Abbott
CLINICAL CHEMISTRY

ALANINE AMINOTRANSFERASE
List No. 7D56-20
30-3115/R3

AEROSET® / *c*8000™

ALANINE AMINOTRANSFERASE

This package insert contains information to run the Alanine Aminotransferase assay on the AEROSET System and the ARCHITECT® c8000 System.

NOTE: Changes Highlighted

NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Support

United States:	**1-877-4ABBOTT (1-877-422-2688)**
Canada:	**1-800-387-8378 (English speaking customers)**
	1-800-465-2675 (French speaking customers)
International:	**Call your local Abbott representative**

Symbols in Product Labeling

EC REP	Authorized Representative		Consult instructions for use
IVD	For in vitro diagnostic use	CE MANUFACTURING SITE ADDRESS	Legal Manufacturer
LOT	Batch code/Lot number	°C	Temperature limitation
R1	Reagent 1		Use by/Expiration date
R2	Reagent 2		
REF	Catalog number/List number		
SN	Serial number		

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NAME

ALANINE AMINOTRANSFERASE

INTENDED USE

The Alanine Aminotransferase (ALT) assay is used for the quantitation of alanine aminotransferase in human serum or plasma.

SUMMARY AND EXPLANATION OF TEST

Alanine Aminotransferase (ALT), also referred to as glutamate pyruvate transaminase (GPT), is an enzyme involved in amino acid metabolism. It is found in many tissues, but the highest levels are found in liver and kidney tissues. Tissue destruction leads to the release of the intracellular enzyme into the circulating blood. Markedly elevated serum ALT levels may be found in a variety of diseases which involve the liver, such as hepatitis, mononucleosis, and cirrhosis. These very high levels of ALT are not usually observed in other disease processes, e.g., myocardial infarction; thus, ALT is regarded as a reasonably specific indicator of liver disease.

PRINCIPLES OF PROCEDURE

ALT present in the sample catalyzes the transfer of the amino group from L-alanine to α-ketoglutarate forming pyruvate and L-glutamate. Pyruvate in the presence of NADH and lactate dehydrogenase (LD), is reduced to L-lactate. In this reaction NADH is oxidized to NAD. The reaction is monitored by measuring the rate of decrease in absorbance at 340 nm due to the oxidation of NADH to NAD.

REAGENTS

Reagent Kit

ALT, List No. 7D56, is supplied as a liquid, ready-to-use, two-reagent kit which contains:

- Reagent 1 (R1) 10 x 70 mL
- Reagent 2 (R2) 10 x 21 mL

Estimated tests per kit are 3,621. Calculation based on minimum reagent fill volume per kit.

Reactive Ingredients

Ingredient		Concentration
R1:	β-NADH	0.16 mg/mL
	Lactate Dehydrogenase	2.57 U/mL
	L-Alanine	392 mmol/L
R2:	α-Ketoglutarate	77 mmol/L
	L-Alanine	1,000 mmol/L

REAGENT HANDLING AND STORAGE

Reagent Handling

Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

Reagent Storage

The unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagent stability is 27 days if the reagent is uncapped and onboard.

WARNINGS AND PRECAUTIONS

Precautions for Users

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.

Information for European customers: For product not classified as dangerous per European Directive 1999/45/EC, safety data sheet available for professional user on request.

SPECIMEN COLLECTION AND HANDLING

Suitable Specimens

Serum and plasma are acceptable specimens.

Serum: Use serum collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation. Separate serum from red blood cells as soon after collection as possible. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results. Erythrocytes contain about 3 to 5 times more ALT than serum.[1]

Plasma: Use plasma (refer to table below for anticoagulants) collected by standard venipuncture techniques into glass or plastic tubes without gel barriers. Separate plasma from red blood cells as soon after collection as possible. Ensure centrifugation is adequate to remove platelets. Erythrocytes contain about 3 to 5 times more ALT than serum.[1]

For total sample volume requirements, refer to the instrument-specific ASSAY PARAMETERS section of this package insert and *Section 5* of the instrument-specific operations manual.

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens.[2] Biosafety Level 2[3] or other appropriate biosafety practices[4,5] should be used for materials that contain or are suspected of containing infectious agents.

