SIMCO CALIBRATION LABORATORY

(A Division of : Sharp Industrial Machinery Maintenance Co. Pvt. Ltd.)

10-3-74/27, Plot No 151, Street No.3, Teacher's Colony, East Marredpally, Secunderabad - 26 Telangana
Tel 040 2773 2341/342, 2773 1510 Mob 77299 91231/33, 98480 46524
E-mail simco.hyd@gmail.com Info@simco-india.com www.simcocalibrationlaboratory.com

SIMCO TM
AN ISO 9001 : 2015 CERTIFIED COMPANY

ilac-MRA

CC-2806

CALIBRATION CERTIFICATE

In accordance with ISO / IEC-17025 : 2017

F10-CC-03

Certificate No. : SL2112TL0701-010	**Issue Date : 11-12-2021**
1. Customer Name & Address: **M/s. Likhitha's Diagnostics and Speciality Lab** ZENRISE, Plot No.201, Mythrinagar, NH-65, Madinaguda, Miyapur, Hyderabad - 500049	**ULR - C C 2 8 0 6 2 1 0 0 0 0 0 7 0 8 5 F** Reference Date : 07-12-2021 Calibration Date : 09-12-2021 Calibration Due Date : 08-12-2022

2. Details of Unit Under Calibration:

Description	: Digital Thermometer With Probe		
Make	: Wavess	Model	: ST-1A
Range	: -50 to 80 °C		
Resolution	: 0.1 °C		
ID No	: LDSL/LAB/DTM/02		

3. Detail of Standard Instruments Used :

Instrument Used	Sl / Id No	Valid up to	Certificate No.
Digital Temperature Indicator With SPRT Sensor	935-14-95 H	11-03-2022	FL/C/TH/09032021-C014

4. Environmental Conditions: Standard Temperature : (25±4)°C Relative Humidity : (50±20) % RH

5. Calibration Procedure: SOP-DTS-01

6. Thermal Calibration: Temperature

7.Calibration Results:

S. No.	Standard Reading (°C)	UUC Reading (°C)	Error (°C)	Expanded Uncertainty in (±°C)
1	-30.013	-30.2	-0.187	0.09
2	-0.028	0.1	0.128	0.09
3	9.961	10.2	0.239	0.09
4	40.014	40.3	0.286	0.09
5	70.065	70.4	0.335	0.09

8. Remarks:

a The instrument was received in good condition and was calibrated at Lab.
b This certificate pertains only to the item calibrated.
c The calibration results reported in this certificate are valid at the time of and at the stated environmental conditions.
d The Measurement Uncertainty is reported approximately at 95% confidence level with coverage factor k = 2
e The calibration is traceable to National standards as per traceability details given in the certificate.
f This calibration certificate shall not be reproduced in full, except with prior written approval of Managing Director, SIMCO Calibration Laboratory.
g This calibration certificate is meant for scientific and industrial purpose only.
h The calibration interval is determined based on customer's requirements.
i The NABL Symbol is used as per NABL guidelines in NABL-133.

Kinnera
Calibrated by

Mrs. P.A. Anandam
Technical Head
Authorised Signatory

LIKHITHA
Diagnostics & Speciality Lab
(A UNIT OF V.S.DIAGNOSTICS)

Kukatpally
MIG 252, Road No.4,
Opp. J.K. Hospital, KPHB Colony,
Hyderabad - 500072
Email : info@likhithadiagnostic.com
Web : www.likhithadiagnostic.com
Ph: 040-23057701, 23053591

Date: 26.04.2022

TO WHOM SO EVER IT MAY CONCERN

Likhitha's Diagnostics and Speciality Lab, Zenrise, Plot No. 201, Mythrinagar, NH-65, Madinaguda, Miyapur, Hyderabad – 500049, herein declares that the processed specimens are retained for 24 – 48 hrs only at 2 - 8°C as per the manufacturer guidelines given in kit inserts and then discarded appropriately.

For unstable parameters laboratory ask for freshly collected specimens.

So laboratory doesn't require -20°C (Freezer compartment) temperature for sample storage and hence only +2 to +8 °C temperature indicator is provided for samples storage refrigerator under equipment document.

Laboratory Director

Likhithas Diagnostics and Speciality Lab,
Zenrise, Miyapur,
Hyderabad – 500049

EN

ALT/GPT (IFCC)

REF

981769 8 x 20 ml (Indiko, Konelab)
981361 7 x 50 ml (Konelab

THIS PACKAGE INSERT IS APPLICABLE FOR USE OUTSIDE THE US.

