

ERBA CONTROLS FOR BIOCHEMISTRY

Assayed Values for ERBA Reagents, LIQUID STABLE Reagents & SYSTEM PACK Reagents in NORMAL and ABNORMAL range

For *in-vitro* Diagnostic use only

INTENDED USE ERBA NORM ERBA PATH

Control Serum (assayed) is intended for monitoring the accuracy and precision of commonly used clinical chemistry assays in normal and pathological range respectively.

PRINCIPLE OF THE PROCEDURE

This human serum control is to be used in the same way as an unknown specimen that would be used in accordance with the direction of the assay procedure.

The results obtained for the control are to be compared with the assigned values given in the "assay data" section of the insert and an evaluation made by standard statistical techniques to determine if the procedure is within the control limits.

COMPOSITION

The Control serum is prepared from human serum with chemical additives and tissue extracts of human and animal origin. Bacteriostatic agents have been added. The control is provided in lyophilized form for increase stability.

WARNING

IT IS RECOMMENDED THAT THIS PRODUCT BE HANDLED WITH SAME PRECAUTIONS USED FOR PATIENT SPECIMEN.

RECONSTITUTION

- Allow the vial and AQUA-4 (supplied in the kit) to attain room temperature. Add exactly 5 ml of AQUA-4 and allow to stand for 30 minutes. Swirl occasionally.
- Swirl the contents gently to ensure homogeneity before using as sample for testing. Avoid formation of foam.

STORAGE & STABILITY

Prior to reconstitution

The control should be stored at 2-8°C and is stable till the expiry date printed on the label.

After reconstitution

The constituents when protected from contamination are stable upto 5 days when stored at 2-8°C except for ALP whose activity may increase with time. Values for ALP, CPK and ACP are temperature dependent. Since Bilirubin, CPK and Uric Acid are photolabile, the control should be protected from light and kept refrigerated when not in use. Apparently Uric acid values may increase over time when assayed by some methods.

LIMITATIONS

The results obtained using the control are dependent upon several factors. Erroneous results can occur from reconstitution inaccuracy and the technique errors associated with the assay procedure. The serum is not compatible for use with o-Tolidine Glucose procedures. Improper storage or handling of the control can also affect the results. If there is a visible evidence of microbial growth in a vial, do not use that vial.

PACK PRESENTATION

Product Code	Pack size	Controls	Aqua-4
120218	4 x 5 ml	ERBA NORM	1 x 20 ml
120219	1 x 5 ml	ERBA NORM	1 x 5 ml
120220	4 x 5 ml	ERBA PATH	1 x 20 ml
120221	1 x 5 ml	ERBA PATH	1 x 5 ml
120222	2 x 2 x 5 ml	ERBA NORM / ERBA PATH (COMBIPACK)	1 x 20 ml

**ERBA CONTROLS FOR BIOCHEMISTRY
ASSAYED VALUES USING ERBA REAGENTS**

PARAMETERS	METHODOLOGY	UNITS	Values for Semi Auto Analyser	
			ERBA NORM	ERBA PATH
ALBUMIN	BCG	g/dl	3.73 ± 0.38	4.67 ± 0.46
BILIRUBIN TOTAL	DIAZO (Surfactant)	mg/dl	1.26 ± 0.377	5.05 ± 1.5
BILIRUBIN DIRECT	DIAZO	mg/dl	0.75 ± 0.23	2.63 ± 0.79
CHOLESTEROL	CHOD - PAP	mg/dl	163 ± 25	214.5 ± 32.1
CREATININE	JAFFE'S KINETIC	mg/dl	0.78 ± 0.13	3.83 ± 0.46
GLUCOSE	GOD - POD	mg/dl	89.65 ± 13.5	293.5 ± 35.16
TOTAL PROTEIN	BIURET	g/dl	5.8 ± 0.7	7.53 ± 0.75
TRIGLYCERIDES	GPO - TRINDER	mg/dl	87.2 ± 13.1	179.8 ± 26.9
UREA	UREASE - GLDH, KINETIC	mg/dl	34.7 ± 4.1	106.5 ± 12.8
URIC ACID	URICASE - POD	mg/dl	4.37 ± 0.74	9.18 ± 1.56
CALCIUM	OCPC	mg/dl	10.5 ± 1.05	11 ± 1.1
CALCIUM	ARSENAZO	mg/dl	10.2 ± 1.02	10.36 ± 1.04
CHLORIDE	MERCURIC THIOCYANATE	mmol/L	98 ± 9.8	113 ± 11.3
PHOSPHORUS	UV MOLYBDATE	mg/dl	4.02 ± 0.48	7.85 ± 0.94
ALP	AMP - Modified IFCC	U/L	78.85 ± 13.6	191.1 ± 32.4
AMYLASE	PNP - G7 blocked (EPS)	U/L	212.9 ± 36.1	419 ± 71.2
AMYLASE	CNPG3	U/L	172.9 ± 29.3	419 ± 71.2
CK - NAC	DGKC	U/L	136 ± 23.2	269.3 ± 45.7
GGT	GLUPA - C	U/L	34.7 ± 5.9	135.9 ± 23.1
LDH-P	DGKC (P-L)	U/L	208.5 ± 35.3	639.9 ± 108.7
SGOT (AST)	IFCC, without pyridoxal phosphate	U/L	56.5 ± 9.6	238.9 ± 40.6
SGPT (ALT)	IFCC, without pyridoxal phosphate	U/L	46.7 ± 7.9	121.4 ± 20.6
MAGNESIUM	CALMAGITE	mg/dl	2.08 ± 0.26	3.87 ± 0.46
HDL C DIRECT	PEG - Modified	mg/dl	46.42 ± 10.2	58.28 ± 12.8
LDL C DIRECT	SURFACTANT	mg/dl	81.9 ± 18	118 ± 25.9
LIPASE	ADVANCED HOMOGENOUS MECELLE METHOD	U/L	44.95 ± 7.6	115 ± 19.6

