ALT, Serum or Plasma

Purpose

This procedure provides instructions for ALT on Abbott Instrumentation. The Alinity c ALT2 assay is used for the quantification of alanine aminotransferase in human serum or plasma on the Alinity c analyzer.

Policy Statements

This procedure applies to all personnel responsible for operating the Abbott Alinity c at Children's Minnesota Laboratory.

Principle

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

The Alanine Aminotransferase2 assay is an automated clinical chemistry assay. 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 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+.[1]

Clinical Significance

Alanine aminotransferase (ALT) is an enzyme found abundantly in the cytosol of the hepatocyte, and its activity in the liver is about 3000 times that of serum activity. Although it is generally thought to be specific to the liver, it is also found in the kidney and in much smaller quantities in heart and skeletal muscle cells. ALT has a plasma half-life of 47 ±10 hours, which is longer than that of aspartate aminotransferase (AST) (17 ±5 hours).

ALT rises in disease states that cause hepatocellular injury. The cause of hepatocellular injury may result in varying magnitudes of elevation in ALT and AST. Borderline ALT elevation is defined as <2 times the upper limit of normal (ULN), mild ALT elevation is defined as 2 to 5 times the ULN, moderate ALT elevation is defined as 5 to 15 times the ULN, and severe ALT elevation is defined as >15 times the ULN. Further work-up and management is determined by the magnitude of elevation in conjunction with other diagnostic factors.[1]

Materials

Product Description	*Product Code*	*Stability*
ALT2 Reagent (1200 tests per box; each box contains 4 reagent sets of 300 tests). Each reagent set consists of an R1 and R2 component. Alinity c **R1:** Active Ingredient: Active ingredients: L-alanine (66.820 g/L), β-NADH (0.305 g/L), lactate dehydrogenase	**MFR#** 04T8420 **CHC#** 32620	**Store at:** 2-8 °C **Unopened:** Until Expiration **Opened:** Stable 30 days onboard the analyzer. Stable until expiration if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.

(5.000 KU/L). Preservative: sodium azide. **R2:** Active ingredients: L-alanine (89.090 g/L), α-ketoglutaric acid (13.150 g/L). Preservative: ProClin 300. Abbott Diagnostics		
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Biorad MultiQual Controls Levels 1 and 3 Each box contains 12 5mL vials of control material. Biorad Laboratories	**Level 1 MFR#** 697 **Level 1 CHC#** 34574 **Level 3 MFR#** 699 **Level 3 CHC#** 34575	**Store at:** 2-8 °C **Unopened:** Until Expiration **Opened:** Stable 30 days onboard the analyzer. Stable until expiration if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.

Special Safety Precautions

The following warnings and precautions apply to: R1 Contains sodium azide. EUH032 Contact with acids liberates very toxic gas. P501 Dispose of contents / container in accordance with local regulations.

The following warnings and precautions apply to: R2 **WARNING** Contains methylisothiazolones. H317 May cause an allergic skin reaction. H402* Harmful to aquatic life. H412 Harmful to aquatic life with long

lasting effects. **Prevention** P261 Avoid breathing mist / vapors / spray. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves / protective clothing / eye protection. P273 Avoid release to the environment. **Response** P302+P352 IF ON SKIN: Wash with plenty of water. P333+P313 If skin irritation or rash occurs: Get medical advice / attention. P362+P364 Take off contaminated clothing and wash it before reuse. **Disposal** P501 Dispose of contents / container in accordance with local regulations.[1]

Calibration material contains human-sourced and/or potentially infectious components.[3]

Sample

Sample: Plasma collected with lithium heparin with or without gel barrier is preferred. Alternatively, serum collected with or without gel barrier is also accepted.

Stability: 3 days at room temperature, 7 days at 2-8 C, or up to 60 days frozen at –20 C or colder.

Test Code

LIS Test code: ALT for ALT in Serum or Plasma.

Analyzer

Primary Analyzer or Method: MACC or MALIC (Minneapolis), SALIC or ARCH4 (St. Paul).

