urine** ☐ **Serology** ☐ **Immunology** ☐

Other (Specify): —

Unacceptable Analyte/ Parameter:

MHL EQAS Sample NO:01 = Chloride
Sample NO:02 = Chloride

Description/Error/ Reason/ Remark:

MHL EQAS Sample NO:01 - SDI Z-Score = 3.55 Unacceptable
Sample NO.02 - SDI Z-Score = 3.40 Unacceptable

Investigations (Root Cause Analysis) :

Phase	Commonest Reasons	Tick / Cross
Pre-Analytical Phase	1. Missed Test Requisition Form (TRF)	☐
	2. Incorrect sample identification	☐
	3. Incorrect sample tube	☐
	4. Sample from IV running area	☐
	5. Delay in sample transportation	☐
	6. Insufficient samples	☐
	7. Sample mix-ups	☐
	8. Tube broken in centrifuge	☐
	9. Wrong timing for Collection	☐
	10. Invalid Specimen: Haemolysed Sample, Lipemic Sample and Icteric Sample	☐
	11. Software errors	☐
Analytical Phase	1. Instrument not calibrated properly	☐
	2. Specimen mix-up	☐
	3. Inadequate specimen	☐
	4. Presence of interfering substances	☐
	5. Wrong analytical method	☐
	6. Lack of precision	☐
Post-Analytical Phase	1. Wrong patient identification	☐
	2. Report not legible	☐
	3. Report delayed	☐
	4. Transcriptional error	☐
	5. Specificity of the test not understood	☐
	6. Previous values are not available for comparison	☐

Health Horizon DIAGNOSTICS	FORMAT OF EXTERNAL QUALITY CONTROL/ PROFICIENCY TESTING (PT) SAMPLES: CORRECTIVE AND PREVENTIVE ACTION FOR UNACCEPTABLE RESULTS	
	ANNEXURE-01	HEALTH HORIZON DIAGNOSTICS

Root Cause Analysis : We checked the Internal quality control of the date when EQAS was run. and found it within acceptable range. Also the specimen handling was cross checked as per our QSP "Handling proficiency Testing and External quality Assurance Sample (HHD-QSP/009/00)

Corrective Action: Corrective action taken on date 25/01/23 We checked Internal Quality control record on date 17/01/2023, IQC result was within range. Also the preventive maintenance of the machin was done by service engineer.

Preventive Action: For the machine Easylyte Plus on date 30/01/2023 after maintenance IQC performed and it was within range.
We have established MOU with a NABL LAB and have planned ILC of serum chloride every three months.

Conclusion Serum chloride had a PT outlier and accordingly CAPA was taken.

Attachment (Attach result form and assessment details):
Attached scan copy!

1) Instrument service Report	4) MOU with NABL Lab
2) Internal quality control data on date 17/01/2023 & 30/01/2023	5) Inter Lab comparision (ILC) Data.
3) IQC BIO-RAD Value sheet Lot NO- 26490. Level-01 26491 Level 02 - 26492	

Comment : Nil

30/01/2023

Recorded By : Sign / Date (Laboratory Manager /Authorized trained person)

Comment : Satisfactory

30/01/2023

Verified By : Sign / Date (Laboratory Director/Authorized trained person)

ANNEXURE : 01

TRANSASIA®

TECHNICAL SERVICE REPORT No. 1517643 DATE: 30/01/23

CUSTOMER DETAILS	INSTRUMENT DETAILS	SERVICE STATUS
NAME: Health	MODEL: Easylyte	☐ WARRANTY ☐ R&R ☐ AMC ☐ CMC ☐ CHARGED CALL
ADDRESS: Hinzen Diagnosis Pune	SR. NO.: 56879	TYPE OF CALL ☐ INSTALLATION ☐ P.M. VISIT [I II III IV] ☐ APPLICATION SUPPORT ☐ BREAKDOWN
TEL NO:	CALL DETAILS (DATE / TIME): COMPLAINT RECD. / RESPONSE / JOB COMPLETED / RESPONSE TIME / TRAVEL TIME 1 Hrs	DOWN TIME: COUNTER READING:
NAME OF THE OPERATOR:		

PROBLEM REPORTED: clonde low

OBSERVATIONS: found some air above

ACTION TAKEN: Replaced probe tubing - clean & wrap pump tubing cleaned solution valve Normal

SITE CONDITION: LINE-NEUTRAL VOLT.: 230 V NEUTRAL-EARTH VOLT.: 1 V LINE-EARTH VOLT.: 229

BRAND OF REAGENT USED:

☐ FOLLOWING PARTS HAVE BEEN REPLACED
☐ FOLLOWING PARTS NEED TO BE REPLACED. PLEASE APPROVE

NO.	DESCRIPTION	QTY.	COST	TOTAL

TOTAL Rs.

INVOICE NO.: DATE:

FOLLOW-UP ACTION (Required if any):

ENGINEER'S/APPLICATION SPECIALIST'S SIGNATURE:
TIME 11:00 to 12:15 pm NAME: Amrut Kulkarni

TO BE FILLED IN BY CUSTOMER

☑ PREVENTIVE MAINTENANCE CARRIED OUT SATISFACTORILY.
☐ FAULT RECTIFIED & INSTRUMENT IS WORKING SATISFACTORILY.
☐ WE HEREBY APPROVE RS. _____ FOR PARTS
☐ COMMENTS (IF ANY):

SEAL DATE 30/01/23 CUSTOMER'S SIGNATURE NAME

BRANCH H. O.
RECEIVED ON:
CHECKED BY:
JOB CARD NO.:

NOTE: Parts replaced are chargeable except during warranty Period. Consumables like printer head, lamp, tubing, paper rolls etc. & breakable parts are not covered by warranty and hence are chargeable. Parts replaced due to negligence in operation will also be charged in every case.

AT TRANSASIA, CUSTOMER SATISFACTION IS OUR PRIME CONCERN. IN CASE YOU HAVE ANY SUGGESTION PLEASE CONTACT: GENERAL MANAGER (TECHNICAL SERVICE), MUMBAI. TEL.: 4030 9000

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Erba Mannheim

ANNEXURE : 02

Internal Quality Control for Chloride

Date:- 17/01/2023

JAN-17-23; 10:26

ANALYSIS

PATIENT'S NAME

BIO-RAD.

Control-Level-02

SAMPLE 003

Na 123.6 K 5.72 Cl 87.1 ✓

Na LO K HI Cl LO

BLOOD Na, K, Cl mmol/L

(CORRELATED VALUES)

JAN-17-23; 10:27

Done By:-

Santosh
17/01/2023

Checked By:-

17/01/2023

Internal quality control for chloride Date:- 30/01/2023

OPER FUNCTS

Na= 1.03X - 1.10
K = 1.02X - 0.24
Cl= 0.99X + 3.46
BLOOD CORRELATION ON
JAN-30-23; 12:23

Na/K/Cl
5EAB
MODE OOA

OPER FUNCTS

SOL'N PURGE
JAN-30-23; 12:25

CALIBRATION

CAL VALUES
Na 56.93 K 56.97 Cl 45.16
JAN-30-23; 12:29

ANALYSIS
PATIENT'S NAME

Pre-Run check Value.

