# Amylase2

FOR USE WITH

ARCHITECT

en

AMY2
04S89
G93316R05
B4S890

**Read Highlighted Changes: Revised November 2023.**

REF 04S8920

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

## NAME

Amylase2 (also referred to as AMY2)

## INTENDED USE

The Amylase2 assay is used for the quantitation of amylase in human serum, plasma, or urine on the ARCHITECT c Systems.

The Amylase2 assay is to be used primarily as an aid in the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

## SUMMARY AND EXPLANATION OF THE TEST

Amylase is an enzyme that cleaves carbohydrates. Amylase is produced primarily in the exocrine pancreas and salivary glands, but it also can be found in small amounts in the fallopian tubes, ovaries, testes, muscles, intestines, and other organs. Serum amylase is degraded and cleared by the kidneys.

Amylase is used primarily in the diagnosis of acute pancreatitis.[1] Acute pancreatitis is a reversible inflammation due to enzymatic necrosis. The most common cause of acute pancreatitis is gallstones. The second most common cause is heavy alcohol consumption.[2] Serum amylase elevation and concomitant urine amylase elevation is seen in patients with acute pancreatitis.[3] However, no reference values for urinary amylase have been established to date for the specific diagnosis of acute pancreatitis.

Diagnosis of pancreatic injury should be considered in the context of serum lipase elevations, since serum amylase is less specific than lipase activity in diagnosing exocrine injury.[4]

## PRINCIPLES OF THE PROCEDURE

The Amylase2 assay is an automated clinical chemistry assay.

The Amylase2 assay is a two-part reaction. Ethylidene-4-NP-G7 (EPS) is hydrolyzed by α-amylase to form 4,6-ethylidene-α-(1,4)-D-glucopyranosyl-Gx and 4-nitrophenyl-α-(1,4)-glucopyranosyl-G(7-x). The 4-nitrophenyl-α-(1,4)-glucopyranosyl-G(7-x) is then hydrolyzed into glucose monomers and the assay chromophore (4-nitrophenol) by α-glucosidase. The resulting change in absorbance at 404 nm is proportional to the α-amylase concentration in the sample.

Methodology: Enzymatic/Colorimetric

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

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## REAGENTS

### Kit Contents

Amylase2 Reagent Kit 04S89

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

| REF | 04S8920 |
|---|---|
| Tests per cartridge set | 160 |
| Number of cartridge sets per kit | 4 |
| Tests per kit | 640 |
| R1 | 14.5 mL |
| R2 | 13.4 mL |

R1 Active ingredient: α-glucosidase 16.000 KU/L. Preservative: sodium azide.

R2 Active ingredient: Ethylidene-4-NP-G7 (EPS) 6.501 g/L. Preservative: sodium azide.

### 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 and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[5-8]

| The following warnings and precautions apply to: R1 and R2 | |
|---|---|
| Contains sodium azide. | |
| 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 ARCHITECT System Operations Manual, Section 8.

#### Reagent Handling

- Do not pool reagents within a kit or between kits.
- Do not use components from one lot with components from another lot.
- Do not reuse containers, caps or plugs due to the risk of contamination and the potential to compromise reagent performance.
- When either the R1 or R2 reagent cartridge becomes empty, replace both cartridges.



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- Upon receipt, reagent cartridges can be used immediately or stored in an upright position.
- 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 ARCHITECT System 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 | 30 days | |
| **Opened** | 2 to 8°C | Until expiration date | Store in upright position. |

Reagents may be stored on or off the ARCHITECT c System. If reagents are removed from the system, store at 2 to 8°C (with replacement caps) in their original boxes.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

### Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or 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 ARCHITECT System Operations Manual, Section 10.

## INSTRUMENT PROCEDURE

The Amylase2 assay file must be installed on the ARCHITECT c System prior to performing the assay.

Installation of all the required SmartWash updates on the ARCHITECT c Systems Assay Disk Version 17.00 (or higher) must be completed prior to performing the assay. See below for impacted assays:

| | | | | VERSION | |
|---|---|---|---|---|---|
| Assay Name | Short Name | REF | Assay Number | Conventional Units / Alternate Units | SI Units / Alternate Units |
| Magnesium | MAG | 3P68 | 1070 | 6 | 4 |
| Magnesium Urine | MAGU | 3P68 | 1099 | 8 | 4 |

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

### Alternate Result Units

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 | 0.01667 | µkat/L |

## 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 |
|---|---|
| Serum | Serum tubes<br>Serum separator tubes |
| Plasma | Lithium heparin tubes<br>Lithium heparin separator tubes<br>Sodium heparin tubes |
| Urine (random specimens or timed specimens collected over intervals up to 24 hours) | Clean plastic or glass container without acidic preservatives[9, 10] |

- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens.

