



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

*in vitro* diagnostic use only

INTENDED USE  
NORM

**PRINCIPLE OF THE PROCEDURE**  
Human serum control is to be used for assessment of method precision & techniques and treated in the same way as an unknown specimen that would be used in accordance with the direction of the assay procedure. Results obtained for the control are to be compared with the assigned values given in the "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 laboratory establish its own means and acceptable ranges provided in the insert should be used as reference.

**POSITION**  
Control serum is prepared from human serum with chemical additives and tissue 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 specimen.

Donations used for production were tested by CE-marked test kits and found to be negative 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.

The work all principles of personal hygiene are to be maintained.

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

**RECONSTITUTION**

1. Allow the vial and AQUA-A (supplied in the vial) to attain room temperature. Invert vial 5-6 times.
2. Add 5 ml of AQUA-A and allow to stand for 30 minutes at rest in a light protected place. Swirl vial gently to ensure homogeneity before using as sample for testing. Invert vial 5-6 times.

**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 overexposure are stable:

|         |                                  |
|---------|----------------------------------|
| 1 day   | at +15 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. Errors in results can occur from reconstitution inaccuracy and the technique errors associated with the assay procedure. The serum is not compatible for use with o-Toluidine Chloride preservatives. 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.

**Assigned Values Using LIQUID STABLE REAGENTS / POWDER REAGENTS LOT No : S062125 EXPIRY: 11/2023**

| PARAMETERS                 | METHODOLOGY          | UNITS  | Values for Liquid Reagents |                |       | Values for Powder Reagents |               |       |
|----------------------------|----------------------|--------|----------------------------|----------------|-------|----------------------------|---------------|-------|
|                            |                      |        | Value                      | Interval       | 1 SD  | Value                      | Interval      | 1 SD  |
| Albumin                    | BCG                  | g/dl   | 3.77                       | 3.21 - 4.34    | 0.19  |                            |               |       |
| Alkaline phosphatase       | AMP                  | µkat/l | 1.56                       | 1.25-1.87      | 0.10  | 1.57                       | 1.25-1.88     | 0.10  |
|                            |                      | U/l    | 93.69                      | 74.95 - 112.43 | 6.25  | 94.38                      | 75.51-113.26  | 6.29  |
| ALT/SGPT                   | IFCC                 | µkat/l | 0.89                       | 0.71-1.06      | 0.06  | 0.80                       | 0.64-0.96     | 0.05  |
|                            |                      | U/l    | 53.27                      | 42.61-63.92    | 3.55  | 48.25                      | 38.60-57.90   | 3.22  |
| Amylase                    | CNP G3               | µkat/l | 0.97                       | 0.78-1.17      | 0.06  | 0.66                       | 0.53-0.80     | 0.04  |
|                            |                      | U/l    | 58.31                      | 46.65-69.97    | 3.89  | 40.00                      | 32.0-48.0     | 2.67  |
| AST/SGOT                   | IFCC                 | µkat/l | 0.89                       | 0.71-1.07      | 0.06  | 0.75                       | 0.59-0.89     | 0.05  |
|                            |                      | U/l    | 53.34                      | 42.67-64.01    | 3.56  | 44.87                      | 35.90-53.85   | 2.99  |
| Bilirubin Direct           | DIAZO                | mg/dl  | 0.92                       | 0.23-0.89      | 0.08  |                            |               |       |
| Bilirubin Total            | DIAZO                | mg/dl  | 1.40                       | 1.05-1.74      | 0.12  |                            |               |       |
| Calcium                    | ARSENAZO III         | mg/dl  | 8.00                       | 6.40-9.60      | 0.53  |                            |               |       |
|                            | OCPC                 | mg/dl  | 7.81                       | 6.25-9.37      | 0.52  |                            |               |       |
| Chloride                   | MERCURIC THIOCYANATE | mmol/l | 100.63                     | 85.54-115.72   | 5.03  |                            |               |       |
| Cholesterol                | CHOD-PAP             | mg/dl  | 122.16                     | 103.84-140.48  | 6.11  | 163.11                     | 138.64-187.58 | 8.16  |
| Creatinine kinase NAC      | DGKC                 | µkat/l | 1.92                       | 1.47-2.39      | 0.16  | 2.20                       | 1.51-2.52     | 0.17  |
|                            |                      | U/l    | 115.00                     | 86.25-143.75   | 9.58  | 121.30                     | 90.98-151.63  | 10.11 |
| Creatinine kinase MB       | IMMUNO               | µkat/l | 0.48                       | 0.36-0.60      | 0.04  | 0.33                       | 0.25-0.42     | 0.03  |
|                            |                      | U/l    | 28.97                      | 21.73-36.21    | 2.41  | 20.19                      | 15.14-25.24   | 1.68  |
| Creatinine                 | JAFFE'S              | mg/dl  | 1.30                       | 1.03-1.58      | 0.09  |                            |               |       |
| Gamma-glutamyl transferase | GLUPA-C              | µkat/l | 0.52                       | 0.39-0.64      | 0.04  | 0.56                       | 0.42-0.70     | 0.05  |
|                            |                      | U/l    | 30.94                      | 23.26-38.62    | 2.56  | 33.76                      | 25.38-42.14   | 2.79  |
| Glucose                    | GOD-POD              | mg/dl  | 86.26                      | 73.32-99.20    | 4.31  | 83.54                      | 71.01-96.07   | 4.18  |
| HDL Cholesterol            | DIRECT               | mg/dl  | 41.13                      | 32.90-49.36    | 2.74  |                            |               |       |
| LDL Cholesterol            | DIRECT               | mg/dl  | 56.41                      | 45.13-67.69    | 3.76  |                            |               |       |
| Lactate dehydrogenase-P    | DGKC                 | µkat/l | 5.44                       | 4.35-6.53      | 0.36  | 4.07                       | 3.26-4.89     | 0.27  |
|                            |                      | U/l    | 326.51                     | 261.21-391.81  | 21.77 | 244.59                     | 195.67-293.51 | 16.31 |
| Lipase                     | ADVANCE HEMOGEN      | µkat/l | 0.91                       | 0.68-1.13      | 0.08  |                            |               |       |
|                            |                      | U/l    | 54.45                      | 40.84-68.06    | 4.54  |                            |               |       |
| Magnesium                  | XYLIDYL BLUE         | mg/dl  | 1.99                       | 1.59-2.39      | 0.13  |                            |               |       |
| Phosphorus                 | UV-MOLYBDATE         | mg/dl  | 4.59                       | 3.90-5.27      | 0.23  |                            |               |       |
| Total Protein              | BIURET               | g/dl   | 5.82                       | 4.94-6.69      | 0.29  |                            |               |       |
| Triglycerides              | GPO                  | mg/dl  | 95.09                      | 80.83-109.35   | 4.75  |                            |               |       |
|                            |                      | mg/dl  | 128.65                     | 109.35-147.95  | 6.43  | 81.13                      | 68.96-93.30   | 4.06  |
| Triglycerides -SR          | GPO                  | mg/dl  | 41.51                      | 35.28-47.73    | 2.08  | 41.51                      | 35.28-47.73   | 2.08  |
|                            |                      | mg/dl  | 41.51                      | 35.28-47.73    | 2.08  |                            |               |       |
| Urea                       | UREASE-GLDH          | mg/dl  | 41.51                      | 35.28-47.73    | 2.08  |                            |               |       |
| Uric Acid                  | URICASE              | mg/dl  | 5.70                       | 4.85-6.56      | 0.29  |                            |               |       |
| Uric Acid-SR               | URICASE              | mg/dl  | 5.50                       | 4.68-6.33      | 0.28  | 6.20                       | 5.27-7.13     | 0.31  |