SAMPLE 003
Na 134.0 K 6.26 Cl 96.8
Na LO K HI Cl LO
BLOOD Na,K,Cl mmol/L
(CORRELATED VALUES)
JAN-30-23; 12:40

ANALYSIS
PATIENT'S NAME

BIORAD QC Level- 2

SAMPLE 004
Na 126.4 K 5.81 Cl 90.0 ✓
Na LO K HI Cl LO
BLOOD Na,K,Cl mmol/L
(CORRELATED VALUES)
JAN-30-23; 12:46

Done By:-
Santosh
30/01/2023

Checked By:-
30/01/2023

ANNEXURE : 03

BIO-RAD

Lyphochek® Assayed Chemistry Control Levels 1 and 2

REF C-310-5 Level 1 12 x 5 mL
C-315-5 Level 2 12 x 5 mL
313X MiniPak 2 x 5 mL

CE 0459 IVD EXP 2023-11-30 LOT 26490 Level 1 26491 Level 2 26492

https://www.myeinserts.com/26490

INTENDED USE

Lyphochek Assayed Chemistry Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Multiple levels of control are available to allow monitoring of the test system's reliability.

For customers in Germany: Quality control materials are required for assessment of laboratory performance as described in the "Guideline for Quality Assurance of Medical Laboratory Examinations following the German Medical Association" (Rili-BÄK regulation).

REAGENT

This product is prepared from human serum with added chemicals, purified biochemical material (tissue extracts of human and animal origin), therapeutic drugs, stabilizers and preservatives. This product is provided in lyophilized form for increased stability.

STORAGE AND STABILITY

This product will be stable until the expiration date when stored unopened at 2 to 8°C.

Reconstituted and Refrigerated: After reconstituting and storing tightly capped at 2 to 8°C, this product will be stable as follows:

- All analytes: 7 days

Except:

- T3 (Free), Acid Phosphatase (Total) and Prostatic Acid Phosphatase (PAP): 3 days

Reconstituted and Frozen: When reconstituted and stored tightly capped at -10 to -20°C, this product will be stable as follows:

- All analytes: 30 days

Except:

- Tobramycin: 20 days
- T3 (Free): 10 days

Once thawed, do not refreeze this product. Discard the remaining material.

This product is shipped under ambient conditions.

PROCEDURE

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used.

Using a volumetric pipet or equivalent, reconstitute each vial with 5.0 mL of distilled or deionized water. Replace the stopper and allow this product to stand for approximately 20 minutes swirling occasionally.

Before sampling, gently swirl the vial several times to ensure homogeneity. If performing trace metal analysis, do not mix by inversion. After each use, promptly replace the stopper and return to the appropriate storage condition.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

LIMITATIONS

1. This product should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the reconstituted product, discard the vial.
3. This product is not intended for use as a standard.

WARNING

⚠ **Biological source material. Treat as potentially infectious.**

Each human donor unit used to manufacture this product was tested as required by FDA accepted methods. Tests results were non-reactive or negative for evidence of infection due to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). This product may also contain other human source materials for which there are no approved tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Safety Data Sheet (SDS) available for professional users on *www.bio-rad.com.*

SPECIFIC PERFORMANCE CHARACTERISTICS

This product is a freeze-dried product manufactured under rigid quality control standards. To obtain consistent assay values, the control requires proper storage and handling as described.

ASSIGNMENT OF VALUES

The mean values and corresponding ±3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product. Data from Unity™ Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. [Customers in Germany have to follow the requirements as described in the Rili-BÄK regulation.] Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

Unity™ Interlaboratory Program is a proprietary Bio-Rad software program holding more than 2 billion QC data points from thousands of laboratories.

INSTRUCTIONS FOR OBTAINING THE DATA CHARTS

The Data Charts are available through the Internet, at *www.myeinserts.com/26490.* Follow the directions at the website to receive email notifications of insert updates. Alternate methods for receiving data charts are available by contacting your local Bio-Rad Laboratories Office.

English • 2023-02 • 4030-00S

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10/22

INSTRUMENT (1)

	Units	Level 1 - 26491		Level 2 - 26492	
		Mean	Range	Mean	Range
BIOSYSTEMS B400/A25/A15 (5) (continued)					
Urea (Urease, UV) (4)	mg/dL	29.9	25.4 – 34.4	91.0	77.4 – 105
Uric Acid (Uricase, colorimetric)	mg/dL	4.91	4.17 – 5.65	8.58	7.29 – 9.87
ERBA XL SERIES (5)					
Albumin	g/dL	3.90	3.30 – 4.50	2.70	2.28 – 3.12
Albumin (India Market Only)	g/dL	3.96	3.36 – 4.56	2.69	2.30 – 3.08
Alkaline Phosphatase (IFCC Optimized) (2)	U/L	115	92.1 – 138	487	391 – 583
Alkaline Phosphatase (India Market Only) (2)	U/L	115	91.0 – 139	476	380 – 572
ALT/SGPT (2)	U/L	27.6	22.2 – 33.0	104	83.5 – 125
ALT/SGPT (Modified IFCC) (India Market Only) (2)	U/L	27.4	22.0 – 32.8	102	81.0 – 122
Amylase (2)	U/L	60.5	48.5 – 72.5	393	315 – 471
AST/SGOT (2)	U/L	38.2	30.7 – 45.7	204	162 – 246
AST/SGOT (Modified IFCC) (India Market Only) (2)	U/L	37.1	29.6 – 44.6	199	160 – 238
Bilirubin (Direct)	mg/dL	0.370	0.280 – 0.460	1.31	0.980 – 1.64
Bilirubin (Direct) (DCA)	mg/dL	0.390	0.300 – 0.480	1.65	1.23 – 2.07
Bilirubin (Total)	mg/dL	0.990	0.750 – 1.23	4.77	3.57 – 5.97
Bilirubin (Total) (DCA)	mg/dL	1.01	0.770 – 1.25	4.70	3.53 – 5.87
Calcium	mg/dL	9.94	8.44 – 11.4	13.4	11.3 – 15.5
Calcium (India Market Only)	mg/dL	9.21	7.83 – 10.6	12.3	10.5 – 14.1
Carbon Dioxide (CO2)	mEq/L	34.5	27.6 – 41.4	19.0	15.2 – 22.8
Chloride	mEq/L	107	96.0 – 118	93.0	83.7 – 102
Chloride (Mercuric Thiocyanate)	mEq/L	109	94.0 – 124	101	86.0 – 116
Cholesterol (HDL) (7)	mg/dL	67.2	53.7 – 80.7	23.9	19.1 – 28.7
Cholesterol (LDL)	mg/dL	149	119 – 179	67.6	54.1 – 81.1
Cholesterol (Total)	mg/dL	251	212 – 290	104	88.0 – 119
Cholinesterase (2)	U/L	7492	5995 – 8989	1131	906 – 1356
Creatine Kinase (CK) (2)	U/L	141	114 – 168	463	370 – 556
Creatinine (Alkaline picrate method)	mg/dL	2.59	2.08 – 3.10	5.74	4.60 – 6.88
Creatinine (Enzymatic)	mg/dL	1.80	1.44 – 2.16	5.21	4.16 – 6.26
Creatinine (Enzymatic) (India Market Only)	mg/dL	1.66	1.33 – 1.99	4.80	3.90 – 5.70
Gamma Glutamyltransferase (GGT) (2)	U/L	66.3	53.1 – 79.5	167	134 – 200
Glucose	mg/dL	91.7	77.9 – 106	304	259 – 349
Glucose (Hexokinase) (India Market Only)	mg/dL	85.4	72.5 – 98.3	285	243 – 327
Iron	µg/dL	236	188 – 284	62.1	49.8 – 74.4
Iron (UIBC)	µg/dL	63.3	50.7 – 75.9	126	102 – 150
Lactate Dehydrogenase (LDH) (2)	U/L	333	267 – 399	888	711 – 1065
Lipase (2)	U/L	43.1	34.4 – 51.8	57.7	46.3 – 69.1
Lithium	mEq/L	0.460	0.400 – 0.520	1.71	1.53 – 1.89
Magnesium	mg/dL	1.91	1.61 – 2.21	4.49	3.83 – 5.15
Phosphorus (India Market Only)	mg/dL	3.87	3.30 – 4.44	7.20	6.00 – 8.40
Phosphorus (New Formulation)	mg/dL	3.91	3.31 – 4.51	7.74	6.57 – 8.91
Potassium	mEq/L	3.61	3.25 – 3.97	5.49	4.95 – 6.03
Protein Serum (Total)	g/dL	6.94	5.89 – 7.99	4.75	4.03 – 5.47
Protein Serum (Total) (India Market Only)	g/dL	6.51	5.52 – 7.50	4.30	3.70 – 4.90
Sodium	mEq/L	140	126 – 154	123	110 – 135
Triglycerides	mg/dL	186	159 – 213	96.1	81.7 – 111
Triglycerides (India Market Only)	mg/dL	182	155 – 209	82.6	70.3 – 94.9
Urea (4)	mg/dL	33.8	28.7 – 38.9	103	88.0 – 118
Uric Acid	mg/dL	5.38	4.57 – 6.19	10.8	9.30 – 12.3