Backup: Each analyzer may act as a backup for the other.

Calibration

Calibration Information

Reference Material	Water Calibration and fixed calibration factor
Calibration Frequency	Calibration is due every 30 days and with each new reagent lot.
Calibration Scheme	The Alanine Aminotransferase2 (ALT2F) assay utilizes the Factor data reduction method to generate a calibration and results. The calibration factor for the Alanine Aminotransferase2 is 8615. The Alanine Aminotransferase2 assay is traceable to the IFCC (International Federation of Clinical Chemistry) reference method. The assigned values for the calibrator and the calibration factor are traceable to the standardization.

Quality Control

Material: Biorad Multiqual, Levels 1 and 3
Frequency: Run 2 levels, once per day.
Acceptable Ranges: Acceptable ranges are set in Unity Real Time software.

Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, section 4 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report.
- To minimize the effect of evaporation, verify that adequate sample cup volume is present prior to running the test.
- Maximum number of replicates sampled from the same sample cup: 10
    - Sample volume for the first test: 5.3 uL + 50 uL for over-aspiration and dead volume
    - Sample volume for each additional test from the same sample cup: 1.6 uL
    - Sample volume for the 1:5 automated dilution: 20.0 uL + 50 uL for over-aspiration and dead volume

Dilutions

Samples with an ALT value exceeding 3258 U/L are flagged with the code ">3258 U/L" and may be diluted with the Automated Dilution Protocol.

Available Auto Dilutions:	1:5
Max Auto Dilution:	1:5
Maximum Manual Dilution:	None
Diluent:	Normal Saline

Calculations

Not applicable.

Interpretation and Resulting

Results will be reported to the first decimal (xx.x).
Results between 7 and 3258 U/L without error messages are released.
Results below 7 U/L without error messages are reported as <7 U/L.
Results greater than 3258 U/L are diluted 1:5 by auto dilution and the reported value up to 16290 U/L is released.
Results greater than 16290 U/L without error messages are reported as >16290 U/L.

Reference Intervals

Critical Values: Not applicable.

Reference Ranges[2]

Age	*Sex*	*Reference Interval (U/L)*
0 days to <1 year	All	7-31
1 to <13 years	All	7-23
13 to <19 years	Female Male	7-20 7-22
Adult	All	7-53

Method Performance Specifications

Analytical Measuring Range: 7-3258 U/L

AMR/Calibration Verification Frequency: Every 6 months

AMR recommended verification product: Maine Standards GC3
AMR proximity budget: 5 U/L (low) or 20% (high)
AMR systematic error budget: 50%

Allowable Error: 6 U/L or 15% (CAP)

Precision: 2 U/L SD or 4.0% CV, whichever is greater

Limitations

HIL Indices Cutoff Values[1,4]				At HIL levels at or above the specified cutoff value, append the appropriate comment AFTER visually confirming presence of interferent: -HP for "Hemolysis present, may affect results." -BIN for "Bilirubin Interference" -LINT for "Lipid Interference"
Interpretation	H	I	L	
Quant (Index)	250	N/A	N/A	
Semi Quant	3+	N/A	N/A	

Interferences from medication or endogenous substances may affect results.[1]

Additional interference information can be found in reagent package insert, page 6.

References

1. ALT2 for Alinity c Reagent Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised July 2021
2. CALIPER Reference Interval Studies, accessed October 27 2020
3. ConCC for Alinity c Calibrator Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised December 2020
4. Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis. CLSI guideline C56-A, 1st Ed, Wayne, PA: CLSI, 2012
5. ALT2 for Architect Reagent Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised July 2021

Appendices

Not applicable.

Training Plan/Competency Assessment

CH 1.04.T1 Abbott Alinity Training
QP 2.30 Orientation and Training
QP 2.40 Competency Assessment

Historical Record

Version	Author	Effective Date	Summary
1	Matt Johnson	2/10/2026	Initial Version