**Alinity c Amylase-04**

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**BIENNIAL REVIEW:**

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**SUPERSEDES: Procedure titled** _____

# INTENDED USE

The Alinity c Amylase assay is used for the quantitation of amylase in human serum, plasma, or urine on the Alinity c analyzer.

# SUMMARY AND EXPLANATION OF THE TEST

Normal individuals have low but measurable serum and urine α-amylase activity which is produced in the pancreas and parotid glands. Measurement of α-amylase activity is of value in diagnosing pancreatitis and other pancreatic disorders which result in elevation of serum and urine α-amylase activity. Numerous methods have been used for clinical analysis.

# PRINCIPLES OF THE PROCEDURE

α-Amylase hydrolyzes the 2-chloro-4-nitrophenyl-α-*D*-maltotrioside (CNPG3) to release 2-chloro-4-nitrophenol (CPNP) and form 2-chloro-4-nitrophenyl-α-*D*-maltoside (CNPG2), maltotriose, and glucose. The rate of formation of the 2-chloro-4-nitrophenol can be detected spectrophotometrically at 404 nm to give a direct measurement of α-amylase activity in the sample.

**Methodology: Enzymatic (CNPG3 Substrate)**

For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.

# REAGENTS

## Kit Contents

Alinity c Amylase Reagent Kit 07P58

Volumes (mL) listed in the table below indicate the volume per cartridge.

| REF | **07P5820** |
|---|---|
| Tests per cartridge | 250 |
| Number of cartridges per kit | 2 |
| Tests per kit | 500 |
| R1 | 50.0 mL |
| R1 Active ingredients: 2-chloro-4-nitrophenyl-α-*D*-maltotrioside (2.25 mmol/L), Sodium chloride (350 mmol/L), Calcium acetate (6 mmol/L), Potassium thiocyanate (900 mmol/L). Inactive ingredients: Preservative: sodium azide (< 0.1%). | |

## Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

**Safety Precautions**

**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. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[1, 2, 3, 4]

| The following warnings and precautions apply to: R1 |
|---|
| Contains sodium azide and potassium thiocyanate. |

| | |
|---|---|
| EUH032 | Contact with acids liberates very toxic gas. |
| P501 | Dispose of contents / container in accordance with local regulations. |

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

**Reagent Handling**

- Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 7.

## Reagent Storage

| | Storage Temperature | Maximum Storage Time | Additional Storage Instructions |
|---|---|---|---|
| **Unopened** | 2 to 8°C | Until expiration date | Store in upright position. |
| **Onboard** | System Temperature | 19 days | |
| **Opened** | 2 to 8°C | Until expiration date | Store in upright position.<br>Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance. |

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright. For information on unloading reagents, **refer to the Alinity ci-series Operations Manual, Section 5.**

## Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when:

- a calibration error occurs
- a control value is out of the specified range

Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10**.

# INSTRUMENT PROCEDURE

The Alinity c Amylase assay file must be installed on the Alinity c analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the Alinity ci-series Operations Manual, Section 2.

For information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.

For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

## Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) =
(Concentration in Alternate result unit)

| Default Result Unit | Conversion Factor | Alternate Result Unit* |
|---|---|---|
| **U/L** | 1.1093 | U/L |

* The Default Result Units for the Amylase assay is U/L. The corresponding Alternate Result Unit is U/L when using International Federation of Clinical Chemistry (IFCC) units.

# SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

## Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types, collection tube types, and anticoagulants have not been verified with this assay.

| Specimen Type | Collection Vessel |
|---|---|
| | |

| Specimen Type | Collection Vessel |
|---|---|
| Serum | Serum tubes (with or without gel barrier) |
| Plasma | Collection tubes<br>Acceptable anticoagulants are:<br>Lithium heparin (with or without gel barrier)<br>Sodium heparin |
| Urine (random specimens or timed specimens collected over intervals shorter than 24 hours) | Clean plastic or glass container without preservatives[5, 6] |

- The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

## Specimen Conditions

- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

## Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low-speed vortex or by inverting 10 times prior to recentrifugation.

## Specimen Storage

| Specimen Type | Temperature | Maximum Storage Time |
|---|---|---|
| Serum/Plasma | 20 to 25°C | 7 days[7] |
| | 2 to 8°C | 7 days[7, 8] |
| | -20°C | 1 year[7] |
| Urine | 20 to 25°C | 2 days[7] |

| Specimen Type | Temperature | Maximum Storage Time |
|---|---|---|
| | 2 to 8°C | > 10 days[7, 8] |
| | -20°C | > 3 weeks[7] |

Avoid multiple freeze/thaw cycles.