ANNEXURE : 04

Health Horizon DIAGNOSTICS	ASSESMENT OF INTER-LAB COMPARISION FOR LAB ANALYTES		
	ANNEXURE - 01	HEALTH HORIZON DIAGNOSTICS	Page 1 of 2

INTER-LAB COMPARISION : **DATE :** 30/03/2023

Criteria: - One sample analyzed in the lab and same sample was send to NABL Accredited Lab for Inter-Lab Comparison.

Test Performed By:- MR. Santosh Hake

ANALYTE NAME	HEALTH HORIZON DIAGNOSTICS ANALYTE RESULT		AG DIAGNOSTICS NABL ACCREDITED LAB ANALYTE RESULT		Actual Result %CV	Evaluation Criteria %CV	Acceptable		Performed By
	Sample – 01	Sample - 02	Sample – 01	Sample - 02			Yes	NO	
Serum Chloride	92.8	---	92.0	---	0.61	5% or ± 3SD	✓	–	Santosh 30/03/2023

Health Horizon Diagnostics Chloride Sample 01 Result = 92.8

NABL Accredited AG Diagnostics Chloride Sample 01 Result = 92.0

Comparison Sample Mean = 92.4,

Comparison Sample SD = 0.56,

Comparison Sample CV = 0.61

Health Horizon DIAGNOSTICS	ASSESMENT OF LOT TO LOT/BATCH TO BATCH VERIFICATION FOR BIOCHEMISTRY		
	ANNEXURE - 01	HEALTH HORIZON DIAGNOSTICS	Page 2 of 2

Note*: Evaluation Criteria referred from MHL EQAS Program PT Sample Participant Summary.

For Inter-Lab Comparison Chloride result evaluation acceptable range = 5 % CV is acceptable or ± 3SD

Remark: NA

Checked By: - 30/03/2023

Technical Manager

Remark: Nil. Inter-lab comparison was evaluated within acceptable range.

Reviewed by: 30/03/2023

LabHead/ Quality Manager

Dr. Ankeeta Lahoti
M.B.B.S., M.D. PATHOLOGY

Health Horizon DIAGNOSTICS

Dr. Harshal Patil
M.D. DNB PATHOLOGY

Lab ID	: 00466 /OPD	Lab Regn Date & Time	: 30-Mar-2023 13:42
Patient Name	: **MR. MOHAMMAD ISRAFIL**	Coll. Date & Time	: 30-Mar-2023 13:42
Age / Sex	: 75 Years / Male	Report Date & Time	: 30-Mar-2023 15:13
Referred By	: APPLE HOSPITAL	Sample Type	: SERUM
		Barcode	* 0 0 4 6 6 *

BIOCHEMISTRY.

Investigation	Result	Unit	Bio. Ref. Range
KIDNEY FUNCTION TEST			
Blood Urea	**85.9**	mg/dL	12.8-42.8
(Method : Urease)			
Creatinine	1.17	mg/dL	0.6-1.3
(Method : Enzymatic)			
Sr. Uric Acid	6.1	mg/dL	3.5-7.2
Method : (Uricase/Peroxidase)			
Test Done on Fully Automated EM 200 Biochemistry Analyzer			
ELECTROLYTES			
Sodium	**121.0**	mEq/lit	135-145
Potassium	**5.47**	mEq/lit	3.5-5.1
Chloride	**92.8**	mmol/L	98-107
Test done on Easy Lite –Fully Automated Electrolyte Analyser			

---------- END OF REPORT ----------

Dr Ankeeta Lahoti
MD Pathology

Address : Varun Capital, Flat No. 401/402, Behind Pashankar Auto, Shivajinagar, Pune, MH - 411005
Email : hhdiagnostics@gmail.com | CALL : +91 8070000444

MOHAMMAD ISRAFIL

Ref.:Dr.--

Sample Collected At:
Synergen Diagnostics
Unit 105, Sai Chambers, Wakadewadi,
Old Mumbai-Pune Highway,
Pune - 411003 Zone SHIVA

SID: 122222693
Collection Date:
30-03-2023 08:24 PM
Registration Date:
30-03-2023 08:24 pm
Report Date:
30-03-2023 08:59 PM

REPORT Age:75.00 Years Sex:MALE

Test Description	Observed Value	Biological Reference Interval
Clinical Chemistry :		
Bilirubin-Total, serum by Diazo method	**2.00**	0.10 - 1.20 mg/dL Neonates : Upto 15.0 mg/dL
Bilirubin-Conjugated, serum by Diazo method	**1.30**	Upto 0.5 mg/dL
Bilirubin-Unconjugated, serum by calculation	**0.70**	0.1 to 1.0 mg/dL
Kindly correlate clinically and follow up.		
Chloride, serum by IMT Indirect	**92.00**	98 to 107 mmol/Lt

End of Report

Shantanu Roy
Dr.Shantanu Roy
D.C.P.,D.N.B. (Path)
Reg.No.-2013/02/0274
A.G Diagnostics Pvt. Ltd.

