

AEROSET®

c8000™

# 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**

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

 ABBOTT LABORATORIES  
Abbott Park, IL 60064, USA

**EC REP** ABBOTT  
Max-Planck-Ring 2  
65205 Wiesbaden  
Germany  
+49-6122-580

 ABBOTT LABORATORIES, Diagnostics Division  
Abbott Park, Illinois 60064

October 2003  
Printed in U.S.A.  
©2002, 2003 Abbott Laboratories

---

**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  $\alpha$ -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: $\beta$ -NADH	0.16 mg/mL
Lactate Dehydrogenase	2.57 U/mL
L-Alanine	392 mmol/L
R2: $\alpha$ -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.<sup>1</sup>

**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.<sup>1</sup>

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.<sup>2</sup> Biosafety Level 2<sup>3</sup> or other appropriate biosafety practices<sup>4,5</sup> 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.<sup>6</sup>

### Specimen Storage

**Serum and plasma:** It is recommended that specimens be assayed on the day of collection.<sup>7, 8</sup> 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.<sup>1, 9-17</sup> 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.<sup>18</sup>

**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<sup>19, 20</sup>/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.<sup>21</sup>

### 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<sup>22</sup>

Interference studies were conducted on the AEROSET System using NCCLS protocol EP7-P.<sup>23</sup> 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.

**SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)**

**AEROSET**

**Precision**

The results from precision studies for serum using NCCLS protocol EP5-T2<sup>24</sup> are found below.

Control	N	Mean (U/L)	Within Run		Between Run		Between Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%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.<sup>25</sup> 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

**SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)**

**c8000**

**Precision**

The results from precision studies for serum using NCCLS protocol EP5-A<sup>26</sup> are found below.

Control	N	Mean (U/L)	Within Run		Between Run		Between Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%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.<sup>25</sup> 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

# AEROSSET SYSTEM ASSAY PARAMETERS

## AEROSSET

### Alanine Aminotransferase Serum/Plasma—Conventional and SI Units

Assay Configuration: Outline Page						
Assay Name	ALT	Assay #	21		Line	B-Line
<b>Quantitative Ranges</b>						
Min Text *	Min 0.0*	Panic-L 0.0	L-Reference-H 0	55	Panic-H 0.0	Max 0.0*
		6**	L-Linear Range-H		942	Max Text *
<b>Reference Ranges*</b>						
	Age		Male		Female	
	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	
	0 Year		0.0 – 0.0		0.0 – 0.0	
<b>Qualitative Ranges</b> 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	Rgt Name/Pos	
Standard	5.3	0.0	0	0		
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			
<b>Rgt Probe</b>			
Reagent	Wash	Vol	
—	—	—	
<b>Cuvette</b>			
Assay Name	Wash	Vol	
—	—	—	
<b>Sample Probe</b>			
Wash			
—			

Refer to **Assay Configuration** in *Section 2* of the **AEROSSET 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 AEROSSET 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			
<input checked="" type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input type="radio"/> Results
Assay: <b>ALT</b> Type: <b>Photometric</b> Version: <b>1</b>			
Number: <b>1021</b>			
<input checked="" type="radio"/> Reaction definition	<input type="radio"/> Reagent / Sample	<input type="radio"/> Validity checks	
Reaction mode: <b>Rate down</b>			
Primary		Secondary	Read times
Wavelength: <b>340</b> / <b>380</b>		Main: <b>21</b> – <b>33</b>	
Last required read: <b>33</b>		Flex: <b>18</b> – <b>22</b>	
Absorbance range: <b>0.5000</b> – <b>1.5000</b>		Color correction: <b>14</b> – <b>16</b>	
Sample blank type: <b>None</b>			

