ANKERITE PUSHPA SRIRAM HOSPITAL PATHOLOGY LAB

EQASOUTLIERLOG

EQUIPMENT ID :Erba Chem-7

S.No.	DATE	TEST	QC Level Range(C1) /Obtained Value	QC Level Range(C2) /Obtained Value	ROOT CAUSE ANALYSIS (RCA)	CORRECTIVE ACTION/ PREVENTIVE ACTION	QC RE-CHECK STATUS (P/F)	REVIEWED BY	APPROVED BY
1	07.12.22	Cholesterol	110.13-148.99 / 129.5	178.18-241.06 / 229.8	Incubator was malfunctioned	Re-Run QC Level (C1,C2) obtained Satisfactory Value/ New Incubator purchased	Pass		
2	07.12.22	Uric Acid	4.67-6.32 / 5.65	8.92-12.07 / 10.46	Same as above	Same as above	Pass		
3	07.12.22	Albumin	2.90-3.92 / 3.60	4.32-5.84 / 4.83	Same as above	Same as above	Pass		
4	07.12.22	Glucose	75.57-102.24 / 89.61	202.33-273.75 / 211.7	Same as above	Same as above	Pass		
5	07.12.22	Creatinine	0.82-1.25 / 1.06	2.31-3.53 / 2.47	Same as above	Same as above	Pass		
6	07.12.22	Bilirubin Total	1.10-1.83 / 1.22	3.14-5.24 / 4.09	Same as above	Same as above	Pass		
7	07.12.22	Triglycerides	79.49-107.55 / 103.7	127.02-171.86 / 168.0	Same as above	Same as above	Pass		
8	07.12.22	Urea	34.43-46.58 / 38.97	75.24-101.80 / 91.91	Same as above	Same as above	Pass		
9	07.12.22	Protein	5.43-7.35 / 6.26	7.22-9.76 / 8.93	Same as above	Same as above	Pass		

Ankerite Pushpa Sriram Hospital
C.R.P.F. Chauraha Mati Road Vill. Bijnor
LUCKNOW

ERBA NORM

CONTROL FOR BIOCHEMISTRY

Assayed Values for ERBA Reagents,

Website : www.erbamannheim.com

LIQUID STABLE REAGENTS / POWDER REAGENTS & SYSTEM PACK REAGENTS IN NORMAL RANGE

For *in vitro* diagnostic use only

IVD

INTENDED USE

ERBA NORM

PRINCIPLE OF THE PROCEDURE

This human serum control is to be used for assessment of method precision & techniques in use and treated 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.

It is recommended that each laboratories estabilish its own means and acceptable ranges. Values provided in the Insert should be used as reference.

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 .

The blood donations used for production were tested by CE- marked test kits and found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV. In addition HCV and HIV have been tested by PCR. Despite of that the danger of infection for biological material can not be excluded with certainty.

During the work all principles of personal hygiene are to be maintained.

When the bottle is broken the contaminated place must be disinfected.

RECONSTITUTION

1. 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 at rest in a light-protected place. Swirl occasionally.

2. Swirl the contents gently to ensure homogenity before using as sample for testing. Avoid formation of foam.

STORAGE & STABILITY

Prior to reconstitution

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

After reconstitution

The constituents when protected from light and contamination are stable:

1 day	at +18 °to +25 °C
1 week	at +2 to+8 °C (Bilirubin: 1 day)
1 month	at –20 °C

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- Toludine 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.

Assayed Values Using LIQUID STABLE REAGENTS / POWDER REAGENTS LOT No.: S062243 EXPIRY: 11/2024

