AST, Serum or Plasma

Purpose

This procedure provides instructions for AST on Abbott Instrumentation. The Alinity c AST2 assay is used for the quantification of AST in human serum or plasma on the Alinity c analyzer.

The Aspartate Aminotransferase2 assay is used for the quantitation of aspartate aminotransferase (AST) in human serum or plasma on the Alinity c system. The Aspartate Aminotransferase2 assay is to be used as an aid in the diagnosis and treatment of certain liver diseases.[1]

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 Aspartate Aminotransferase2 assay is an automated clinical chemistry assay. AST present in the sample catalyzes the transfer of the amino group from L-aspartate to α-ketoglutarate, forming oxaloacetate and L-glutamate. Oxaloacetate in the presence of nicotinamide adenine dinucleotide (NADH) and malate dehydrogenase (MDH) is reduced to L-malate. 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

AST is a liver enzyme that is also found in the heart, skeletal muscle and kidney. AST has two isoenzymes that are found in either the mitochondria or cytoplasm in cells. Alcohol-induced hepatocyte injury induces predominantly mitochondrial damage. AST requires vitamin B6 as a cofactor for the enzymatic reaction. Decreased AST levels may indicate vitamin B6 deficiency and uremia. AST is most commonly used in conjunction with other laboratory findings [alanine aminotransferase (ALT) or lactate dehydrogenase (LDH)]. The DeRitis ratio (AST/ALT quotient) is found to be elevated in alcohol-induced liver disease, viral hepatitis, cirrhosis and acute fulminant hepatic failure. A ratio of greater than two suggests that alcohol is the cause of liver injury.1

Materials

Product Description	*Product Code*	*Stability*
AST2 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	**MFR#** 04T8620 **CHC#** 32621	**Store at:** 2-8 °C **Unopened:** Until Expiration **Opened:** Stable 30 days onboard the analyzer. Stable until expiration if returned to 15-30 °C storage with replacement caps tightly secured and in upright position.

R1: Active ingredients: L-aspartic acid (103.860 g/L), β-NADH (0.610 g/L), lactate dehydrogenase (4.000 KU/L), and malate dehydrogenase (2.000 KU/L). Preservative: sodium azide. **R2:** Active ingredient: α-ketoglutaric acid (6.570 g/L). Preservative: ProClin 300. Abbott Diagnostics		
AST2 Reagent (1200 tests per box; each box contains 4 reagent sets of 300 tests). Each reagent set consists of an R1 and R2 component. Architect c **R1:** Active ingredients: L-aspartic acid (103.860 g/L), β-NADH (0.610 g/L), lactate dehydrogenase (4.000 KU/L), and malate dehydrogenase (2.000 KU/L). Preservative: sodium azide. **R2:** Active ingredient: α-ketoglutaric acid (6.570 g/L). Preservative: ProClin 300. Abbott Diagnostics	**MFR#** 04S9020 **CHC#** 32540	**Store at:** 2-8 °C **Unopened:** Until Expiration **Opened:** Stable 30 days onboard the analyzer. Stable until expiration if returned to 15-30 °C storage with replacement caps tightly secured and in upright position.
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: 4 days at room temperature, 7 days at 2-8 C, or up to 12 weeks frozen at –20 C or colder.

Test Code

LIS Test code: AST for AST 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 Aspartate Aminotransferase2 (AST2F) assay utilizes the Factor data reduction method to generate a calibration and results. The calibration factor for the Aspartate Aminotransferase2 assay is 8654. The Aspartate 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: 5.3 uL

Dilutions

Samples with an AST value exceeding 4001 U/L are flagged with the code ">4001 U/L" and may be diluted with the Manual Dilution Protocol.

Available Auto Dilutions:	None
Maximum Auto Dilution:	None
Maximum Manual Dilution:	1:5
Diluent:	Normal Saline
Manual Dilution Instruction:	Urine only -- Add 50 uL patient sample to 200 uL normal saline in a labeled sample cup. Mix well and program manually for manual 1:5 dilution. Discard dilution after testing.

Calculations

Not applicable.

Interpretation and Resulting

Results will be reported to the whole number (xx).
Results between 5 and 4001 U/L without error messages are released.
Results below 5 U/L without error messages are reported as <5 U/L.
Results greater than 4001 U/L are diluted 1:5 by manual dilution and the reported value up to 20,005 U/L is released.
Results greater than 20,000 U/L without error messages are reported as >20,000 U/L.

Reference Intervals

Critical Values: Not applicable.

Reference Ranges[2]

Age	*Sex*	*Reference Interval (g/dL)*
0 to <15 days	All	34-173
15 days to <1 year	All	21-72
1 to <7 years	All	22-47
7 to <12 years	All	19-39
12 to 18 years	Female Male	14-28 15-38
Adult	All	5-37

Method Performance Specifications

Analytical Measuring Range: 5-4001 U/L

AMR/Calibration Verification Frequency: Every 6 months

AMR recommended verification product: Maine Standards GC3
AMR proximity budget: 10 U/L (low) or 20% (high)
AMR systematic error budget: 50%

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

Precision: 1.3 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)	15	N/A	N/A	
Semi Quant	1+	N/A	4+	

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

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

References

1. AST2 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. ST2 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