Guder et al. suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above.[7]

Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Stored specimens must be inspected for particulates. If present, mix with a low-speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

### Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

## PROCEDURE

### Materials Provided

07P58 Alinity c Amylase Reagent Kit

### Materials Required but not Provided

- Alinity c Amylase assay file
- Commercially available controls containing amylase
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

### Assay 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.
- To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:

- Sample volume for single test: 4 µL.

  NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.

- Refer to the commercially available control kit package insert for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

## Sample Dilution Procedures

Samples with an amylase value exceeding 6554 U/L (7270 U/L using IFCC units) are flagged with the code "> 6554 U/L" (> 7270 U/L using IFCC units) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

**Serum/Plasma Automated Dilution Protocol**

The system performs a 1:2 dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

**Urine Automated Dilution Protocol**

If using an automated dilution protocol, the system performs a dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor. For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

**Manual Dilution Procedure**

Dilute the sample with saline (0.85% to 0.90% NaCl).

The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result. If a diluted sample result is less than the lower value of the measuring interval of 4 U/L (4 U/L using IFCC units), do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

## Calibration

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration is stable for approximately 19 days (456 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable

ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

## Quality Control Procedures

- At least two levels of controls (normal and abnormal) are to be run every day testing performed.
- If quality control results do not meet the acceptance criteria defined laboratory Quality control procedure, sample results may be suspect. Follow the established quality control procedures to troubleshoot. Recalibration may be necessary. For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10.**
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Commercial controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

### Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[9]

### Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

# RESULTS

## Calculation

The Alinity c Amylase assay utilizes the Factor data reduction method to generate a calibration and results.

For information on alternate result units, refer to the INSTRUMENT PROCEDURE, Alternate Result Units section of this package insert.

The calibration factor for the Alinity c Amylase assay is 3431 (3806 using IFCC units).

The IFCC unit provides traceability of serum and plasma sample results to the IFCC reference method.[10]

## Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

## Measuring Interval

Measuring interval is defined as the range of values in U/L (U/L using IFCC units) which meets the limits of acceptable performance for linearity, imprecision, and bias.

**The measuring interval of the Alinity c Amylase assay is 4 to 6554 U/L** (4 to 7270 U/L using IFCC units).

# LIMITATIONS OF THE PROCEDURE

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

# EXPECTED VALUES

reference ranges provided by the manufacturer will be adopted, effort made to verify locally.

For pediatrics reference ranges, Caliber Canadian intensive studies from Architect will be adopted. As per the following website:

**https://caliperdatabase.org**

**Reference Range**

**Serum/Plasma***11*

| | **Range (U/L)** |
|---|---|
| Newborn | 5 to 65 |
| Adult | 25 to 125 |
| > 70 years | 20 to 160 |

A study was conducted using 150 serum samples from volunteers. Data were analyzed as described by CLSI NCCLS C28-A.*12* From this study, 95% of all specimens fell within 23 U/L to 96 U/L, with samples ranging from 19 U/L to 129 U/L.

**Meharry Ref Ranges:**

| | **Range (U/L)** |
|---|---|
| 0-15 days | 3 to 10 |
| 16 days to 13 weeks | 2 to 22 |
| 14 weeks to 1 year | 3 to 50 |
| 2 years to 19 years | 25 to 101 |
| 20 years to 70 years | 25 to 125 |
| 71 years to 150 years | 20-160 |

**Urine***11*

| | Range (U/hour) |
|---|---|
| Timed | 1 to 17 |

**Timed Urinary Excretion**

To convert results from U/L to U/hour (timed amylase excretion)

Where:

V = timed urine volume (mL)

a = amylase activity (U/L)

t = collection period (hours)

Timed amylase excretion = [(V × a) ÷ (t × 1000)] U/hour

# SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity c analyzer and the ARCHITECT c System and AEROSET System utilized the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c analyzer.

## Precision

Within-Laboratory Precision

**Serum/Plasma**

A study was performed based on guidance from CLSI EP05-A2. Testing was conducted using 1 lot of the Alinity c Amylase Reagent Kit, 1 lot of commercially available controls and 1 instrument. Three control levels were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.*13*

| Sample | n | Mean (U/L) | Within-Run (Repeatability) | | Within-Laboratory (Total)[a] | |
|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV |
| Control Level 1 | 118 | 37 | 0.7 | 1.9 | 0.7 | 1.9 |
| Control Level 2 | 120 | 114 | 0.8 | 0.7 | 0.9 | 0.8 |
| Control Level 3 | 120 | 335 | 1.4 | 0.4 | 4.0 | 1.2 |

[a] Includes within-run, between-run, and between-day variability.

| Sample | n | Mean (U/L using IFCC units) | Within-Run (Repeatability) | | Within-Laboratory (Total)[a] | |
|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV |
| Control Level 1 | 118 | 41 | 0.7 | 1.8 | 0.7 | 1.8 |
| Control Level 2 | 120 | 127 | 1.3 | 1.0 | 1.3 | 1.0 |
| Control Level 3 | 120 | 371 | 1.9 | 0.5 | 4.5 | 1.2 |

[a] Includes within-run, between-run, and between-day variability.