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

- Do not use:
  - heat-inactivated specimens
  - pooled specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- 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.
- 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.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

### Specimen Storage

| Specimen Type | Temperature | Collection Vessel | Maximum Storage Time |
|---|---|---|---|
| Serum/Plasma | Room temperature (20 to 25˚C) | Serum tubes*<br>Serum separator tubes<br>Lithium heparin tubes*<br>Sodium heparin tubes*<br>Lithium heparin separator tubes | 24 hours |
| | 2 to 8˚C | Serum tubes*<br>Lithium heparin tubes*<br>Sodium heparin tubes* | 24 hours |
| | | Serum separator tubes<br>Lithium heparin separator tubes | 7 days |
| Urine | Room temperature (20 to 25˚C) | Glass or plastic container | 24 hours[11] |
| | 2 to 8˚C | Glass or plastic container | 3 days[11] |

*The maximum storage time for these collection vessels is supported by Oddoze, et al.[12]

Serum/Plasma: Specimens may be stored at -20˚C for up to 3 months. Avoid multiple freeze/thaw cycles.[13, 14]

Urine: If testing will be delayed more than 3 days, store frozen.

It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.

For additional information on sample handling and processing, refer to CLSI GP44-A4.[14] The storage information provided here is based on references or data maintained by the manufacturer.

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

04S89 Amylase2 Reagent Kit

### Materials Required but not Provided

- Amylase2 assay file found on www.corelaboratory.abbott
- 04V1501 Consolidated Chemistry Calibrator
- 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 ARCHITECT System Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

### Assay Procedure

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

- If using primary or aliquot tubes, refer to the ARCHITECT System Operations Manual, Section 5 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 effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 4.0 µL.

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the ARCHITECT System Operations Manual, Section 5.
- Refer to the Consolidated Chemistry Calibrator package insert REF 04V1501 and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

### Sample Dilution Procedures

Samples with an amylase value exceeding 3009 U/L (50.16 µkat/L) are flagged with the code "> 3009 U/L" ("> 50.16 µkat/L") and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

#### Serum/Plasma Automated Dilution Protocol

The automated dilution factor verified for the Amylase2 serum/plasma assay is 1:1.98.

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 ARCHITECT System Operations Manual, Section 2.

| Dilution Name | Dilution Factor |
|---|---|
| 1:2 | 1:1.98 |

#### Urine Automated Dilution Protocol

The automated dilution factor verified for the Amylase2 urine assay is 1:2.86.

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 ARCHITECT System Operations Manual, Section 2.

| Dilution Name | Dilution Factor |
|---|---|
| 1:3 | 1:2.86 |

#### Manual Dilution Procedure

Specimens with an amylase value exceeding 3009 U/L (50.16 µkat/L) can be manually diluted using a 1:2 (serum/plasma) or 1:3 (urine) dilution.

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

The operator must enter the sample dilution in the Patient or Control order screen. The system will use this sample dilution to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the sample dilution, the result must be manually multiplied by the appropriate sample dilution before reporting the result.

For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

### Calibration

For instructions on performing a calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Calibration can be performed using one of 2 methods:

- Calibration method, using the Consolidated Chemistry Calibrator REF 04V1501. For the Calibration method, use assay file AMY2.
- Calibration Factor method, using a fixed calibration factor value to calculate result. For the Calibration Factor method, use assay file AMY2F.

Calibration is stable for approximately 30 days (720 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

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- At least 2 levels of controls (low and high) 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 meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

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.[15]

## RESULTS

### Calculation

#### Calibration method

The Amylase2 (AMY2) assay utilizes the Linear data reduction method to generate a calibration and results for both the serum/plasma and urine applications.

Urine sample quantification (AMY2-U) is achieved using the calibration generated with the AMY2 assay parameter file.

#### Calibration Factor method

For the serum/plasma application, the Amylase2 (AMY2F) assay utilizes the Factor data reduction method to generate a calibration and results.

For the urine application, the Amylase2 (AMY2-UF) assay utilizes the Use Cal Factor/Blank data reduction method to generate a calibration and results.

The calibration factor for the Amylase2 is 4412.