ABBR.	PARAMETERS	METHODOLOGY	UNITS	Values for Liquid Reagents			Values for Powder Reagents		
				Value	Interval	1 SD	Value	Interval	1 SD
ALB	Albumin	BCG	g/dl	3.41	2.90-3.92	0.17			
ALP	Alkaline phosphatase	AMP	U/l	101.31	81.05-121.57	6.75	96.98	77.58-116.38	6.47
ALT/GPT	ALT/SGPT	IFCC	U/l	57.47	45.98-68.96	3.83	51.87	41.50-62.24	3.46
AMY	Amylase	CNPG3	U/l	68.78	55.02-82.53	4.59	48.20	38.56-57.84	3.21
AST/GOT	AST/SGOT	IFCC	U/l	51.31	41.05-61.57	3.42	46.76	37.41-56.11	3.12
BID	Bilirubin Direct	DIAZO	mg/dl	0.96	0.72-1.19	0.08			
BIT	Bilirubin Total	DIAZO	mg/dl	1.47	1.10-1.83	0.12			
CA	Calcium	ARSENAZO III	mg/dl	7.93	6.34-9.51	0.53			
		OCPC	mg/dl	7.78	6.22-9.33	0.52			
CL	Chloride	MERCURIC THIOCYANATE	mmol/l	105.00	89.25-120.75	5.25			
CHOL	Cholesterol	CHOD-PAP	mg/dl	129.56	110.13-148.99	6.48	160.10	136.09-184.12	8.01
CK	Creatinine kinase NAC	DGKC	U/l	113.73	85.30-142.16	9.48	120.50	90.38-150.63	10.04
CK MB	Creatinine kinase MB	IMMUNO	U/l	30.64	22.98-38.30	2.55	20.50	15.38-25.63	1.71
CREA	Creatinine	JAFFE'S	mg/dl	1.03	0.82-1.25	0.07			
GGT	Gamma-glutamyl transferase	GLUPA-C	U/l	30.51	22.94-38.09	2.53	30.13	22.65-37.61	2.49
GLU	Glucose	GOD-POD	mg/dl	88.90	75.57-102.24	4.45	92.14	78.32-105.96	4.61
HDL	HDL Cholesterol	DIRECT	mg/dl	39.13	31.31-46.96	2.61			
		Phosphotungstic Acid	mg/dl	16.00	12.8-19.2	1.07			
LDL	LDL Cholesterol	DIRECT	mg/dl	59.33	47.47-71.20	3.96			
LDH-P	Lactate dehydrogenase-P	DGKC	U/l	386.32	309.06-463.58	25.75	289.50	231.6-347.40	19.30
LIP	Lipase	ADVANCE HEMOGEN	U/l	58.03	43.53-72.54	4.84			
MG	Magnesium	XYLIDYL BLUE	mg/dl	1.95	1.64-2.26	0.10			
PHOS	Phosphorus	UV-MOLYBDATE	mg/dl	5.34	4.54-6.14	0.27			
TP	Total Protein	BIURET	g/dl	6.39	5.43-7.35	0.32			
TGL	Triglycerides	GPO	mg/dl	93.52	79.49-107.55	4.68			
	Triglycerides -SR	GPO	mg/dl	124.50	105.83-143.18	6.23	73.00	62.05-83.95	3.65
UREA	Urea	UREASE-GLDH	mg/dl	40.50	34.43-46.58	2.03	40.36	34.30-46.41	2.02
UA	Uric Acid	URICASE	mg/dl	5.50	4.67-6.32	0.27			
	Uric Acid-SR	URICASE	mg/dl	5.53	4.70-6.36	0.28	6.17	5.24-7.09	0.31

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

Manufactured by : **TRANSASIA BIO-MEDICALS LTD.,** Khatiyan No. 235, Khasra No.24, Namthang Etaka, Mahakuma Namchi, South Sik

In Technical Collaboration with : **ERBA diagnostics Mannheim GmbH** Mallaustr., 69-73, D - 68219, Mannheim / G

ERBA PATH

CONTROL FOR BIOCHEMISTRY

Assayed Values for ERBA Reagents.

Website : www.erbamannheim.com

IVD

LIQUID STABLE REAGENTS / POWDER REAGENTS & SYSTEM PACK REAGENTS IN ABNORMAL RANGE

For *in vitro* diagnostic use only

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ERBA PATH

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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.

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STORAGE & STABILITY

Prior to reconstitution

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

After reconstitution

The constituents when protected from light and contamination are stable:

1 day	at +18 °to +25 °C
1 week	at +2 to+8 °C (Bilirubin: 1 day)
1 month	at –20 °C

LIMITATIONS

The results obtained using the control are dependent upon several factors. Erroneous results c occur from reconstitution inaccuracy and the technique errors associated with the assay procedure. The serum is not compatible for use with o- Toludine 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.