**Urine**

A study was performed based on guidance from CLSI EP05-A2. Testing was conducted using 1 lot of the Alinity c Amylase Reagent Kit, 1 lot of commercially available controls and 1 instrument. Two control levels were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.*13*

| Sample | n | Mean (U/L) | Within-Run (Repeatability) | | Within-Laboratory (Total)[a] | |
|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV |
| Control Level 1 | 120 | 71 | 0.6 | 0.8 | 0.7 | 1.0 |
| Control Level 2 | 120 | 263 | 1.2 | 0.5 | 1.7 | 0.6 |

[a] Includes within-run, between-run, and between-day variability.

| Sample | n | Mean (U/L using IFCC units) | Within-Run (Repeatability) | | Within-Laboratory (Total)[a] | |
|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV |
| Control Level 1 | 120 | 79 | 0.6 | 0.8 | 0.7 | 0.9 |
| Control Level 2 | 120 | 292 | 1.3 | 0.4 | 1.8 | 0.6 |

[a] Includes within-run, between-run, and between-day variability.

## Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2. Testing was conducted using 3 lots of the Alinity c Amylase Reagent Kit on each of 2 instruments over a minimum of 3 days. The maximum observed Limit of Blank (LoB), Limit of Detection (LoD), and

Limit of Quantitation (LoQ) values are summarized below.[14]

| | U/L | U/L (using IFCC units) |
|---|---|---|
| LoB[a] | 2 | 2 |
| LoD[b] | 4 | 4 |
| LoQ[c] | 4 | 4 |

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

## Linearity

A study was performed based on guidance from CLSI EP06-A.[15]

**This assay is linear across the measuring interval of 4 to 6554 U/L** (4 to 7270 U/L using IFCC units).

## Interference

This study was performed on the AEROSET System.

Potentially Interfering Endogenous Substance

Interference studies were conducted using CLSI protocol NCCLS EP7-P.[16] Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

| Potentially Interfering Substance | Interferent Level | | Amylase | |
|---|---|---|---|---|
| | Default Units | Alternate Units | Target Level (U/L) | Recovery (% of Target) |
| Bilirubin | 7.5 mg/dL | 128 µmol/L | 95.9 | 107.3 |
| | 15 mg/dL | 257 µmol/L | 95.9 | 114.1 |
| Hemoglobin | 125 mg/dL | 1.25 g/L | 69.7 | 92.8 |
| | 250 mg/dL | 2.50 g/L | 69.7 | 82.6 |
| Intralipid | 1000 mg/dL | 10.0 g/L | 83.2 | 98.4 |
| | 2000 mg/dL | 20.0 g/L | 83.2 | 96.6 |

For the urine application, glucose up to 1000 mg/dL, ascorbate up to 200 mg/dL, protein up to 50 mg/dL, sodium oxalate up to 60 mg/dL, boric acid up to 250 mg/dL, and sodium fluoride up to 400 mg/dL demonstrated less than 10% interference. Acetic acid (8.5 N) 6.25 mL/dL, hydrochloric acid (6 N) 2.5 mL/dL, nitric acid (6 N) 5.0 mL/dL, and sodium carbonate 1.25 g/dL demonstrated greater than 10% interference.

Interferences from medication or endogenous substances may affect results.[17]

## Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[18]

| | | Units | n | Correlation Coefficient | Intercept | Slope | Concentration Range |
|---|---|---|---|---|---|---|---|
| Alinity c Amylase vs ARCHITECT Amylase | Serum | U/L | 126 | 1.00 | 0.41 | 1.00 | 8 - 6309 |
| | | U/L (using IFCC units) | 126 | 1.00 | 0.45 | 1.00 | 9 - 6999 |
| | Urine | U/L | 51 | 1.00 | -0.28 | 0.99 | 5 - 5780 |
| | | U/L (using IFCC units) | 51 | 1.00 | -0.27 | 0.99 | 5 - 6412 |

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