MC-3143

ANNEXURE : 05

AGREEMENT FOR PROVISION OF DIAGNOSTIC LABORATORY SERVICES

This agreement **for Provision of Diagnostic Laboratory Services** is executed on 01-03-2023.

BY AND BETWEEN

A.G Diagnostics Private Limited, a company incorporated under the provisions of companies act 2013 & having its office at Nayantara, Bhandarkar Road Pune 411004 (hereinafter referred to as **"AGD"** which expression shall, unless repugnant to the context thereof, mean and include its legal representatives, partners, administrators and permitted assigns), represented through its authorised signatory Mr. Amol Deshmukh of the one part.

AND

Health Horizon Diagnostics, whose details are specified under Annexure A (hereinafter referred to as the **"Client"** which expression shall, unless repugnant to the context thereof, mean and include its legal representatives, partners, administrators and permitted assigns) represented **by** Dr. Harshal Patil of the other part. AGD & the Client hereinafter also be collectively referred to as **"Parties"** & individually as the **"Party"**.

WHEREAS

a. AGD is engaged in providing reliable, fast and affordable Pathology laboratory and wellness services to patients, clinicians & other laboratories in and around Pune. AGD has best of equipment, technology & manpower of international standards with a sound infrastructure and properly laid down systems. AGD is accredited by NABL through Certificate No. MC-3143.

b. The Client after the mutual discussions between both the Parties has agreed to avail services of AGD. In furtherance of the same, the Parties are desirous of entering into this Contract to record the terms and conditions subject to which AGD shall provide its Services, and the Client shall pay the fees.

Therefore, it is agreed to record the understanding between the parties on the terms & conditions as set forth below:

1. **SERVICES**:

1.1 The Client hereby engages AGD to provide services listed in AGD's latest DOS and Annexure B.
1.2 AGD will provide the services as per its Directory of Services (DOS). Changes if any shall be communicated to the Client 15 days in advance in writing. Client will make the necessary changes to its records & shall consider the changes as final.
1.3 Client acknowledges that under unavoidable / unforeseen circumstances AGD may discontinue any service or change the method of testing without prior intimation to the Client. However, to minimize the impact on the patient / healthcare, the same will be intimated to the Client at earliest.
1.4 If the samples are collected at the Client's premises, AGD shall offer Logistics support as described through Clause 2.

2. **LOGISTICS**:

2.1 AGD shall arrange for the pickup of samples from the Client's premises on all the weekdays during working hours of AGD.
2.2 AGD shall not provide logistic services on Sundays & public holidays.

2.3 The representatives of both the parties will mutually decide on the periodicity of the sample pick up based on the workload.
2.4 AGD shall ensure that the samples are transported to the laboratory from the Client's premises in optimum storage conditions. It is responsibility of the Client to ensure packing in such a manner to ensure sample integrity during transit.
2.5 In event of sample loss due to unavoidable circumstances, AGD shall not be held responsible.
2.6 The responsibility for appropriate sample collection as per test requirements and labelling after correct patient identification and providing relevant clinical history in the Test Requisition Form remains with the client.

3. **REPORTS**:

3.1 AGD shall deliver the reports to the Client as per the Turnaround time committed in the DOS, however in unforeseen circumstances reports may be delayed. AGD agrees to ensure that the delay is minimal & the Client shall not raise any claim for refund or initiate any action against AGD.
3.2 Mode of delivery: It is agreed between the parties that preferred mode of delivery is Auto email services by AGD wherein the Client shall provide a correct email id on which reports shall be emailed by AGD. The responsibility towards appropriate access to this email id on the Client's end, remains with the Client. The email id for providing auto email provided by Client to AGD is as mentioned in Annexure A.
3.3 The hard copy shall be delivered by the Logistics person if the Client desires so.
3.4 It is further agreed between the parties that Auto Email Service shall not be available for tests inclusive of but not limited to where reports have graphics, attachment of certain kinds, two signatures etc. **Annexure C** includes the list of few such tests.

4. **COMPENSATION FOR SERVICES**:

4.1 The Invoice shall be generated Monthly based on test charges agreed upon through Annexure B and will be sent to the Client at its office mentioned in this agreement unless otherwise specified & agreed upon.
4.2 Clients shall check the Invoice & intimate any discrepancy to AGD within 5 working days. AGD will verify the same & shall amend the invoice accordingly, if necessary & resubmit to the Client. However, if the discrepancy is not reported, Client agrees to pay the entire invoice amount.
4.3 Client agrees to pay the invoice amount in 8 working days. Under any circumstances Client shall not withhold any payment. If there is any discrepancy, Client shall release remaining amount immediately & shall release the discrepant amount upon successful resolution of the issue reported, in any case not later than 30 days.

4.4 **PAYMENT MODE**:

4.4.1 **Cheque/Demand Draft (DD)**: The Payment in favour of **"A.G Diagnostics Pvt. Ltd".**
4.4.2 **NEFT**: Details as below:
A/C Name : **A.G Diagnostics Pvt. Ltd.**
Bank Name : ICICI Bank Ltd
Branch : Bhandarkar Road-Pune
A/C No. : 624005020746
RTGS/NEFT IFSC code: ICIC0006240
MICR : 411229006
4.4.3 **Cash**: Clients shall prefer any of the above modes of payment & avoid cash payment. However, if such need arises the Client shall intimate AGD in writing. AGD shall not be responsible for any cash payments released without such intimation.

4.5 If the Client fails to pay within 15 days of receipt of invoice, AGD reserves the right to hold the services till the outstanding amount is cleared. In case of non-payment within agreed upon duration, AGD will charge interest @ 1.25% per month from the due date.
4.6 AGD PAN number is **AAQCA0978E**

5. DURATION/TERM:

5.1 This agreement shall commence from 01-03-2023 & will be in force up to 28-02-2026 for a period of 36 months.

6. RENEWAL:

6.1 The agreement may be renewed for a further period on mutual terms & conditions as agreed between the parties.

7. **TERMINATION:**

7.1 Either party can terminate this agreement by giving clear 30 days' notice in writing. Either party shall also be entitled to terminate this Agreement with immediate effect if any breach of terms and conditions contained in this agreement. Before terminating this agreement both parties agree to settle all dues towards each other.

8. **CONFIDENTIALITY:**

8.1 Either party shall not disclose and /or divulge to any person/s and /or companies any information related to the terms & conditions of this agreement. AGD agrees not to disclose to any third party any information with regards to the tests conducted by AGD.

9. **DISPUTES & ARBITRATION:**

9.1 If any dispute or difference of any kind whatsoever shall arise between the Parties in connection with or arising out of this agreement whether before or after the termination or breach of this agreement the Parties shall promptly & in good faith negotiate to find an amicable resolution & settlement.

9.2 In the event no amicable resolution or settlement is reached within a period of 30 days such a dispute or difference shall be referred to a mutually acceptable single arbitrator under the provisions of the Indian Arbitration & conciliation Act 1996. The arbitration proceedings shall be held in Pune.