The Amylase2 assay is traceable to the IFCC (International Federation of Clinical Chemistry) reference method.[16]

For additional information, refer to the ARCHITECT System Operations Manual, Appendix C.

### 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 ARCHITECT System Operations Manual, Section 5.

### Reportable Interval

Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.[17]

**Serum/Plasma**

| | U/L | µkat/L |
|---|---|---|
| Analytical Measuring Interval (AMI)[a] | 3 - 3009 | 0.05 - 50.16 |
| Extended Measuring Interval (EMI)[b] | 3009 - 5957 | 50.16 - 99.30 |
| Reportable Interval[c] | 2 - 5957 | 0.03 - 99.30 |

[a] AMI: The AMI is determined by the range of values in U/L (µkat/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] EMI: The EMI extends from the ULoQ to the ULoQ × dilution factor.

[c] The reportable interval extends from the LoD to the upper limit of the EMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the analytical measuring interval. Samples with a serum/plasma amylase value below 3 U/L (0.05 µkat/L) are reported as "< 3 U/L" ("< 0.05 µkat/L").

**Urine**

| | U/L | µkat/L |
|---|---|---|
| Analytical Measuring Interval (AMI)[a] | 3 - 3009 | 0.05 - 50.16 |
| Extended Measuring Interval (EMI)[b] | 3009 - 8597 | 50.16 - 143.31 |
| Reportable Interval[c] | 1 - 8597 | 0.02 - 143.31 |

[a] AMI: The AMI is determined by the range of values in U/L (µkat/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] EMI: The EMI extends from the ULoQ to the ULoQ × dilution factor.

[c] The reportable interval extends from the LoD to the upper limit of the EMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the analytical measuring interval. Samples with a urine amylase value below 3 U/L (0.05 µkat/L) are reported as "< 3 U/L" ("< 0.05 µkat/L").

## LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- Amylase2 testing should not be performed on acidified urine samples due to enzyme instability.[18, 19]
- Treatment with icodextrin can result in decreased amylase results at therapeutically relevant interferent concentrations[20] and samples from patients with this treatment should not be tested.
- SmartWashes for assays impacted by Amylase2 must be configured to avoid interference due to reagent carryover. See the INSTRUMENT PROCEDURE section of this package insert for the required assay file updates.

## EXPECTED VALUES

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

**Reference Range**

**Serum/Plasma**

| | | Range (U/L) | Range* (µkat/L) |
|---|---|---|---|
| Pediatric[21] | | | |
| | 0 - 14 days | 3 - 10 | 0.05 - 0.17 |
| | 15 days - < 13 weeks | 2 - 22 | 0.03 - 0.37 |
| | 13 weeks - < 1 year | 3 - 50 | 0.05 - 0.83 |
| | 1 year - < 19 years | 25 - 101 | 0.42 - 1.68 |
| Adults[22] | | 28 - 100 | 0.47 - 1.67 |

**Urine**

| | | Range | Range* |
|---|---|---|---|
| Random[22] | | | |
| | Male | 16 - 491 U/L | 0.27 - 8.18 µkat/L |
| | Female | 21 - 447 U/L | 0.35 - 7.45 µkat/L |
| Timed Urine[23] | | 1 - 17 U/hour | 0.02 - 0.28 µkat/hour |
| Adult (24-hour urine)[23] | | 170 - 2000 U/L | 2.83 - 33.34 µkat/L |

* Alternate result units were calculated by Abbott and are not included in the citation provided.

Results should be compared with age adjusted normal values to evaluate their significance as applicable.

## SPECIFIC PERFORMANCE CHARACTERISTICS

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

Unless otherwise specified, the study results provided in this package insert were generated using the Calibration method.

### Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.[24]

**Serum/Plasma**

Testing was conducted using 3 lots of the Amylase2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Two controls and 3 serum panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

| | | | Within-Run (Repeatability) | | Within-Laboratory[a] | |
|---|---|---|---|---|---|---|
| Sample | n | Mean (U/L) | SD | %CV | SD (Range[b]) | %CV (Range[b]) |
| Control Level 1 | 80 | 77 | 0.5 | 0.6 | 1.5 (1.3 - 1.5) | 2.0 (1.7 - 2.0) |
| Control Level 2 | 80 | 413 | 3.3 | 0.8 | 6.7 (6.5 - 6.7) | 1.6 (1.6 - 1.6) |
| Panel A | 80 | 4 | 0.3 | 7.4 | 0.5 (0.3 - 0.5) | 11.0 (6.7 - 11.0) |
| Panel B | 80 | 162 | 0.8 | 0.5 | 3.3 (3.2 - 3.5) | 2.1 (2.0 - 2.2) |
| Panel C | 80 | 2629 | 14.8 | 0.6 | 51.6 (51.6 - 54.5) | 2.0 (2.0 - 2.1) |