Analyte Recovery

Analyte recovery in serum/plasma specimens was determined as a mean %Recovery of serum collected in glass tubes.

Anticoagulant	%Recovery
Lithium Heparin	100.3
Sodium Heparin	100.1
EDTA	97.1
Sodium Citrate	80.2
Plastic Tube/Serum	99.9
SST Gel Tube/Serum	100.8

Do not use ammonium heparin.[6]

Specimen Storage

Serum and plasma: It is recommended that specimens be assayed on the day of collection.[7, 8] Separated specimens are stable for 3 days at 30°C, 7 days at 2 to 8°C, or 60 days at -40°C or colder.[1, 9-17] When samples were stored at -20°C for 8 days, an 11% reduction in ALT activity was observed; a 20% reduction in ALT activity was observed when specimens were stored at -20°C for one month.[18]

NOTE: Stored specimens must be adequately mixed and centrifuged to remove precipitants prior to testing.

PROCEDURE

Materials Provided

ALT Reagent Kit, List No. 7D56

Materials Required but not Provided

- AEROSET System or ARCHITECT c8000 System
- Control Material
- Saline (0.85 to 0.90% sodium chloride), if desired for specimen dilution

Assay Procedure

For a detailed description of how to run an assay, refer to *Section 5* of the instrument-specific operations manual.

Specimen Dilution Procedures

The AEROSET System and the ARCHITECT c8000 System have Automatic Dilution features; refer to *Section 2* of the instrument-specific operations manual for additional information.

Serum and plasma: Specimens with alanine aminotransferase values exceeding 942 U/L (4,113 U/L for Flex Rate linearity) are flagged and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a 1:5 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

Manual Dilution Procedure

Manual dilutions should be performed as follows:

- Use saline (0.85% to 0.90% sodium chloride) to dilute the sample.
- The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor.
- If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

NOTE: If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution. For detailed information on ordering dilutions, refer to *Section 5* of the instrument-specific operations manual.

CALIBRATION

Calibration is stable for approximately 27 days (648 hours) and calibration is required with each change in reagent lot number. Verify calibration with at least two levels of controls according to the established Quality Control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

A calibration factor (8141) must be entered.

- AEROSET System—**Assay Configuration** screen, **Calibration** page
- ARCHITECT c8000 System—**Configure assay parameters** window, **Calibration** view

For a detailed description of how to calibrate an assay, refer to *Section 6* of the instrument-specific operations manual.

QUALITY CONTROL

The following process is the recommendation of Abbott Laboratories for quality control during the ALT procedure. As appropriate, refer to your laboratory Standard Operating Procedure(s) and/or Quality Assurance Plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established Quality Control procedures for your laboratory.
- If quality control results do not fall within an acceptable range defined by your laboratory, patient values may be suspect. Follow the established Quality Control procedures for your laboratory.
- If quality control results fall outside acceptance criteria, recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent lot.

RESULTS

Refer to the instrument-specific operations manual for information on results calculations.

- **AEROSET System Operations Manual**—*Appendix A*
- **ARCHITECT System Operations Manual**—*Appendix C*

LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND HANDLING and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

EXPECTED VALUES

Reference Range

Serum[19, 20]**/Plasma**

	Range (U/L)
Adult	0 to 55

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

SPECIFIC PERFORMANCE CHARACTERISTICS

AEROSET / c8000

Linearity

ALT is linear up to 942 U/L.

Flex Rate Linearity is 4,113 U/L.

To use Flex Rate Linearity, the Operator must edit the linear high value to 4,113 on the appropriate screen.

- AEROSET System—**Assay Configuration** screen, **Outline** page
- ARCHITECT c8000 System—**Configure assay parameters** screen, **Results** view

Linearity was verified using NCCLS protocol EP6-P.[21]

Limit of Detection (LOD)

The LOD is the mean concentration of an analyte-free sample + 2 SD, where SD = the pooled, within-run standard deviation of the analyte-free sample. The LOD for ALT is 1.3 U/L.

Limit of Quantitation (LOQ)

The LOQ is the analyte concentration at which the CV = 20%. The limit of quantitation for ALT is 5.1 U/L.