Assayed Values Using LIQUID STABLE REAGENTS / POWDER REAGENTS LOT No.: S062131B EXPIRY: 11/2023

ABBR.	PARAMETERS	METHODOLOGY	UNITS	Values for Liquid Reagents			Values for Powder Reagents		
				Value	Interval	1 SD	Value	Interval	1 SD
ALB	Albumin	BCG	g/dl	5.08	4.32-5.84	0.25			
ALP	Alkaline phosphatase	AMP	µkat/l	5.29	4.23-6.35	0.35	5.19	4.15-6.23	0.34
			U/l	317.73	254.18-381.28	21.18	311.79	249.43-374.15	20.79
ALT/GPT	ALT/SGPT	IFCC	µkat/l	2.33	1.86-2.80	0.15	2.16	1.72-2.59	0.14
			U/l	140.22	112.18-168.26	9.35	129.69	103.75-155.63	8.65
AMY	Amylase	CNPG3	µkat/l	2.84	2.27-3.41	0.19	2.00	1.60-2.40	0.13
			U/l	170.96	136.77-205.15	11.40	120.10	96.08-144.12	8.01
AST/GOT	AST/SGOT	IFCC	µkat/l	2.48	1.98-2.98	0.16	2.10	1.68-2.52	0.14
			U/l	149.16	119.33-178.99	9.94	126.24	100.99-151.49	8.42
BID	Bilirubin Direct	DIAZO	mg/dl	2.39	1.80-2.99	0.20			
BIT	Bilirubin Total	DIAZO	mg/dl	4.19	3.14-5.24	0.35			
CA	Calcium	ARSENAZO III	mg/dl	10.03	8.52-11.53	0.50			
		OCPC	mg/dl	10.99	8.79-13.19	0.73			
CL	Chloride	MERCURIC THIOCYANATE	mmol/l	121.59	103.35-139.83	6.08			
CHOL	Cholesterol	CHOD-PAP	mg/dl	209.62	178.18-241.06	10.48	301.87	256.59-347.15	15.09
CK	Creatinine kinase NAC	DGKC	µkat/l	4.66	3.50-5.83	0.38	4.63	3.47-5.79	0.38
			U/l	280.00	210-350	23.33	277.96	208.47-347.45	23.16
CK MB	Creatinine kinase MB	IMMUNO	µkat/l	1.01	0.76-1.26	0.08	1.19	0.89-1.49	0.09
			U/l	60.90	45.68-76.13	5.08	71.84	53.88-89.80	5.99
CREA	Creatinine	JAFFE'S	mg/dl	2.92	2.31-3.53	0.20*			
GGT	Gamma-glutamyl transferase	GLUPA-C	µkat/l	2.10	1.58-2.62	0.17	2.24	1.69-2.80	0.18
			U/l	126.36	94.98-157.74	10.46	134.94	101.43-168.45	11.17
GLU	Glucose	GOD-POD	mg/dl	238.04	202.33-273.75	11.90	198.70	168.90-228.51	9.94
HDL	HDL Cholesterol	DIRECT	mg/dl	73.64	58.91-88.37	4.91			
LDL	LDL Cholesterol	DIRECT	mg/dl	117.76	94.21-141.31	7.85			
LDH-P	*Lactate dehydrogenase-P*	DGKC	µkat/l	10.57	8.45-12.68	0.70	7.63	6.11-9.16	0.50
			U/l	634.48	507.58-761.38	42.30	458.35	366.68-550.02	30.56
LIP	Lipase	ADVANCE HEMOGEN	µkat/l	1.46	1.10-1.83	0.12			
			U/l	88.07	66.05-110.08	7.34			
MG	Magnesium	XYLIDYL BLUE	mg/dl	3.58	2.86-4.29	0.24			
PHOS	Phosphorus	UV-MOLYBDATE	mg/dl	7.57	6.43-8.71	0.38			
TP	Total Protein	BIURET	g/dl	8.49	7.22-9.76	0.42			
TGL	Triglycerides	GPO	mg/dl	149.44	127.02-171.86	7.47			
	Triglycerides -SR	GPO	mg/dl	160.30	136.26-184.35	8.02	130.03	110.53-149.53	6.50
UREA	Urea	UREASE-GLDH	mg/dl	88.52	75.24-101.80	4.43	96.67	82.17-111.17	4.83
UA	Uric Acid	URICASE	mg/dl	10.49	8.92-12.07	0.52			
	Uric Acid-SR	URICASE	mg/dl	9.95	8.46-11.44	0.50	11.53	9.80-13.26	0.58

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

Manufactured by : **TRANSASIA BIO-MEDICALS LTD.,** Khatiyan No. 235, Khasra No.24, Namthang Elaka, Mahakuma Namchi, South Sikkim –

