

REGIONAL AYURVEDA RESEARCH INSTITUTE

VIJAYAWADA

Calibration Monitor

No.	Test	Curve Type	Type	Consumable	Lot #	Conc.	Abs	Factor	Calib Exp. (Days)	Acceptable Limit
1	GLUF	Linear	BLANK	BLANK	12345	0.000	0.0549	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	200.000	0.6098	360.3929	0	15
2	GLUP	Linear	BLANK	BLANK	12345	0.000	0.0549	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	200.000	0.6098	360.3929	0	15
3	GLR	Linear	BLANK	BLANK	12345	0.000	0.0549	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	200.000	0.6098	360.3929	0	15
4	CRENZ	Linear	BLANK	BLANK	12345	0.000	0.0072	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	3.830	0.0794	53.0839	0	15
5	UREA	Linear	BLANK	BLANK	12345	0.000	-0.0099	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	101.000	-0.1641	-655.2059	0	15
6	UA	Linear	BLANK	BLANK	12345	0.000	0.0015	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	5.480	0.0685	81.8521	0	15
7	CHOL	Linear	BLANK	BLANK	12345	0.000	0.0509	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	157.000	0.2802	684.6925	0	15
8	TGL	Linear	BLANK	BLANK	12345	0.000	0.0172	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	133.000	0.1179	1320.0992	0	15
9	HDLC	Linear	BLANK	BLANK	12345	0.000	0.0031	0.0000	0	15
		Linear	STD1	HDLCAL	S122269	72.600	0.0993	754.6777	0	15

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10	BIT	Linear	BLANK	BLANK	12345	0.000	0.0003	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	4.700	0.1765	26.6818	0	15
11	BID	Linear	BLANK	BLANK	12345	0.000	0.0003	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	2.170	0.0967	22.4987	0	15
12	SGOTM	Linear	BLANK	BLANK	12345	0.000	-0.0008	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	102.000	-0.0161	-6688.5244	0	15
13	SGPTM	Linear	BLANK	BLANK	12345	0.000	-0.0013	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	90.600	-0.0285	-3330.8823	0	15
14	ALPU	Linear	BLANK	BLANK	12345	0.000	0.0003	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	261.000	0.0634	4136.2915	0	15
15	PRO	Linear	BLANK	BLANK	12345	0.000	0.0885	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	4.940	0.3779	17.0698	0	15
16	ALBB	Linear	BLANK	BLANK	12345	0.000	0.0906	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	3.460	0.5605	7.3633	0	15
17	GGT	Linear	BLANK	BLANK	12345	0.000	0.0012	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	114.000	0.0633	1834.2720	0	15
18	A1C	Point-To-Point	BLANK	HBA1C CAL1	12345	0.000	-0.0004	0.0000	0	0
		Point-To-Point	STD1	HBA1C CAL2	S042274A	4.800	0.0941	50.8205	0	0

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		Point-To-Point	STD2	HBA1C CAL3	S042274	8.300	0.3655	22.6838	0	0
		Point-To-Point	STD3	HBA1C CAL4	S042274	11.700	0.6075	19.2482	0	0
		Point-To-Point	STD4	HBA1C CAL5	S042274	15.700	0.7756	20.2333	0	0
19	BDDCA	Linear	BLANK	BLANK	12345	0.000	0.0011	0.0000	0	15
		Linear	STD1	MULTICAL	1707039A	2.470	0.0538	46.8246	0	15
20	CA	Linear	BLANK	BLANK	12345	0.000	0.0931	0.0000	0	15
		Linear	STD1	MULTICAL	1609103.	10.700	0.4061	34.1798	0	15
21	GLU	Linear	BLANK	BLANK	12345	0.000	0.0549	0.0000	0	15
		Linear	STD1	MULTICAL	2204083A	200.000	0.6098	360.3929	0	15
22	HBA1C	Exponential	BLANK	BLANK	12345	0.000	0.3835	0.0000	0	0
		Exponential	STD1	HBA1C CAL 1	1612017	5.190	0.5281	35.8673	0	0
		Exponential	STD2	HBA1C CAL 2	1612017	8.120	0.8012	19.4375	0	0
		Exponential	STD3	HBA1C CAL 3	1612017	12.400	1.3484	12.8511	0	0
		Exponential	STD4	HBA1C CAL 4	1612017	17.100	1.5028	15.2767	0	0
23	LDL	Linear	BLANK	BLANK	12345	0.000	0.0012	0.0000	0	15
		Linear	STD1	LDL	1703052	118.000	0.1813	655.3735	0	15
24	PHOS	Linear	BLANK	BLANK	12345	0.000	0.3461	0.0000	0	15
		Linear	STD1	MULTICAL	1609103.	5.240	0.5991	20.7115	0	15