9.3 Notwithstanding anything contained herein, the parties shall have the right to institute legal proceedings to prevent any such continuing breach of provisions of this Agreement to seek specific relief & the courts in Pune shall have exclusive jurisdiction on any matter arising out of this Agreement.

10. MISCELLANEOUS

10.1 **Intellectual Property Rights.** All intellectual property rights belonging to a Party prior or after the execution of this agreement shall remain vested in that Party. None of the intellectual property rights in either Party's trademarks and/or brands shall be used by the other Party for any purpose, without such other Party's prior written consent.

10.2 **Entire Agreement**. This agreement supersedes any earlier contracts, communications that may have been entered into between the Parties on the said subject matter. All the Annexures which are mentioned in this agreement, shall be treated as integral part of this agreement. It is clarified that AGD is entitled to amend the AGD DoS from time to time at its sole discretion. In the event AGD amends the DoS such updated AGD DoS shall be deemed to be incorporated into this Contract by reference and such amended AGD DoS shall be made available to the Client.

A. G. DIAGNOSTICS PVT. LTD. PUNE

10.3 **Force Majeure.** If the compliance of its obligations under this Contract by either Party is delayed, prevented, restricted or interfered with by reason of Force Majeure then the Party so affected, upon giving prompt written notice to the other Party, shall not be liable for non-performance of such obligations.

IN WITNESS OF the Parties hereto have executed this Agreement on the date mentioned above

For and on behalf of the Client:	For and on behalf of AGD:
HEALTH HORIZON DIAGNOSTICS PUNE	A.G. DIAGNOSTICS PVT. LTD. PUNE
Name: Dr. Harshal Patil	Name: Mr. Amol Deshmukh
Title: Director	Title: General Manager

A.G. DIAGNOSTICS PVT. LTD. PUNE

2.1.1. V1

ANNEXURE A

Client Details

Details of the Client:

Sl. #	Particulars Required	Details
1	Name of the Client	Health Horizon Diagnostics
2	Client Constitution	Proprietorship/Partnership/ Private Ltd Co/Public Ltd Co)
3	Trade Licence No/CIN	Please provide Trade Licence No or CIN
4	Permanent Account No.	
5	Name(s) of Proprietor / Partners / Directors	1. Dr. Harshal Patil 2. Dr. Ankeeta Lahoti 3. 4. 5.
6	Email Id of Proprietor / Partners / Directors	1. hhdiagnostics@gmail.com 2. 3. 4. 5.
7	Nature of Business (Laboratory/Hospital/Others)	Laboratory
8	Office Address	Flat No. 401 & 402, CTS No.364,365/13,FP No.713, 714/13, Varun Capital, Shivaji Nagar,Pune-411005
9	Contact Person Name	Mr. Dhananjay Abhang
10	Contact Person Phone No.	8070000444
11	**Contact Person e-mail ID for auto email services**	synergendiagnostics@gmail.com
12	Authorised Signatory Name	Dr. Harshal Patil
13	Authorised Signatory Designation	Director
14	Authorised Signatory email address	hhdiagnostics@gmail.com
15	Bank details from where payments will be made to AGD	Bank Name: Account Name: Account Type: Savings/Current/OD/CC Bank Address: IFSC Code:

A.G. DIAGNOSTICS PVT. LTD. PUNE

2.1.2. V1

ANNEXURE B

Commercials

Subject to Clause 1, the term 'Services' shall mean any of the services detailed in column (B) hereto, which have been agreed to be provided by AGD in relation to the Samples. Also, subject to Clause 4.1, the term 'test charges' in relation to a Service shall mean the cost prescribed against such Service in column (C) below:

S. No.	Services (B)	Test Charges (C)
1)	All types of medical diagnostic laboratory services currently being provided by AGD. A list of all the tests currently being provided by AGD is provided in latest AGD DoS.	List Price as per AGD Directory of Services & discount structure as given below

Standard Discount Structure:

Sr. No	Category of Tests	Discount % on List Price in DoS
1	**A3**	30 %
2	**A4**	20 %
3	**A5**	10 %
4	**A6**	0 %

Special Discount:

Sr. No	Test	Test Charges (₹)	Discounted Charges (₹)
1	FSH	500	150
2	LH	500	150
3	Beta HCG	840	200
4	E2- Estradiol	700	200
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2.1.3 V2.

ANNEXURE C

List of Tests excluded from Auto Email services.

Sr. No	Name of Test
1	Histopathology Reports
2	Double Marker Test- First Trimester
3	Triple Marker Test- Second Trimester
4	Quadruple Test
5	Hemoglobin Electrophoresis
6	Protein Electrophoresis
7	Immunofixation Electrophoresis

A.G. DIAGNOSTICS PVT. LTD. PUNE

Health Horizon
DIAGNOSTICS

HEALTH HORIZON DIAGNOSTICS

METROPOLIS HEALTHCARE LTD.

EXTERNAL QUALITY ASSURANCE SERVICE

(MHL EQAS PROGRAM)

CORRECTIVE AND PREVENTIVE ACTION

FOR

UNACCEPTABLE RESULTS OF

BILIRUBIN DIRECT TEST

HHD-QSP/009/00

Health Horizon DIAGNOSTICS	FORMAT OF EXTERNAL QUALITY CONTROL/ PROFICIENCY TESTING (PT) SAMPLES: CORRECTIVE AND PREVENTIVE ACTION FOR UNACCEPTABLE RESULTS	
	ANNEXURE-01	HEALTH HORIZON DIAGNOSTICS

Type of Evaluation: External Quality Control / Proficiency Testing (PT) Sample ☑

Other ☐ **(Specify):** —

Evaluation Date: 25/01/2023

Investigation: **Hematology** ☐ **Biochemistry** ☑ **Urine** ☐ **Serology** ☐ **Immunology** ☐

Other (Specify): _____

Unacceptable Analyte/ Parameter:

IMHL EQAS Sample NO:02 = Bilirubin Direct.

Description/Error/ Reason/ Remark:

IMHL EQAS: Bilirubin Direct.
Sample NO:02 = SDI Z-score = -2.32
Warning alert flag.