In Technical Collaboration with : **ERBA diagnostics Mannheim GmbH** **Mallaustr., 69-73, D - 68219, Mannheim / Germa**

07/12/22 12:20:34

ALB Reagent OD 0.0278

ALB STD O.D. 0.3165
NET O.D : 0.2887
CONC : 4 g/dl
FACTOR :13.855

C1 SMP O.D. 0.2873

C1 ALB 3.60 g/dl +1SD

C2 SMP O.D. 0.3761

C2 ALB 4.83 g/dl

07/12/22 10:36:48

BIT Reagent OD 0.0010

C1 SMP O.D. 0.0589

C1 BIT 1.22 mg/dl -2SD
1:2S

C2 SMP O.D. 0.1957

C2 BIT 4.09 mg/dl

07/12/22 12:43:37

CHO Reagent OD 0.0317

CHO STD O.D. 0.3094
NET O.D : 0.2777
CONC : 200 mg/dl
FACTOR :720.20

C1 SMP O.D. 0.2115

C1 CHO 129.5 mg/dl

07/12/22 12:52:31

C2 SMP O.D. 0.3508

C2 CHO 229.8 mg/dl +

LINEAR REACTION

07/12/22 10:04:41

CRE DELTA STD O.D. 0.1236
NET O.D : 0.1236
CONC : 2 mg/dl
FACTOR :16.181

LINEAR REACTION

C1 DELTA SMP O.D. 0.0653

C1 CRE 1.06 mg/dl

LINEAR REACTION

C2 DELTA SMP O.D. 0.1529

C2 CRE 2.47 mg/dl -2SD
2:2S

LINEAR REACTION

07/12/22 11:30:37

GLU Reagent OD 0.0330

GLU STD O.D. 0.3767
NET O.D : 0.3437
CONC : 100 mg/dl
FACTOR :290.95

C1 SMP O.D. 0.3410

C1 GLU 89.61 mg/dl

C2 SMP O.D. 0.7606

C2 GLU 211.7 mg/dl +1SD

07/12/22 13:11:33

TRI Reagent OD 0.0777

TRI STD O.D. 0.3075
NET O.D : 0.2298
CONC : 200 mg/dl
FACTOR :870.32

C1 SMP O.D. 0.1968

C1 TRI 103.7 mg/dl +2SD
2:2S

C2 SMP O.D. 0.2707

C2 TRI 168.0 mg/dl +2SD
1:2S

07/12/22 11:47:39

URE DELTA STD O.D. -0.068
NET O.D : -0.068
CONC : 50 mg/dl
FACTOR :-735.3

LINEAR REACTION

C1 DELTA SMP O.D. -0.053

C1 URE 38.97 mg/dl

LINEAR REACTION

C2 DELTA SMP O.D. -0.125

C2 URE 91.91 mg/dl

LINEAR REACTION

07/12/22 12:08:30

UAC Reagent OD 0.0489

UAC STD O.D. 0.2358
NET O.D : 0.1869
CONC : 6 mg/dl
FACTOR :32.103

C1 SMP O.D. 0.2248

C1 UAC 5.65 mg/dl

C2 SMP O.D. 0.3747

C2 UAC 10.46 mg/dl

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Place of delivery: UTTAR PRADESH

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Order Date: 05.12.2022

Invoice Number : IN-1046
Invoice Details : HR-2093623225-2223
Invoice Date : 05.12.2022

Sl. No	Description	Unit Price	Qty	Net Amount	Tax Rate	Tax Type	Tax Amount	Total Amount
1	Laboratory Digital Dry Bath Incubator with 24 Test Tube Block for clinical, pharmaceutical, chemical, food safety, environment and quality inspection Use Laboratory | B09TY4YCLG (DP028 DRY BATH) HSN:8421	₹4,236.44	1	₹4,236.44	18%	IGST	₹762.56	₹4,999.00
TOTAL:							**₹762.56**	**₹4,999.00**

Amount in Words:
Four Thousand Nine Hundred Ninety-nine only

For DROPLET EQUIPMENTS:

Authorized Signatory

Whether tax is payable under reverse charge - No

Payment Transaction ID: 3HEUhaxoEKNkQ9kiG7pg	**Date & Time:** 05/12/2022, 13:07:12 hrs	**Invoice Value:** 4,999.00	**Mode of Payment:** Credit Card