ERBA NORM
ERBA PATH

LOT NO : 24784
LOT NO : 24785

EXPIRY : 03/2013
EXPIRY : 05/2013

* Note

- a) For End Point assays - Values obtained after calibration using respective standard.
- b) For Bilirubin and Kinetic assays - Values obtained using fixed factor.
- c) Assay Temperature = 37°C.



Website : www.erbamannheim.com

**ERBA CONTROLS FOR BIOCHEMISTRY
ASSAYED VALUES USING SYSTEM PACK REAGENTS**

PARAMETERS	METHODOLOGY	UNITS	ERBA NOTRM		ERBA PATH	
			MEAN ± RANGE	MEAN ± RANGE		
ALBUMIN	BCG	g/dl	4.01 ± 0.4	4.95 ± 0.49		
ALP	AMP	U/L	71.17 ± 12	191.93 ± 32.5		
ALPHA AMYLASE	CNPG3	U/L	161.43 ± 27.4	353.10 ± 60		
BILIRUBIN DIRECT	DIAZO	mg/dl	0.56 ± 0.17	2.74 ± 0.82		
BILIRUBIN TOTAL	DIAZO	mg/dl	1.25 ± 0.375	6.26 ± 1.87		
CALCIUM	ARSENAZO	mg/dl	10.19 ± 1.22	10.17 ± 1.22		
CHLORIDE	MERCURIC THIOCYANATE	mmol/L	102.30 ± 10.23	116.82 ± 11.6		
CHOLESTEROL	CHOD - PAP	mg/dl	164.57 ± 24.6	223.40 ± 33.5		
CK - NA C	DGKC	U/L	179.07 ± 30.4	281.38 ± 47.8		
CREATININE	JAFFE'S KINETIC	mg/dl	1.27 ± 0.16	5.32 ± 0.78		
GGT	GLUFA - C	U/L	48.57 ± 7.9	190.91 ± 32.3		
GLUCOSE	GOD - POD	mg/dl	93.78 ± 14	294.00 ± 44.1		
SGOT (AST)	IFCC, without pyridoxal phosphate	U/L	54.64 ± 9.3	244.16 ± 41.5		
SGPT (ALT)	IFCC, without pyridoxal phosphate	U/L	46.14 ± 7.85	128.71 ± 21.8		
HDL	DIRECT	mg/dl	48.78 ± 10.7	68.29 ± 12.8		
LDL	DIRECT	mg/dl	74.30 ± 16.3	108.90 ± 24		
LDH-P	DGKC	U/L	228.22 ± 38.8	733.35 ± 124.6		
MAGNESIUM	CALMAGITE	mg/dl	1.99 ± 0.239	3.55 ± 0.43		
PHOSPHORUS	AMMONIUM MOLYBDATE UV	mg/dl	4.12 ± 0.5	7.93 ± 1.18		
TOTAL PROTEIN	BIURET	g/dl	6.33 ± 0.77	8.19 ± 1.0		
TRIGLYCERIDES	GPO - TRINDER	mg/dl	103.35 ± 12.4	232.56 ± 34.8		
UREA	UREASE - GLDH KINETIC	mg/dl	36.20 ± 4.35	107.97 ± 12.9		
URIC ACID	URICASE - TRINDER	mg/dl	4.69 ± 0.79	9.62 ± 1.61		
SODIUM	ISE INDIRECT POTENTIOMETRY	mmol/L	142.23 ± 14.23	178.09 ± 17.8		
LITHIUM	ISE INDIRECT POTENTIOMETRY	mmol/L	0.98 ± 0.098	2.62 ± 0.26		
POTASSIUM	ISE INDIRECT POTENTIOMETRY	mmol/L	4.31 ± 0.043	6.82 ± 0.68		
LIPASE	ADVANCED HOMOGENOUS MICELLE METHOD	U/L	48.90 ± 8.3	85.65 ± 14.5		

