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**ALANINE AMINOTRANSFERASE**

**SERUM OR PLASMA**

**ABBOTT ARCHITECT**

**Intended Use**

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

**Clinical Significance**

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.

**Principle**

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.

**Methodology:** NADH (without P-5'-P)

**Specimen Collection and Handling**

**Suitable Specimens**

Serum and plasma are acceptable specimens.

**CAUTION:** Erythrocytes contain approximately 3 to 5 times more ALT than does serum.

Hemolysis in serum or plasma can increase test results.

• **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.

Centrifuge according to tube manufacturer’s instructions to ensure proper separation of serum from blood cells. 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.

• **Plasma:** Use plasma collected by standard venipuncture techniques into glass or plastic tubes. Refer to table below for acceptable anticoagulants. Ensure centrifugation is adequate to remove platelets.

Centrifuge according to tube manufacturer’s instructions to ensure proper separation of plasma from blood cells.

**Specimen Storage**

**Serum and Plasma:** It is recommended that specimens be assayed on the day of collection. 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. 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 1 month.

**NOTE:** Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

**Materials and Equipment Required**

**TEST INSTRUMENT**: Abbott ARCHITECT System

**MATERIALS PROVIDED**

7D56 ALT Reagent Kit

**MATERIALS REQUIRED BUT NOT PROVIDED**

• Control Material

• • Saline (0.85% to 0.90% NaCl) for specimens that require dilution

**Reagent Handling and Storage:**

***CAUTION*:**

1. For in vitro diagnostic use.

2. Do not use components beyond the expiration date.

3. 4. Do not mix reagents prepared at different times.

**CAUTION:** This product requires the handling of human specimens.

It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

**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.

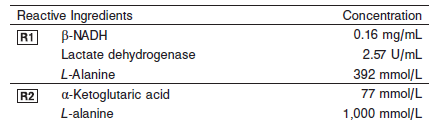
**Reagent Storage**

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.

Reagent Preparation:

7D56-21 ALT is supplied as a liquid, ready-to-use, two-reagent kit which contains: R1 & R2



**Quality Control:** Minimum 2 levels of ChemistryControl (Normal and Abnormal)

**Calibration**

**Frequency:**

Calibration is stable for 27 days (648 hours) for any one lot.

**A new calibration is required:**

1. If quality control results do not meet acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
2. Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

**Calibration Procedure:**

A calibration factor must be entered on the **Configure assay parameters** window, **Calibration** view. Refer to the ASSAY PARAMETERS section ofthe package insert for the specific factor.

• ARCHITECT *c* Systems—**Configure assay parameters** window, **Calibration** view

**Troubleshooting and Overall Acceptance Criteria Failure**

See ARCHITECT Operations Manual for further calibration troubleshooting.

**Quality Control:**

Abbott recommends, 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.

Some controls may require addition of Liquid Stabilizer.

• If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.

• If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory.

Recalibration may be necessary.

• Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

**Procedure**

For a detailed description of how to run an assay, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

**Calculations**

Refer to *Appendix C* of the **ARCHITECT System Operations Manual** for information on results calculations.

**Reporting Results**

The result unit for the ALT assay can be reported as U/L

**Specific Performance Characteristics**

**Reference Ranges**

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

**Serum/Plasma:**



**Critical Values: N/A**

**Performance Characteristics**

**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 **Configure assay** **parameters** window, **Results** view.

**Dilution:**

**Serum and Plasma:** Specimens with ALT values exceeding 942 U/L (4,113 U/L for Flex Rate Linearity) are flagged and may be diluted by following 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% NaCl) 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 **ARCHITECT System Operations Manual**.

**Limit of Quantitation (LOQ):** The LOQ for ALT is 5.1 U/L.

**Limit of Detection (LOD):** The LOD for ALT is 2.0 U/L.

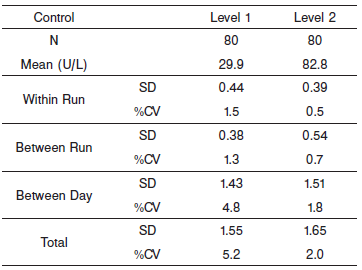
**Limitation of Procedure:**

Erythrocytes contain approximately 3 to 5 times more ALT than does serum.

Hemolysis in serum or plasma can increase test results

**Precision:**

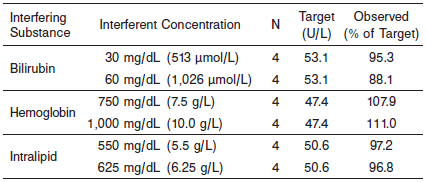
The imprecision of the ALT assay is ≤ 5.2% Total CV.



#### Interfering Substances:

**Interfering Substances**

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



**References:**

1. ABBOTT ARCHITECT ALT package insert

Abbott Laboratories

Diagnostics Division

Abbott Park, IL 60064

Sept 2012 304663/R02

1. Abbott ARCHITECT Operator’s Guide

**Related Documents:**

**Attachments:**