Configure assay parameters – Reagent / Sample			
<input type="radio"/> Reaction definition	<input checked="" type="radio"/> Reagent / Sample	<input type="radio"/> Validity checks	
Reagent: <b>ALT00</b> Reagent volume: <b>160</b> R1      R2			
Diluent: <b>Saline</b> Water volume: _____ <b>40</b>			
Diluent dispense mode: <b>Type 0</b> Dispense mode: <b>Type 0</b> <b>Type 0</b>			
Dilution name	Sample	Diluted sample	Dilution factor
<b>STANDARD :</b>	<b>5.3</b>	_____	<b>1:1.00</b> ●
<b>1:5</b>	<b>20.0</b>	<b>5.3</b>	<b>80</b> = <b>1:5.00</b> ○
_____ :	_____	_____	_____ = _____      ○

Configure assay parameters – Validity checks			
<input type="radio"/> Reaction definition	<input type="radio"/> Reagent / Sample	<input checked="" type="radio"/> Validity checks	
Reaction check: <b>End Subtraction</b>			
Read time: <b>1 – 1</b>		<b>2 – 2</b>	
Calculation limits: <b>0.0001 – 9.9999</b>			
Rate linearity %: <b>10</b>			

Configure assay parameters – Calibration			
<input type="radio"/> General	<input checked="" type="radio"/> Calibration	<input type="radio"/> SmartWash	<input type="radio"/> Results
Assay: <b>ALT</b> Calibration method: <b>Factor</b>			
Factor: <b>8141.0000</b>			
<input checked="" type="radio"/> Calibrators	<input type="radio"/> Volumes	<input type="radio"/> Intervals	<input type="radio"/> Validity checks
Calibrator set: <b>None</b>		Calibrator level: <b>0</b>	Concentration: <b>0</b>
Replicates: <b>3</b> [Range 1 – 3]		Blank: <b>Water</b>	

Configure assay parameters – Volumes			
<input type="radio"/> Calibrators	<input checked="" type="radio"/> Volumes	<input type="radio"/> Intervals	<input type="radio"/> Validity checks
Calibrator: _____			
Calibrator level: _____		Sample: <b>5.3</b>	Diluted sample: _____
Blank: <b>Water</b>		Diluent: _____	Water: _____

Configure assay parameters – Intervals			
<input type="radio"/> Calibrators	<input type="radio"/> Volumes	<input checked="" type="radio"/> Intervals	<input type="radio"/> Validity checks
Calibration intervals:			
Full interval: <b>648</b> (hours)			

Configure assay parameters – Validity checks			
<input type="radio"/> Calibrators	<input type="radio"/> Volumes	<input type="radio"/> Intervals	<input checked="" type="radio"/> Validity checks
Blank absorbance range: _____ - _____			

Configure assay parameters – SmartWash				
<input type="radio"/> General	<input type="radio"/> Calibration	<input checked="" type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: <b>ALT</b>				
COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
<b>Cuvette</b>	<b>Trig</b>	<b>Detergent B</b>	<b>345</b>	

Configure assay parameters – Results			
<input type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input checked="" type="radio"/> Results
Assay: <b>ALT</b> Result units: <b>U/L</b>			
Assay defaults:			
Low-Linearity: <b>6<sup>†</sup></b>			
High-Linearity: <b>942</b>			
Gender and age specific ranges:			
GENDER	AGE (UNITS)	NORMAL	EXTREME
<b>Either</b>	<b>0 – 130 (Y)</b>	<b>0 – 55</b>	

Configure result units	
Assay: <b>ALT</b>	
Version: <b>1</b>	
Result units: <b>U/L</b>	
Decimal places: <b>0</b> [Range 0 – 4]	
Correlation factor: <b>1.0000</b>	
Intercept: <b>0.0000</b>	