INTENDED USE

For *in vitro* diagnostic use in the quantitative determination of alanine aminotransferase (L-Alanine: 2-Oxoglutarate Aminotransferase (ALT), EC 2.6.1.2) activity in human serum or plasma on Thermo Scientific™ Indiko™ and Konelab™ analyzers.

Any reference to the Konelab systems also refers to the T Series.

SUMMARY (1)

Alanine aminotransferase (ALAT/ALT), formerly called glutamic pyruvic transaminase (GPT), and Aspartate aminotransferase (ASAT/AST), formerly called glutamic oxalacetic transaminase (GOT), belong to a group of enzymes, the aminotransferases or transaminases, which catalyze the reversible transformation of α-keto acids into amino acids by transfer of amino groups.
Both AST and ALT are normally present in human plasma, bile, cerebrospinal fluid and saliva, but they are not found in urine unless a kidney lesion is present. In viral hepatitis and other forms of liver disease associated with hepatic necrosis, serum AST and ALT level are elevated even before the clinical signs and symptoms of disease appear. Levels of both enzymes may reach values as high as 100 times the upper reference limit, although 20- to 50-fold elevations are most frequently encountered.
Although serum levels of both AST and ALT become elevated whenever processes affect liver cell integrity, ALT is the more liver-specific enzyme. Increased AST levels can occur in connection with damages of heart or skeletal muscle as well as of liver parenchyma. Serum elevation of ALT activity is rarely observed in other conditions than parenchymal liver disease.

PRINCIPLE OF THE PROCEDURE

ALT catalyzes the transfer of the amino group from alanine to oxoglutarate with the formation of glutamate and pyruvate. Pyruvate is reduced to lactate by lactate dehydrogenase (LDH).

$$\text{L-Alanine} + \text{2-Oxoglutarate} \xrightarrow{\text{ALT}} \text{L-Glutamate} + \text{Pyruvate}$$

$$\text{Pyruvate} + \text{NADH} + \text{H}^+ \xrightarrow{\text{LDH}} \text{D-Lactate} + \text{NAD}^+$$

In this same reaction an equivalent amount NADH is oxidized to NAD. The resulting decrease in absorbance at 340 nm is followed and is directly proportional to the activity of ALT in serum.
The IFCC reference method includes pyridoxal -5'-phosphate (P-5'-P) at a level of 0.1 mmol/l, which has been shown to be sufficient to activate apo ALT in 5 minutes (2).

REAGENT INFORMATION

Kit code 981361 contains	Kit code 981769 contains
7 vials of 40 ml Reagent A	8 vials of 16 ml Reagent A
7 vials of 10 ml Reagent B	8 vials of 4 ml Reagent B

Concentrations

Reagent A: Enzyme reagent		Reagent B: Substrate	
Tris buffer, pH 7.15	137.5 mmol/l	2-oxoglutarate	82.5 mmol/l
L-Alanine	700 mmol/l	NADH	1.0 mmol/l
LDH	> 1650 U/l	NaN_3	< 0.1 %
NaN_3	< 0.1 %		

Note: Liquid pyridoxal-5'-phosphate is not included in the kit. It can be ordered separately by code number 981839.

Precautions

For *in vitro* diagnostic use only. Exercise the normal precautions required for handling all laboratory reagents.
The reagents contain sodium azide as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
The product has to be disposed of as laboratory chemical in accordance with local regulations.

Preparation

Note: Check that there are no bubbles in the bottleneck or on the surface of the reagent when you insert the reagent vials or vessels in the analyzer.

1-reagent system (without P-5'-P)
Add the contents of Reagent B to the bottle of Reagent A. Cap vial and mix. The monoreagent must be protected from light!
3-reagent system (with P-5'-P)
Reagents are ready for use.

Simultaneous measurement of 1-reagent and 2- or 3-reagent methods for the same analyte is not possible. Please choose one method and insert on-board only the reagents needed for the selected method.

Storage and Stability

The reagents are stable as shown below.

Reagents, in unopened vials	are stable at 2…8 °C until the expiration date printed on the label when protected from light.
Reagents, on-board	Refer to the Application Notes of your analyzer

Refer to the Application Notes of your analyzer for the on board stability of reagents.