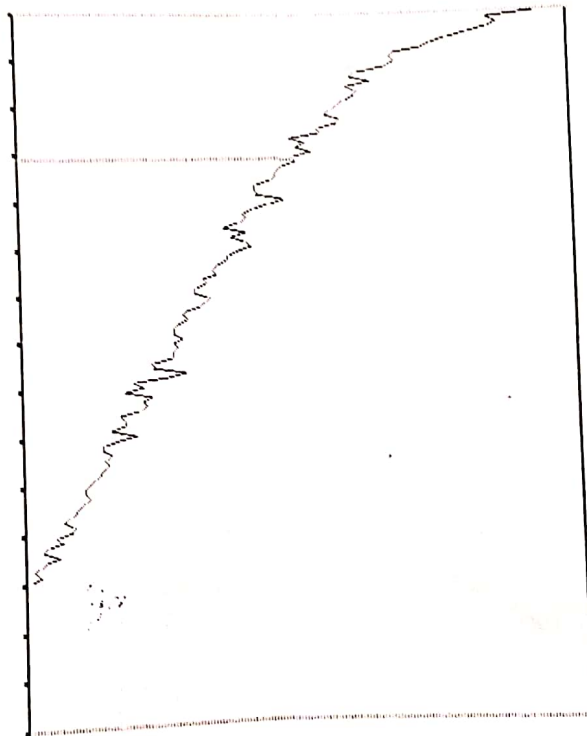
a) For End Point Assay-Values obtained after calibration using respective calibrator. b) For Bilirubin and Kinetic Assay-Values obtained using fixed factor. c) Assay Temperature = 37°C