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

---

## BIBLIOGRAPHY

1. Henry RJ, Cannon DC, Winkelman JW. *Clinical Chemistry Principles and Technics*, 2nd ed. Hagerstown, MD: Harper and Row, 1974:888.
2. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030, Occupational exposure to bloodborne pathogens; final rule. *Federal Register* 1991;56(235):64175–82.
3. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. HHS Publication (CDC), 4th ed. Washington, DC: US Government Printing Office, May 1999.
4. World Health Organization. *Laboratory Biosafety Manual*. Geneva: World Health Organization, 1993.
5. National Committee for Clinical Laboratory Standards. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition (M29-A2)*. Wayne, PA: National Committee for Clinical Laboratory Standards, 2001.
6. Burtis CA, Ashwood ER, eds. *Tietz Textbook of Clinical Chemistry*, 2nd ed. Philadelphia, PA: WB Saunders, 1994:795–7.
7. Williams K, Williams A, Kline L, et al. Stability of serum alanine aminotransferase activity. *Transfusion* 1987;27(5):431–3.
8. Cuccherini B, Nussbaum S, Seeff L, et al. Stability of aspartate aminotransferase and alanine aminotransferase activities. *J Lab Clin Med* 1983;102(3):370–6.
9. Ruby SG, Relber NE, Lonser RE. Preanalytical variation in alanine aminotransferase. *Clin Chem* 1988;34(4):744–5.
10. Heins M, Heil W, Withold W. Storage of serum and whole blood samples? Effects of time and temperature on 22 serum analytes. *Eur J Clin Chem Clin Biochem* 1995;33:231–8.
11. Dale JC, Pruett SK. Phlebotomy—a minimalist approach. *Mayo Clin Proc* 1993;68(3):249–55.
12. Young D. *Effects of Preanalytical Variables on Clinical Laboratory Tests*. AACC Press, 2nd ed. 1997:3–12.
13. Elfath D, Cooney J, McDaniel R, et al. Effect of frozen storage of serum on the level of 22 chemistry analytes. *Clin Chem* 1991;37:931.
14. Faulkner AM, Lukes-Hall AM, White GW. Evaluation of the Grenier plasma separator blood tube. *Ann Clin Biochem* 1990;27:386–7.
15. Wilding P, Zilva JA, Wilde CE. Transport of specimens for clinical chemistry analysis. *Ann Clin Biochem* 1977;14:301–6.
16. Schwartz MK. Interferences in diagnostic biochemical procedures. *Adv Clin Chem* 1973;16:10.
17. Mosley JW, Goodwin RF. Stability of serum glutamic pyruvic transaminase activity on storage. *Am J Clin Pathol* 1985;44:591–5.
18. Donnelly JG, Soldin SJ, Nealon DA, et al. Stability of twenty-five analytes in human serum at 22°C, 4°C, and -20°C. *Pediatr Pathol Lab Med* 1995;15:869–74.
19. Kaplan LA, Pesce AJ, eds. *Clinical Chemistry Theory, Analysis, and Correlation*, 2nd ed. St Louis, MO: Mosby; 1989:895–8.
20. Sherman KE, Dodd RY, et al. Alanine aminotransferase levels among volunteer blood donors: geographic variation and risk factors. *J Infect Dis* 1982;145(3):383–6.
21. Passey RB, Bee DE, Caffo A, et al. *Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline (EP6-P)*. Villanova, PA: The National Committee for Clinical Laboratory Standards, 1986.
22. Young DS. *Effects of Drugs on Clinical Laboratory Tests*, 4th ed. Washington, DC: AACC Press, 1995:3–6–3–16.
23. Powers DM, Boyd JC, Glick MR, et al. *Interference Testing in Clinical Chemistry; Proposed Guideline (EP7-P)*. Villanova, PA: The National Committee for Clinical Laboratory Standards, 1986.
24. Kennedy JW, Carey RN, Coolen RB, et al. *Evaluation of Precision Performance of Clinical Chemistry Devices—Second Edition; Tentative Guideline (EP5-T2)*. Villanova, PA: The National Committee for Clinical Laboratory Standards, 1992.
25. Kennedy JW, Carey RN, Coolen RB, et al. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (EP9-A)*. Villanova, PA: The National Committee for Clinical Laboratory Standards, 1995.
26. Kennedy JW, Carey RN, Coolen RB, et al. *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline (EP5-A)*. Wayne, PA: The National Committee for Clinical Laboratory Standards, 1999.

---

## TRADEMARKS

AEROSSET and ARCHITECT are registered trademarks of Abbott Laboratories.

c8000 is a trademark of Abbott Laboratories.

All other trademarks, brands, product names, and trade names are the property of their respective companies.