SPECIMEN COLLECTION

Note: When processing samples in sample collection tubes, follow the instructions of the tube manufacturer carefully to avoid erroneous results. Pay special attention to the preanalytical variables such as mixing, standing time before centrifugation and centrifuge settings.
See also section *Interference*.

Sample Type

Clear serum or heparin plasma can be used.

Precautions

Human samples should be handled and disposed of as if they were potentially infectious.

Storage (3)

The sample can be stored as shown below.

Sample	3 days at 20…25 °C, 7 days at 4…8 °C, or 7 days at -20 °C

TEST PROCEDURE

Refer to the Application Notes for an automated procedure on your analyzer. Any application which has not been validated by Thermo Fisher Scientific Oy cannot be performance guaranteed and therefore must be evaluated by the user.

Indiko instrument settings

Enter the application parameters via barcode found in the Indiko application sheet or via electronical file as appropriate.

Konelab instrument settings

Enter manually the application parameters found in the Konelab application sheet.

Materials provided

Reagents as described above.

Materials required but not provided

Pyridoxal-5'-phosphate (code 981839) for 3-reagent system.
Controls as indicated below.

Calibration

The response dA/min is converted to result units by a calculation factor.
Or use eCal (981830) as a calibrator according to the instructions provided for your analyzer.

Traceability

Refer to the package insert of eCal.

Quality Control

Use quality control (CQ) samples at least once a day and every time a new bottle of reagent is used. It is recommended to use at least two levels (low and high) of controls or sample pools.
Always follow the local, state and federal regulations in performing QC.
Available controls:
Nortrol, code 981043
Abtrol, code 981044
The control intervals and limits must be adapted to the individual laboratory requirements.
The results of the quality control samples should fall within the limits pre-set by the laboratory.

CALCULATION OF RESULTS

The results are calculated automatically by the analyzer as follows:

Activity in U/l = dA/min x Factor

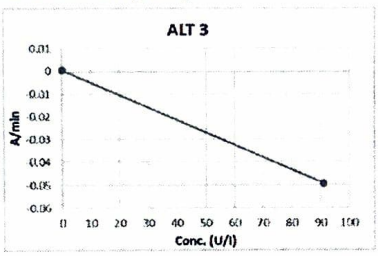
$$\text{Theoretical factor} = -\frac{\text{TV} \times 1000}{6.3 \times \text{SV} \times \text{P}}$$

TV	Total reaction volume in ml
SV	Sample volume in ml
6.3	Extinction coefficient of NADH at 340 nm
P	Cuvette pathlength = 1

Conversion factor µkat/l = (U/l)/60

If eCal (981830) is used as a calibrator, the results are calculated automatically by the analyzer using a calibration curve.

Calibration Curve (Indiko)



The calibration curve is lot dependent.

LIMITATIONS OF THE PROCEDURE

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Interference

A study was performed using the CLSI document EP7-A as a guideline.Criterion: Difference within ± 10% of initial values.

Indiko: 1-reagent system

Interfering Substance	Interferent Concentration	Target ALT (U/l)	Difference from Target (%)
Conjugated Bilirubin	780 µmol/l (46 mg/dl) 970 µmol/l (57 mg/dl)	68 189	-10.0 -7.4
Unconjugated Bilirubin	1000 µmol/l (58 mg/dl) 1100 µmol/l (64 mg/dl)	73 199	-10.0 -8.5
Hemoglobin in hemolysate	6 g/l 6 g/l	77 211	+7.3 +2.0
Lipemia: Intralipid® (trademark of Fresenius Kabi AB)	2.5 g/l* 2.5 g/l*	76 208	-3.8 -2.1

* During interfering testing, Init. abs high error messages were displayed.

Indiko: 3-reagent system

Interfering Substance	Interferent Concentration	Target ALT (U/l)	Difference from Target (%)
Conjugated Bilirubin	750 µmol/l (44 mg/dl) 970 µmol/l (57 mg/dl)	72 196	-10.0 -8.4
Unconjugated Bilirubin	1100 µmol/l (64 mg/dl) 1100 µmol/l (64 mg/dl)	75 203	-9.0 -7.6
Hemoglobin in hemolysate	6 g/l 6 g/l	78 212	+3.9 +1.1
Lipemia: Intralipid® (trademark of Fresenius Kabi AB)	1.3 g/l* 1.3 g/l*	78 213	-1.6 -1.2

* During interfering testing, Init. abs high error messages were displayed.

thermoscientific