ALT  
A B S O R B A N C E

1.5972

1.6896

1.7819



X Axis: 1 Unit = 20 sec  
Sample O.D. (initial) = 1.6931  
DELTA Sample O.D./m = -0.031

05/07/21 13:33:28

C1 ALT 55.52 IU/L -3SD  
LINEAR REACTION  
RX ABSLIM UNDER

Range 30.0 - 57.0

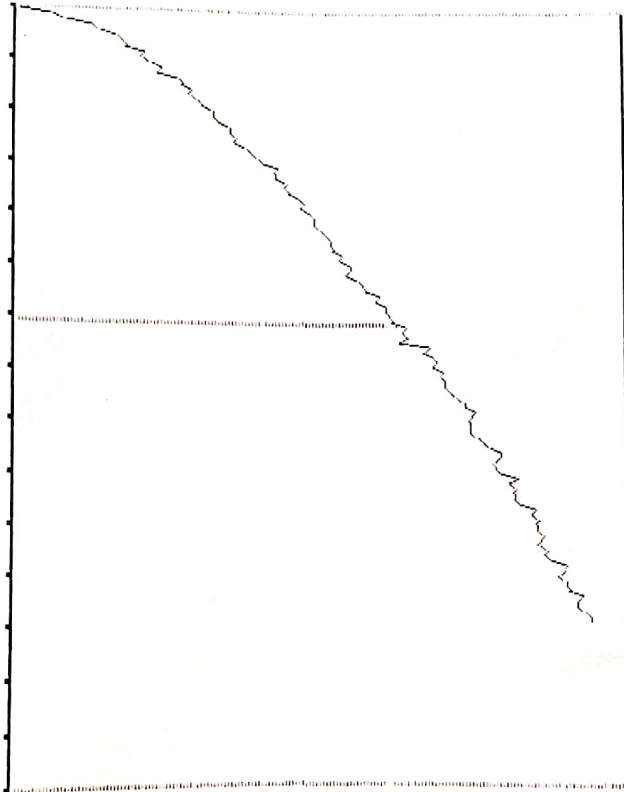
ALP

A B S O R B A N C E

1.5881

1.6404

1.6926



X Axis: 1 Unit = 10 sec  
Sample O.D. (initial) = 1.6562  
DELTA Sample O.D./m = 0.0347

05/07/21 13:48:21

C1 ALP 95.91 IU/L -3SD  
LINEAR REACTION

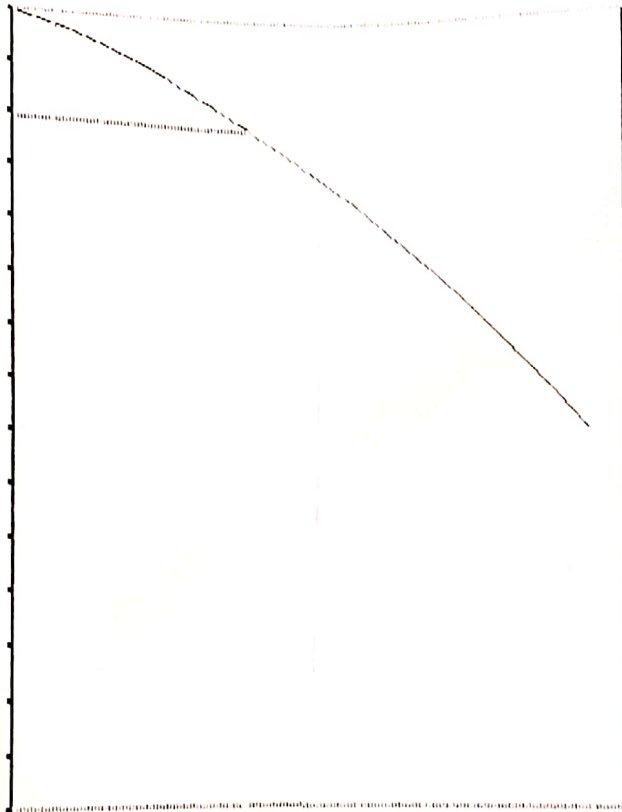
Range 75.0 - 112.0

CRE  
ABSORBANCE

0.4123

0.4598

0.5073



X Axis: 1 Unit = 10 sec  
Sample O.D. (initial) = 0.4505  
DELTA Sample O.D. = 0.0568

05/07/21 14:02:51

C1 CRE 1.43 mg/dL -3SD  
LINEAR REACTION

Range - 1.03 - 1.578

05/07/21 14:09:37

C1 CHO 157.7 mg/dL -3SD

Range  
138 - 176.50

05/07/21 14:11:00