Investigations (Root Cause Analysis) :

Phase	Commonest Reasons	Tick / Cross
Pre-Analytical Phase	1. Missed Test Requisition Form (TRF)	☐
	2. Incorrect sample identification	☐
	3. Incorrect sample tube	☐
	4. Sample from IV running area	☐
	5. Delay in sample transportation	☐
	6. Insufficient samples	☐
	7. Sample mix-ups	☐
	8. Tube broken in centrifuge	☐
	9. Wrong timing for Collection	☐
	10. Invalid Specimen: Haemolysed Sample, Lipemic Sample and Icteric Sample	☐
	11. Software errors	☐
Analytical Phase	1. Instrument not calibrated properly	☐
	2. Specimen mix-up	☐
	3. Inadequate specimen	☐
	4. Presence of interfering substances	☐
	5. Wrong analytical method	☐
	6. Lack of precision	☐
Post-Analytical Phase	1. Wrong patient identification	☐
	2. Report not legible	☐
	3. Report delayed	☐
	4. Transcriptional error	☐
	5. Specificity of the test not understood	☐
	6. Previous values are not available for comparison	☐

Health Horizon DIAGNOSTICS	FORMAT OF EXTERNAL QUALITY CONTROL/ PROFICIENCY TESTING (PT) SAMPLES: CORRECTIVE AND PREVENTIVE ACTION FOR UNACCEPTABLE RESULTS	
	ANNEXURE-01	HEALTH HORIZON DIAGNOSTICS

Root Cause Analysis : MHL · EQAS Biochemistry Sample NO:02 Bilirubin Direct test run on ERBA EM-200 Andlyser. ~~Int~~ We checked the Internal quality control of the date when EQAS was run and found it within a acceptable range. Also PT/EQAS specimen handling was cross checked as per our QSP "Handling proficiency Testing and External quality Assurance Sample (HHD-QSP/009/00)

Corrective Action: Corrective action taken on date 25/01/23 We checked Internal quality control record on date 17/01/2023 · IQC result was within range. Also the preventive maintenance of the instrument was done by the service engineer.

Preventive Action: For ~~Analyser~~. ERBA EM-200 on date 30/01/23 After maintenance IQC performed and it was within range.

Conclusion serum Bilirubin Direct had a PT outlier, It was a warning signal and accordingly corrective and preventive action was taken.

Attachment (Attach result form and assessment details):

~~Attached~~ scan copy :-

1) Instrument Service Report	—
2) Internal QC data on date 17/01/2023 & 30/01/2023 for Bilirubin Direct Test	
3) IQC BIORAD Value sheet Lot NO. 26490 Level-02- 26492	

Comment : Nil

Dr Manager 30/01/2023

Recorded By : Sign / Date (Laboratory Manager /Authorized trained person)

Comment : Satisfactory

Mahesh 30/01/2023

Verified By : Sign / Date (Laboratory Director/Authorized trained person)

SR. NO	LIST OF DOCUMENTS
01	Annexure: 01: Instrument service Report
02	Annexure: 02: Internal Quality Control Data Date of 17/01/2023 & 30/01/2023
03	Annexure: 03: Internal Quality Control BIO-RAD Value Sheet Lot No. 26490, Level 01 :26491 & Level 02: 26492

ANNEXURE : 01

TRANSASIA

TECHNICAL SERVICE REPORT No. 1517640

DATE : 29/11/23

CUSTOMER DETAILS	INSTRUMENT DETAILS	SERVICE STATUS
NAME : Heath	MODEL : Erma c	☐ WARRANTY ☐ R&R ☒ AMC ☐ CMC ☐ CHARGED CALL
ADDRESS : Horizon Diagnostic Pune	SR. NO. : B1001819	TYPE OF CALL ☐ INSTALLATION ☐ P.M. VISIT [I] [II] [III] [IV] ☐ APPLICATION SUPPORT ☐ BREAKDOWN
TEL NO :	CALL DETAILS	
NAME OF THE OPERATOR :		DOWN TIME :
PROBLEM REPORTED :	TRAVEL TIME 1Hr	COUNTER READING :

CALL DETAILS	DATE	TIME
COMPLAINT RECD.		
RESPONSE		
JOB COMPLETED		
RESPONSE TIME		

NIL

OBSERVATIONS : preventive maintenance

ACTION TAKEN :

Done pm as per protocol

clean both chamber. Replaced lamp

Replaced laundry tubings clean lamp cooling path

All filter cleaned

SITE CONDITION : LINE-NEUTRAL VOLT. : 240 V | NEUTRAL-EARTH VOLT. : 0 V | LINE-EARTH VOLT. : 240 V

BRAND OF REAGENT USED :

☐ FOLLOWING PARTS HAVE BEEN REPLACED
☐ FOLLOWING PARTS NEED TO BE REPLACED. PLEASE APPROVE

NO.	DESCRIPTION	QTY.	COST	TOTAL

TOTAL Rs.

TO BE FILLED IN BY CUSTOMER

☐ PREVENTIVE MAINTENANCE CARRIED OUT SATISFACTORILY.
☐ FAULT RECTIFIED & INSTRUMENT IS WORKING SATISFACTORILY
☐ WE HEREBY APPROVE RS. _____ FOR PARTS
☐ COMMENTS (IF ANY) :

Abhaugen

SEAL DATE 30/11/23 CUSTOMER'S SIGNATURE NAME :

INVOICE NO. : DATE :

FOLLOW-UP ACTION (Required if any) :

BRANCH H. O.
RECEIVED ON :
CHECKED BY :

ENGINEER'S/APPLICATION SPECIALIST'S SIGNATURE :
TIME : 12.5 to 2 pm NAME : Amrut Kulkarni

JOB CARD NO. :

NOTE : Parts replaced are chargeable except during warranty Period. Consumables like printer head, lamp, tubing, paper rolls etc. & breakable parts are not covered by warranty and hence are chargeable. Parts replaced due to negligence in operation will also be charged in every case.

AT TRANSASIA, CUSTOMER SATISFACTION IS OUR PRIME CONCERN. IN CASE YOU HAVE ANY SUGGESTIONS PLEASE CONTACT : GENERAL MANAGER (TECHNICAL SERVICE), MUMBAI. TEL. : 4030 9000

TRANSASIA BIO-MEDICALS LTD.

Head Office : Transasia House, 8, Chandivali Studio Road, Andheri (E), Mumbai - 400 072. Tel. : (022) 4030 9000 Fax : (022) 2857 3030
Mumbai : Toll Free No. 1800 103 8226, Whatsapp No. : 8451048434, SMS No. : 9212433444

Indore	Tel. : (0731) 403 3946	Chennai	Tel. : (044) 2822 7149	Kolkata	Tel : (033) 2215 7839 Fax : 2215 5035
Lucknow	Tel. : (0522) 443 0900	Pune	Tel. : (020) 2616 2658	Delhi	Tel. : (011) 2576 5451/2573 2223
Chandigarh	Tel. : (0172) 464 3837	Hyderabad	Tel. : (040) 4430 9000	Ahmedabad	Tel./Fax : (079) 02640 7030/4032 1903
Jaipur	Tel. : 93092 63147	Guwahati	Tel. : 91369 50480	Bangalore	Tel./Fax : (080) 2558 8044
Patna	Tel. : 77669 00553	Chuttack	Tel. : (0671) 232 4555		
Kochi	Tel. : (0484) 402 0511	Hubli	Tel. : (0836) 465 0900		

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ISO 13485 & ISO 9001 Certified Co.