Interfering Substances[22]

Interference studies were conducted on the AEROSET System using NCCLS protocol EP7-P.[23] Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

Interfering Substance	Interferent Concentration		N	Target (U/L)	Observed (% of Target)
Bilirubin	30 mg/dL	(513 µmol/L)	4	53.1	95.3
Bilirubin	60 mg/dL	(1,026 µmol/L)	4	53.1	88.1
Hemoglobin	750 mg/dL	(7.5 g/L)	4	47.4	107.9
Hemoglobin	1,000 mg/dL	(10.0 g/L)	4	47.4	111.0
Intralipid	550 mg/dL	(5.5 g/L)	4	50.6	97.2
Intralipid	625 mg/dL	(6.25 g/L)	4	50.6	96.8

Bilirubin solutions at the above concentrations were prepared by the addition of a bilirubin stock to human serum pools. Hemoglobin solutions at the above concentrations were prepared by addition of hemolysate to human serum pools. Intralipid solutions at the above concentrations were prepared by addition of Intralipid to human serum pools.

AEROSET

Precision

The results from precision studies for serum using NCCLS protocol EP5-T2[24] are found below.

Control	N	Mean (U/L)	Within Run SD	Within Run %CV	Between Run SD	Between Run %CV	Between Day SD	Between Day %CV	Total SD	Total %CV
Level 1	80	30.3	0.41	1.4	0.13	0.4	0.51	1.7	0.67	2.2
Level 2	80	63.6	0.55	0.9	0.18	0.3	0.54	0.8	0.79	1.2

Method Comparison

Correlation studies were performed using NCCLS protocol EP9-A.[25] Serum results from the ALT assay on the AEROSET System were compared with the Boehringer Mannheim ALT assay (NADH oxidation methodology) on the Hitachi 717 Analyzer. Serum results observed on the AEROSET System ranged from 4.8 to 130.0 U/L.

	Serum
N	74
Y - Intercept	-4.356
Correlation Coefficient	0.989
Slope	0.870

Precision

The results from precision studies for serum using NCCLS protocol EP5-A[26] are found below.

Control	N	Mean (U/L)	Within Run SD	Within Run %CV	Between Run SD	Between Run %CV	Between Day SD	Between Day %CV	Total SD	Total %CV
Level 1										
Instrument 1	80	29.2	0.37	1.3	0.42	1.4	1.23	4.2	1.35	4.6
Instrument 2	80	29.9	0.44	1.5	0.38	1.3	1.43	4.8	1.55	5.2
Instrument 3	80	29.4	0.45	1.5	0.28	0.9	0.89	3.0	1.03	3.5
Level 2										
Instrument 1	80	80.4	0.42	0.5	0.30	0.4	1.25	1.6	1.36	1.7
Instrument 2	80	82.8	0.39	0.5	0.54	0.7	1.51	1.8	1.65	2.0
Instrument 3	80	81.7	0.57	0.7	0.00	0.0	1.00	1.2	1.15	1.4

Method Comparison

Correlation studies were performed based on NCCLS protocol EP9-A.[25] Serum results from the ALT assay on the ARCHITECT c8000 System were compared with the ALT assay on the AEROSET System. Serum results observed on the AEROSET System ranged from 7.0 to 3,935.2 U/L.

	Instrument 1	Instrument 2	Instrument 3
N	83	83	82
Y - Intercept	-3.683	1.739	3.730
Correlation Coefficient	1.000	1.000	1.000
Slope	0.940	0.969	0.965

AEROSET SYSTEM ASSAY PARAMETERS

AEROSET

Alanine Aminotransferase Serum/Plasma—Conventional and SI Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
ALT	21	B-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H		Panic-H	Max	Max Text
*	0.0*	0.0	0	55	0.0	0.0*	*
		6**	L-Linear Range-H		942		

Reference Ranges*

Age	Male	Female
	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read Time-Main/Flex	Linearity%
RATE DOWN	340 / 380	21 – 33 / 18 – 22	10
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
_____ (___)	0 – 0	14 – 16	0.5 – 1.5

	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	5.3	0.0	0	0		Rgt Name/Pos
Dil 1	20.0	5.3	80	0	Diluent	DILUENT D–18*
Dil 2	5.3	0.0	0	0	Type#***	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#***
Reagent 1	ALT0061 – ___*	160	0	0
Reagent 2	ALT0052 – ___*	40	0	0