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

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

| | | | Within-Run (Repeatability) | | Within-Laboratory[a] | |
|---|---|---|---|---|---|---|
| Sample | n | Mean (µkat/L) | SD | %CV | SD (Range[b]) | %CV (Range[b]) |
| Control Level 1 | 80 | 1.28 | 0.007 | 0.5 | 0.025 (0.021 - 0.025) | 2.0 (1.6 - 2.0) |
| Control Level 2 | 80 | 6.88 | 0.056 | 0.8 | 0.113 (0.108 - 0.113) | 1.6 (1.6 - 1.6) |
| Panel A | 80 | 0.07 | 0.003 | 4.4 | 0.005 (0.005 - 0.006) | 7.0 (7.0 - 8.0) |
| Panel B | 80 | 2.69 | 0.013 | 0.5 | 0.055 (0.053 - 0.058) | 2.1 (2.0 - 2.1) |
| Panel C | 80 | 43.82 | 0.246 | 0.6 | 0.858 (0.858 - 0.909) | 2.0 (2.0 - 2.1) |

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

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

**Urine**

Testing was conducted using 3 lots of the Amylase2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Two controls and 5 human urine panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

| | | | Within-Run (Repeatability) | | Within-Laboratory[a] | |
|---|---|---|---|---|---|---|
| Sample | n | Mean (U/L) | SD | %CV | SD (Range[b]) | %CV (Range[b]) |
| Control Level 1 | 80 | 55 | 0.4 | 0.8 | 0.5 (0.5 - 0.6) | 1.0 (1.0 - 1.1) |
| Control Level 2 | 80 | 180 | 0.8 | 0.4 | 1.3 (1.3 - 1.9) | 0.7 (0.7 - 1.1) |
| Panel A | 80 | 6 | 0.3 | 5.4 | 0.5 (0.3 - 0.5) | 7.9 (5.0 - 8.8) |
| Panel B | 80 | 18 | 0.4 | 2.1 | 0.4 (0.3 - 0.5) | 2.4 (1.4 - 2.9) |
| Panel C | 80 | 538 | 2.7 | 0.5 | 5.3 (5.3 - 6.8) | 1.0 (1.0 - 1.3) |
| Panel D | 80 | 1891 | 10.2 | 0.5 | 20.4 (20.4 - 23.7) | 1.1 (1.1 - 1.2) |
| Panel E | 80 | 2625 | 12.2 | 0.5 | 20.3 (19.6 - 20.3) | 0.8 (0.7- 0.8) |

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

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

| | | | Within-Run (Repeatability) | | Within-Laboratory[a] | |
|---|---|---|---|---|---|---|
| Sample | n | Mean (µkat/L) | SD | %CV | SD (Range[b]) | %CV (Range[b]) |
| Control Level 1 | 80 | 0.92 | 0.005 | 0.6 | 0.007 (0.007 - 0.011) | 0.7 (0.7 - 1.2) |
| Control Level 2 | 80 | 3.00 | 0.013 | 0.4 | 0.021 (0.021 - 0.032) | 0.7 (0.7 - 1.1) |
| Panel A | 80 | 0.10 | 0.005 | 5.4 | 0.008 (0.006 - 0.010) | 8.5 (6.0 - 10.7) |
| Panel B | 80 | 0.30 | 0.008 | 2.5 | 0.009 (0.005 - 0.010) | 2.9 (1.7 - 3.5) |
| Panel C | 80 | 8.97 | 0.044 | 0.5 | 0.089 (0.089 - 0.114) | 1.0 (1.0 - 1.3) |
| Panel D | 80 | 31.53 | 0.170 | 0.5 | 0.341 (0.341 - 0.394) | 1.1 (1.1 - 1.2) |
| Panel E | 80 | 43.76 | 0.204 | 0.5 | 0.338 (0.327 - 0.338) | 0.8 (0.7- 0.8) |

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

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

Reproducibility

A study was performed based on guidance from CLSI EP05-A3.[24]

**Serum/Plasma**

Testing was conducted using 1 lot of the Amylase2 reagent, 1 lot of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Each instrument was operated by a different technician, and each technician prepared an individual sample set. Five controls were tested in a minimum of 3 replicates at 2 separate times per day on 5 different days.