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No.	Test	Curve Type	Type	Consumable	Lot #	Conc.	Abs	Factor	Calib Exp. (Days)	Acceptable Limit
25	SGOT	Linear	BLANK	BLANK	12345	0.000	0.0000	0.0000	0	15
		Linear	STD1	Multical	1511127	93.800	-0.0366	-2562.8416	0	15

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Result Reprint

Report Type : Controls 13-Feb-2023

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD
1	S062131B	ERBA PATH	ALPU	434 U/L	-2SD	82035	13-Feb-2023 12:23:11	502.870	33.520
2	S062131B	ERBA PATH	GGT	177.4 U/L		82042	13-Feb-2023 12:25:17	186.430	12.430
3	S062131B	ERBA PATH	BID	1.40 mg/dl	-1SD	82049	13-Feb-2023 12:27:24	1.640	0.140
4	S062131B	ERBA PATH	BIT	5.14 mg/dl		82056	13-Feb-2023 12:29:30	5.240	0.440
5	S062131B	ERBA PATH	UREA	97.7 mg/dl		82063	13-Feb-2023 12:31:36	95.160	4.750
6	S062131B	ERBA PATH	CRENZ	3.54 mg/dl		82070	13-Feb-2023 12:33:43	3.710	0.210
7	S062131B	ERBA PATH	CHOL	230 mg/dl	-2SD	82083	13-Feb-2023 12:37:37	265.520	13.280
8	S062131B	ERBA PATH	HDLC	79.4 mg/dl		82090	13-Feb-2023 12:39:44	84.280	5.620
9	S062131B	ERBA PATH	UA	12.3 mg/dl		82097	13-Feb-2023 12:41:50	11.750	0.590
10	S062131B	ERBA PATH	PRO	8.26 g/dl	-2SD	82104	13-Feb-2023 12:43:56	9.310	0.470
11	S062131B	ERBA PATH	TGL	175.7 mg/dl	-1SD	82111	13-Feb-2023 12:46:03	188.080	9.400
12	S062131B	ERBA PATH	SGOTM	142.3 U/L		82118	13-Feb-2023 12:48:09	151.890	10.130
13	S062131B	ERBA PATH	SGPTM	116.6 U/L	-2SD	82125	13-Feb-2023 12:50:15	138.750	9.250
14	S062131B	ERBA PATH	ALBB	5.06 g/dl	+1SD	82132	13-Feb-2023 12:52:22	4.780	0.240
15	S062131B	ERBA PATH	GLU	244.8 mg/dl		82139	13-Feb-2023 13:11:31	252.030	12.600

XL MULTICAL

Cat. No.	Pack Name	Packaging (Content)
XSYS0034	XL MULTICAL	4 x 3 ml



INTENDED USE

XL Multical is a lyophilized calibrator based on human serum. The concentrations and activities are suitable for calibration of clinical chemistry assays on automated clinical chemistry analyzers.

STORAGE AND HANDLING

Unreconstituted lyophilized calibrator is stable till the expiry date mentioned on the label when stored at 2–8 °C.

Stability of the reconstituted calibrator*:

at 15–25 °C	8 hours
at 2–8 °C	2 days
at (-25) – (-15) °C	4 weeks (when frozen once)

*Exceptions:

Stability of Total Bilirubin in the reconstituted calibrator (when stored protected from light):

at 15–25 °C	6 hours
at 2–8 °C	1 day
at (-25) – (-15) °C	2 weeks (when frozen once)

Stability of Direct Bilirubin in the reconstituted calibrator (when stored protected from light):

at 15–25 °C	3 hours
at 2–8 °C	8 hours
at (-25) – (-15) °C	2 weeks (when frozen once)

Store calibrator tightly capped and protected from light when not in use. Store vials upright to avoid spills and leakage. Seal the vials tightly after use to prevent evaporation.

RECONSTITUTION

1. Remove the screw cap and rubber stopper from the vial to be used. Avoid loss of lyophilizate.
2. Add exactly 3.0 ml of distilled/deionized water using a volumetric pipette.
3. Replace the stopper and cap for each vial and dissolve the contents on a roller mixer completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.