ERBA NORM

ERBA PATH

* Note :

LOT NO : 24784

LOT NO : 24785

a) Values obtained after calibration using XL Multicalibrator.

b) Assay Temperature = 37°C.

EXPIRY : 03/2013

EXPIRY : 05/2013

CONVENTIONAL UNITS

The conversion factors and significant digits places to be used in reporting the mean values and ranges (for both SI and conventional units) are presented in Table 1:

Table : 1

Analyte	S.I. Units	Significant Digits	Conversion Factor	Significant Digits	Conventional Units
Albumin	g/L	XX	0.1	XX	g/dl
Bicarbonate	mmol/L	XX	1	XX	mEq/L
Bilirubin	µmol/L	XXX	0.059	X,XX	mg/dl
Calcium	mmol/L	X,XX	4	XX,X	mg/dl
Chloride	mmol/L	XXX	1	XXX	mEq/L
Cholesterol	mmol/L	XX	38.7	XXX	mg/dl
Creatinine	mmol/L	X,XX	11.3	XX	mg/dl
Glucose	mmol/L	XX,X	18	XXX	mg/dl
Magnesium	mmol/L	X,XX	2.43	X,XX	mg/dl
Phosphorus	mmol/L	X,XX	3.1	X,XX	mg/dl
Total Protein	g/L	XX	0.1	XX	g/dl
Triglycerides	mmol/L	XX	87.5	XXX	mg/dl
Urea	mmol/L	X,XX	6.01	XX	mg/dl
Uric Acid	mmol/L	XXX	16.8	XX	mg/dl



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**ERBA CONTROLS FOR BIOCHEMISTRY
ASSAYED VALUES USING LIQUID STABLE REAGENTS**

PARAMETERS	METHODOLOGY	UNITS	Values for EC-5 V2 / Chem 7*			
			ERBA NORM		ERBA PATH	
			MEAN	± RANGE	MEAN	± RANGE
BILIRUBIN TOTAL	DIAZO	mg/dl	1.26	± 0.377	5.05	± 1.5
BILIRUBIN DIRECT	DIAZO	mg/dl	0.75	± 0.23	2.63	± 0.79
CHOLESTEROL	CHOD - PAP	mg/dl	166.5	± 24.8	222.9	± 33.4
CREATININE	JAFFE'S KINETIC	mg/dl	0.78	± 0.13	3.83	± 0.46
GLUCOSE	GOD - POD	mg/dl	87.4	± 13.1	281.9	± 42.2
TRIGLYCERIDES	GPO - TRINDER	mg/dl	89.38	± 13.4	186.35	± 24.8
UREA	UREASE - GLDH, KINETIC	mg/dl	34.37	± 5.1	103.4	± 15.5
URIC ACID	URICASE - TRINDER	mg/dl	4.24	± 0.72	8.9	± 1.5
ALP	AMP	U/L	75.65	± 12.8	175.2	± 29.7
AMYLASE	CNPG3	U/L	172.9	± 29.3	364.8	± 62
LDH-P	DGKC	U/L	207.55	± 35.2	595.2	± 101.2
SGOT (AST)	IFCC, without pyridoxal phosphate	U/L	54.8	± 9.31	228.15	± 38.7
SGPT (ALT)	IFCC, without pyridoxal phosphate	U/L	43.86	± 7.5	115.5	± 19.6
CK	DGKC	U/L	141.5	± 24	219.5	± 37.3

ERBA NORM LOT NO : 24784
ERBA PATH LOT NO : 24785

EXPIRY : 03/2013
EXPIRY : 05/2013

- * Note :
- a) For End Point Assay - Values obtained after calibration using respective calibrator
 - b) For Billirubin and Kinetic Assays - Values obtained using fixed factor
 - c) Assay Temperature = 37°C.

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The quality systems of this facility have been
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9001:2000



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