Erba Mannheim

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ANNEXURE : 02

Internal Quality Control BIO-RAD Level - 2

Result Reprint

Report Type : Controls

Sr #	Lot #	Consumable	Test	Result	Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	26492	BIORAD LEVEL 2	SGPTD	107.9	U/L		84511	17-Jan-2023 10:43:24	102.000	6.800	81.6 - 122.4
2	26492	BIORAD LEVEL 2	SGOTD	196.9	U/L		84512	17-Jan-2023 10:43:42	199.000	12.990	160.03 - 237.97
3	26492	BIORAD LEVEL 2	ALPU	449	U/L	-1SD	84513	17-Jan-2023 10:44:00	487.000	32.000	391 - 583
4	26492	BIORAD LEVEL 2	BID	1.54	mg/dl	+2SD	84514	17-Jan-2023 10:44:18	1.310	0.110	0.98 - 1.64
5	26492	BIORAD LEVEL 2	BIT	5.19	mg/dl	+1SD,HV!	84515	17-Jan-2023 10:44:36	4.770	0.400	3.57 - 5.97
6	26492	BIORAD LEVEL 2	UREA	95.9	mg/dl	-1SD	84516	17-Jan-2023 10:44:54	103.000	5.000	88 - 118
7	26492	BIORAD LEVEL 2	CRENZ	5.44	mg/dl		84517	17-Jan-2023 10:45:12	5.210	0.350	4.16 - 6.26
8	26492	BIORAD LEVEL 2	GLU	302.0	mg/dl		84518	17-Jan-2023 10:45:30	304.000	15.000	259 - 349
9	26492	BIORAD LEVEL 2	TRIG	92.5	mg/dl	HV!	84519	17-Jan-2023 10:45:48	96.100	4.960	81.22 - 110.98
10	26492	BIORAD LEVEL 2	CHOL	97	mg/dl	-1SD	84520	17-Jan-2023 10:46:06	104.000	5.000	89 - 119
11	26492	BIORAD LEVEL 2	HDLC	24.3	mg/dl		84521	17-Jan-2023 10:46:24	23.900	1.600	19.1 - 28.7
12	26492	BIORAD LEVEL 2	UA	11.1	mg/dl		84522	17-Jan-2023 10:46:42	10.800	0.500	9.3 - 12.3
13	26492	BIORAD LEVEL 2	ALB	2.72	g/dl		84523	17-Jan-2023 10:47:01	2.690	0.130	2.3 - 3.08
14	26492	BIORAD LEVEL 2	PRO	4.67	g/dl		84524	17-Jan-2023 10:47:19	4.750	0.240	4.03 - 5.47

Done By :- Janhavi 17/01/23

Checked By :- 17/01/23

Print Date 17-Jan-2023

Internal Quality Control BIORAD - Level- 2.

Result Reprint

Report Type : Controls

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	26492	BIORAD LEVEL 2	SGPTD	114.6 U/L	+1SD	98709	30-Mar-2023 10:57:35	102.000	6.800	81.6 - 122.4
2	26492	BIORAD LEVEL 2	SGOTD	216.1 U/L	+1SD	98710	30-Mar-2023 10:57:53	199.000	12.990	160.03 - 237.97
3	26492	BIORAD LEVEL 2	ALPU	479 U/L		98711	30-Mar-2023 10:58:11	487.000	32.000	391 - 583
4	26492	BIORAD LEVEL 2	BID	1.54 mg/dl	+2SD	98712	30-Mar-2023 10:58:29	1.310	0.110	0.98 - 1.64
5	26492	BIORAD LEVEL 2	BIT	4.61 mg/dl		98713	30-Mar-2023 10:58:47	4.770	0.400	3.57 - 5.97
6	26492	BIORAD LEVEL 2	UREA	105.4 mg/dl		98714	30-Mar-2023 10:59:05	103.000	5.000	88 - 118
7	26492	BIORAD LEVEL 2	CRENZ	5.31 mg/dl		98715	30-Mar-2023 10:59:23	5.210	0.350	4.16 - 6.26
8	26492	BIORAD LEVEL 2	GLU	285.5 mg/dl	-1SD	98716	30-Mar-2023 10:59:41	304.000	15.000	259 - 349
9	26492	BIORAD LEVEL 2	TRIG	83.5 mg/dl	-1SD	98717	30-Mar-2023 10:59:59	90.520	4.960	75.64 - 105.4
10	26492	BIORAD LEVEL 2	CHOL	107 mg/dl		98718	30-Mar-2023 11:00:17	104.000	5.000	89 - 119
11	26492	BIORAD LEVEL 2	HDLC	23.4 mg/dl		98719	30-Mar-2023 11:00:35	23.900	1.600	19.1 - 28.7
12	26492	BIORAD LEVEL 2	UA	10.5 mg/dl		98720	30-Mar-2023 11:00:53	10.800	0.500	9.3 - 12.3
13	26492	BIORAD LEVEL 2	ALB	2.58 g/dl		98721	30-Mar-2023 11:01:11	2.690	0.130	2.3 - 3.08
14	26492	BIORAD LEVEL 2	PRO	4.46 g/dl	-1SD	98722	30-Mar-2023 11:01:29	4.750	0.240	4.03 - 5.47

Done By:- 30/03/23

Checked By: 30/03/23

Print Date 30-Mar-2023

ANNEXURE : 03

BIO-RAD

Lyphochek® Assayed Chemistry Control Levels 1 and 2

REF C-310-5 Level 1 12 x 5 mL
C-315-5 Level 2 12 x 5 mL
313X MiniPak 2 x 5 mL

CE 0459 IVD EXP 2023-11-30 LOT 26490 Level 1 26491 Level 2 26492

https://www.myeinserts.com/26490

INTENDED USE

Lyphochek Assayed Chemistry Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Multiple levels of control are available to allow monitoring of the test system's reliability.

For customers in Germany: Quality control materials are required for assessment of laboratory performance as described in the "Guideline for Quality Assurance of Medical Laboratory Examinations following the German Medical Association" (Rili-BÄK regulation).

REAGENT

This product is prepared from human serum with added chemicals, purified biochemical material (tissue extracts of human and animal origin), therapeutic drugs, stabilizers and preservatives. This product is provided in lyophilized form for increased stability.

STORAGE AND STABILITY

This product will be stable until the expiration date when stored unopened at 2 to 8°C.

Reconstituted and Refrigerated: After reconstituting and storing tightly capped at 2 to 8°C, this product will be stable as follows:

- All analytes: 7 days

Except:

- T3 (Free), Acid Phosphatase (Total) and Prostatic Acid Phosphatase (PAP): 3 days

Reconstituted and Frozen: When reconstituted and stored tightly capped at -10 to -20°C, this product will be stable as follows:

- All analytes: 30 days

Except:

- Tobramycin: 20 days
- T3 (Free): 10 days

Once thawed, do not refreeze this product. Discard the remaining material.

This product is shipped under ambient conditions.

PROCEDURE

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used.

Using a volumetric pipet or equivalent, reconstitute each vial with 5.0 mL of distilled or deionized water. Replace the stopper and allow this product to stand for approximately 20 minutes swirling occasionally.

Before sampling, gently swirl the vial several times to ensure homogeneity. If performing trace metal analysis, do not mix by inversion. After each use, promptly replace the stopper and return to the appropriate storage condition.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

LIMITATIONS

1. This product should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the reconstituted product, discard the vial.
3. This product is not intended for use as a standard.