VALUE ASSIGNMENT

The calibrator values were determined using the method mentioned in the enclosed value sheet. The calibrator values were obtained via single determination performed in different laboratories and the values assigned by a consensus of the results obtained by these laboratories.

LIMITATIONS

Erroneous results can occur from reconstitution inaccuracies and technical errors associated with the assay procedure.

Do not use the reconstituted calibrator if there is visible evidence of microbial growth in the vial.

WARNING

Human source material used in the manufacturing of this product has been tested by FDA – approved methods and found non reactive for hepatitis B, surface antigen (HbsAg), antibody to Hepatitis C (HCV) and antibody to HIV1/2.

The test procedures do not guarantee that all infectious agents will be detected. Because no test method can offer complete assurance that Hepatitis B virus, Hepatitis C virus and HIV 1/2 or other infectious agents are absent, the material should be handled as potentially infectious.

Lot No.: 2204083A

Expiry: 07/2023

ASSAYED VALUES USING XL SysPack REAGENT

Short name	Parameter	Methodology	Unit	Value	Unit	Value
ALB	Albumin	BCG	g/dl	3.46	g/l	34.6
ALP	Alkaline phosphatase	IFCC with AMP buffer	U/l	261	µkat/l	4.35
ALT/GPT	Alanine aminotransferase	IFCC without PDP	U/l	90.6	µkat/l	1.51
AMY	Amylase	CNPG3	U/l	186	µkat/l	3.11
AST/GOT	Aspartate aminotransferase	IFCC without PDP	U/l	102	µkat/l	1.70
BID	Bilirubin Direct	Diazo (Walter & Gerarde)	mg/dl	2.17	µmol/l	37.2
		DCA	mg/dl	2.35	µmol/l	40.2
BIT	Bilirubin Total	Diazo (Walter & Gerarde)	mg/dl	4.70	µmol/l	80.4
		DCA	mg/dl	4.44	µmol/l	76.0
CA	Calcium	Arsenaso III	mg/dl	10.6	mmol/l	2.64
CHE	Cholinesterase	Butyrylthiocholine	U/l	5130	µkat/l	85.7
CHOL	Cholesterol	CHOD-PAP	mg/dl	157	mmol/l	4.07
CK	Creatine kinase NAC	DGKC	U/l	337	µkat/l	5.63
CK MB**	Creatine kinase MB	Immunoinhibition	U/l	426	µkat/l	7.10
CL	Chloride	Mercuric Thiocyanate	mmol/l	102	mmol/l	102
		Jaffe's kinetic	mg/dl	3.82	µmol/l	338
CREA	Creatinine	Enzymatic	mg/dl	3.83	µmol/l	339
		Glupa-C	U/l	114	µkat/l	1.90
GGT	Gamma-glutamyl transferase	Glupa-C	U/l	114	µkat/l	1.90
GLU	Glucose	GOD-POD / HK G6P-DH	mg/dl	202	mmol/l	11.2
LDH	Lactate dehydrogenase	DGKC	U/l	507	µkat/l	8.47
LIP	Lipase	Enzymatic colorimetric test	U/l	103	µkat/l	1.72
MG	Magnesium	Xylidyl Blue	mg/dl	2.72	mmol/l	1.12
PHOS	Phosphorus	Ammonium Molybdate UV	mg/dl	5.49	mmol/l	1.77
TG	Triglycerides	GPO-Trinder (single reagent)	mg/dl	137	mmol/l	1.55
		GPO-Trinder (two reagents)	mg/dl	133	mmol/l	1.50
TP	Total Protein	Biuret	g/dl	4.94	g/l	49.4
UA	Uric Acid	Uricase-Trinder	mg/dl	5.48	µmol/l	326
UREA	Urea	Urease - GLDH, kinetic	mg/dl	101	mmol/l	16.8

**Higher CK-MB to total CK ratio is due to the atypical ratio of the individual isoenzyme fractions.

NOTE

Values for XL analysers are now available on websites:

www.erbalachema.com

• Product Support

→XL-analysers: Calibrator/control values for uploading

USED SYMBOLS

LOT	Lot Number	IVD	In vitro Diagnostics	See Instruction for Use
REF	Catalogue Number	Manufacturer	CONT	Content
Expiry Date		Storage Temperature		

QUALITY SYSTEM CERTIFIED
ISO 13485

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N/06/19/K/INT
539961
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