Reaction Check	Read Time–A/B	Range	Minimum
END SUB	1 – 1 / 2 – 2	0.0001 – 9.9999	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	0	U/L

Assay Configuration: Calibration Page

Calib Mode	Factor	Interval (H)
Factor	8141.0	648
Blank/Calib Replicates	**Span**	**Span Abs Range**
3 / 0	BLK – 1	0.0 – 0.0

	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	BLK Abs Range
BLK	Water	5.3	0.0	0	0	0.0 – 0.0
C1		2.0	0.0	0	0	Cal Deviation
C2		2.0	0.0	0	0	0.0

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
—	—	—

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Refer to **Assay Configuration** in *Section 2* of the **AEROSET System Operations Manual** for information regarding assay parameters.

* User defined or instrument defined.

** The linear low value (L-Linear Range) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

***This field is not available with AEROSET Software v1.00ER005 or 1.00ER005.2.

ARCHITECT c8000 SYSTEM ASSAY PARAMETERS

c8000

Alanine Aminotransferase Serum/Plasma—Conventional and SI Units

Configure assay parameters – General

● General ○ Calibration ○ SmartWash ○ Results ○ Interpretation

Assay: **ALT** Type: **Photometric** Version: **1**
Number: **1021**

● Reaction definition ○ Reagent / Sample ○ Validity checks

Reaction mode: **Rate down**

	Primary	Secondary		Read times		
Wavelength:	**340**	/ **380**	Main:	**21**	–	**33**
Last required read:	**33**		Flex:	**18**	–	**22**
Absorbance range:	**0.5000**	– **1.5000**	Color correction:	**14**	–	**16**
Sample blank type:	**None**					

○ Reaction definition ● Reagent / Sample ○ Validity checks

		R1	R2
Reagent:	**ALT00**	Reagent volume:	**160**	**40**
Diluent:	**Saline**	Water volume:	___	___
Diluent dispense mode:	**Type 0**	Dispense mode:	**Type 0**	**Type 0**

Dilution name	Sample	Diluted sample	Diluent	Water		Dilution factor	Default dilution
STANDARD :	**5.3**	___	___	___	=	**1:1.00**	●
1:5 :	**20.0**	**5.3**	**80**	___	=	**1:5.00**	○
_____ :	___	___	___	___	=		○

○ Reaction definition ○ Reagent / Sample ● Validity checks

Reaction check: **End Subtraction**

	A	B
Read time:	**1 – 1**	**2 – 2**

Calculation limits: **0.0001 – 9.9999**

Rate linearity %: **10**

Configure assay parameters – Calibration

○ General ● Calibration ○ SmartWash ○ Results ○ Interpretation

Assay: **ALT** Calibration method: **Factor**
Factor: **8141.0000**

● Calibrators ○ Volumes ○ Intervals ○ Validity checks

Calibrator set: **None**
Calibrator level: Blank: **Water**
Concentration: **0**

Replicates: **3** [Range 1 – 3]

○ Calibrators ● Volumes ○ Intervals ○ Validity checks

Calibrator:

Calibrator level	Sample	Diluted sample	Diluent	Water
Blank: **Water**	**5.3**	___	___	___

○ Calibrators ○ Volumes ● Intervals ○ Validity checks

Calibration intervals:
Full interval: **648** (hours)

○ Calibrators ○ Volumes ○ Intervals ● Validity checks

Blank absorbance range: _____ – _____

Configure assay parameters – SmartWash

○ General ○ Calibration ● SmartWash ○ Results ○ Interpretation

Assay: **ALT**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
Cuvette	**Trig**	**Detergent B**	**345**	

Configure assay parameters – Results

○ General ○ Calibration ○ SmartWash ● Results ○ Interpretation

Assay: **ALT** Result units: **U/L**
Assay defaults:
Low-Linearity: **6** †
High-Linearity: **942**
Gender and age specific ranges:

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**0 – 55**	

Configure result units

Assay: **ALT**
Version: **1**

Result units: **U/L**
Decimal places: **0** [Range 0 – 4]

Correlation factor: **1.0000**
Intercept: **0.0000**

† The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

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TRADEMARKS