WARNING

⚠ **Biological source material. Treat as potentially infectious.**

Each human donor unit used to manufacture this product was tested as required by FDA accepted methods. Tests results were non-reactive or negative for evidence of infection due to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). This product may also contain other human source materials for which there are no approved tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Safety Data Sheet (SDS) available for professional users on *www.bio-rad.com.*

SPECIFIC PERFORMANCE CHARACTERISTICS

This product is a freeze-dried product manufactured under rigid quality control standards. To obtain consistent assay values, the control requires proper storage and handling as described.

ASSIGNMENT OF VALUES

The mean values and corresponding ±3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product. Data from Unity™ Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. [Customers in Germany have to follow the requirements as described in the Rili-BÄK regulation.] Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

Unity™ Interlaboratory Program is a proprietary Bio-Rad software program holding more than 2 billion QC data points from thousands of laboratories.

INSTRUCTIONS FOR OBTAINING THE DATA CHARTS

The Data Charts are available through the Internet, at *www.myeinserts.com/26490.* Follow the directions at the website to receive email notifications of insert updates. Alternate methods for receiving data charts are available by contacting your local Bio-Rad Laboratories Office.

English • 2023-02 • 4030-00S

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10/22

INSTRUMENT (1)

	Units	Level 1 - 26491		Level 2 - 26492	
		Mean	Range	Mean	Range
BIOSYSTEMS B400/A25/A15 (5) (continued)					
Urea (Urease, UV) (4)	mg/dL	29.9	25.4 – 34.4	91.0	77.4 – 105
Uric Acid (Uricase, colorimetric)	mg/dL	4.91	4.17 – 5.65	8.58	7.29 – 9.87
ERBA XL SERIES (5)					
Albumin	g/dL	3.90	3.30 – 4.50	2.70	2.28 – 3.12
Albumin (India Market Only)	g/dL	3.96	3.36 – 4.56	2.69	2.30 – 3.08
Alkaline Phosphatase (IFCC Optimized) (2)	U/L	115	92.1 – 138	487	391 – 583
Alkaline Phosphatase (India Market Only) (2)	U/L	115	91.0 – 139	476	380 – 572
ALT/SGPT (2)	U/L	27.6	22.2 – 33.0	104	83.5 – 125
ALT/SGPT (Modified IFCC) (India Market Only) (2)	U/L	27.4	22.0 – 32.8	102	81.0 – 122
Amylase (2)	U/L	60.5	48.5 – 72.5	393	315 – 471
AST/SGOT (2)	U/L	38.2	30.7 – 45.7	204	162 – 246
AST/SGOT (Modified IFCC) (India Market Only) (2)	U/L	37.1	29.6 – 44.6	199	160 – 238
Bilirubin (Direct)	mg/dL	0.370	0.280 – 0.460	1.31	0.980 – 1.64
Bilirubin (Direct) (DCA)	mg/dL	0.390	0.300 – 0.480	1.65	1.23 – 2.07
Bilirubin (Total)	mg/dL	0.990	0.750 – 1.23	4.77	3.57 – 5.97
Bilirubin (Total) (DCA)	mg/dL	1.01	0.770 – 1.25	4.70	3.53 – 5.87
Calcium	mg/dL	9.94	8.44 – 11.4	13.4	11.3 – 15.5
Calcium (India Market Only)	mg/dL	9.21	7.83 – 10.6	12.3	10.5 – 14.1
Carbon Dioxide (CO2)	mEq/L	34.5	27.6 – 41.4	19.0	15.2 – 22.8
Chloride	mEq/L	107	96.0 – 118	93.0	83.7 – 102
Chloride (Mercuric Thiocyanate)	mEq/L	109	94.0 – 124	101	86.0 – 116
Cholesterol (HDL) (7)	mg/dL	67.2	53.7 – 80.7	23.9	19.1 – 28.7
Cholesterol (LDL)	mg/dL	149	119 – 179	67.6	54.1 – 81.1
Cholesterol (Total)	mg/dL	251	212 – 290	104	88.0 – 119
Cholinesterase (2)	U/L	7492	5995 – 8989	1131	906 – 1356
Creatine Kinase (CK) (2)	U/L	141	114 – 168	463	370 – 556
Creatinine (Alkaline picrate method)	mg/dL	2.59	2.08 – 3.10	5.74	4.60 – 6.88
Creatinine (Enzymatic)	mg/dL	1.80	1.44 – 2.16	5.21	4.16 – 6.26
Creatinine (Enzymatic) (India Market Only)	mg/dL	1.66	1.33 – 1.99	4.80	3.90 – 5.70
Gamma Glutamyltransferase (GGT) (2)	U/L	66.3	53.1 – 79.5	167	134 – 200
Glucose	mg/dL	91.7	77.9 – 106	304	259 – 349
Glucose (Hexokinase) (India Market Only)	mg/dL	85.4	72.5 – 98.3	285	243 – 327
Iron	µg/dL	236	188 – 284	62.1	49.8 – 74.4
Iron (UIBC)	µg/dL	63.3	50.7 – 75.9	126	102 – 150
Lactate Dehydrogenase (LDH) (2)	U/L	333	267 – 399	888	711 – 1065
Lipase (2)	U/L	43.1	34.4 – 51.8	57.7	46.3 – 69.1
Lithium	mEq/L	0.460	0.400 – 0.520	1.71	1.53 – 1.89
Magnesium	mg/dL	1.91	1.61 – 2.21	4.49	3.83 – 5.15
Phosphorus (India Market Only)	mg/dL	3.87	3.30 – 4.44	7.20	6.00 – 8.40
Phosphorus (New Formulation)	mg/dL	3.91	3.31 – 4.51	7.74	6.57 – 8.91
Potassium	mEq/L	3.61	3.25 – 3.97	5.49	4.95 – 6.03
Protein Serum (Total)	g/dL	6.94	5.89 – 7.99	4.75	4.03 – 5.47
Protein Serum (Total) (India Market Only)	g/dL	6.51	5.52 – 7.50	4.30	3.70 – 4.90
Sodium	mEq/L	140	126 – 154	123	110 – 135
Triglycerides	mg/dL	186	159 – 213	96.1	81.7 – 111
Triglycerides (India Market Only)	mg/dL	182	155 – 209	82.6	70.3 – 94.9
Urea (4)	mg/dL	33.8	28.7 – 38.9	103	88.0 – 118
Uric Acid	mg/dL	5.38	4.57 – 6.19	10.8	9.30 – 12.3

HEALTH HORIZON DIAGNOSTICS

DEFICIENCIES RESPONSE SHEET

FOR LDL-CHOLESTEROL

Health Horizon DIAGNOSTICS	DEFICIENCIES RESPONSE SHEET	
	HEALTH HORIZON DIAGNOSTICS	Page 1 of 1

OBSERVATION:

N0 PT EVIDENCED FOR LDL-CHOL.

RESPONSE:

As per the query raised for the test LDL , we wanted to correct the method for LDL test which is used in our laboratory is calculated and not by Direct method. Kindly accept this method and guide us regarding the same.

RECORDED BY:
Technicial Manager 08/04/2023

REVIEWED BY:
Lab Head/Quality Manager 08/04/2023