| | | | Repeatability | | Within-Laboratory[a] | | Reproducibility[b] | |
|---|---|---|---|---|---|---|---|---|
| Sample | n | Mean (U/L) | SD | %CV | SD | %CV | SD | %CV |
| Control Level 1 | 90 | 74 | 0.4 | 0.6 | 0.6 | 0.8 | 0.6 | 0.9 |
| Control Level 2 | 90 | 416 | 2.5 | 0.6 | 3.0 | 0.7 | 3.1 | 0.7 |

| Sample | n | Mean (U/L) | Repeatability SD | Repeatability %CV | Within-Laboratory[a] SD | Within-Laboratory[a] %CV | Reproducibility[b] SD | Reproducibility[b] %CV |
|---|---|---|---|---|---|---|---|---|
| Control Level A | 90 | 37 | 0.4 | 1.0 | 0.5 | 1.3 | 0.6 | 1.6 |
| Control Level B | 90 | 113 | 0.8 | 0.7 | 0.8 | 0.7 | 0.9 | 0.8 |
| Control Level C | 90 | 351 | 1.2 | 0.4 | 1.3 | 0.4 | 1.6 | 0.4 |

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

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

| Sample | n | Mean (µkat/L) | Repeatability SD | Repeatability %CV | Within-Laboratory[a] SD | Within-Laboratory[a] %CV | Reproducibility[b] SD | Reproducibility[b] %CV |
|---|---|---|---|---|---|---|---|---|
| Control Level 1 | 90 | 1.23 | 0.006 | 0.5 | 0.009 | 0.7 | 0.010 | 0.8 |
| Control Level 2 | 90 | 6.93 | 0.041 | 0.6 | 0.050 | 0.7 | 0.051 | 0.7 |
| Control Level A | 90 | 0.61 | 0.004 | 0.7 | 0.005 | 0.8 | 0.009 | 1.4 |
| Control Level B | 90 | 1.89 | 0.012 | 0.7 | 0.013 | 0.7 | 0.015 | 0.8 |
| Control Level C | 90 | 5.85 | 0.020 | 0.3 | 0.023 | 0.4 | 0.027 | 0.5 |

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

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

**Urine**

Testing was conducted using 1 lot of the Amylase2 reagent, 1 lot of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Each instrument was operated by a different technician, and each technician prepared an individual sample set. Four controls were tested in a minimum of 3 replicates at 2 separate times per day on 5 different days.

| Sample | n | Mean (U/L) | Repeatability SD | Repeatability %CV | Within-Laboratory[a] SD | Within-Laboratory[a] %CV | Reproducibility[b] SD | Reproducibility[b] %CV |
|---|---|---|---|---|---|---|---|---|
| Control Level 1 | 90 | 54 | 0.5 | 1.0 | 0.5 | 1.0 | 0.6 | 1.1 |
| Control Level 2 | 90 | 171 | 1.2 | 0.7 | 1.2 | 0.7 | 1.6 | 0.9 |
| Control Level A | 90 | 66 | 0.4 | 0.7 | 0.5 | 0.8 | 0.9 | 1.3 |
| Control Level B | 90 | 232 | 1.6 | 0.7 | 2.2 | 1.0 | 2.4 | 1.0 |

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

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

| Sample | n | Mean (µkat/L) | Repeatability SD | Repeatability %CV | Within-Laboratory[a] SD | Within-Laboratory[a] %CV | Reproducibility[b] SD | Reproducibility[b] %CV |
|---|---|---|---|---|---|---|---|---|
| Control Level 1 | 90 | 0.90 | 0.007 | 0.8 | 0.008 | 0.9 | 0.009 | 1.0 |
| Control Level 2 | 90 | 2.86 | 0.019 | 0.7 | 0.020 | 0.7 | 0.026 | 0.9 |
| Control Level A | 90 | 1.10 | 0.007 | 0.6 | 0.010 | 0.9 | 0.014 | 1.3 |
| Control Level B | 90 | 3.86 | 0.026 | 0.7 | 0.037 | 1.0 | 0.039 | 1.0 |

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

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

## Accuracy

A study was performed to estimate the bias of the Amylase2 assay relative to material standardized to the Certified Reference Material IRMM/IFCC-456.

**Calibration method**

Testing was conducted using 3 lots of the Amylase2 reagent, 2 lots of the Consolidated Chemistry Calibrator, and 3 instruments. The bias ranged from 0.5% to 2.4% across all instruments, calibrator and reagent lots.

**Calibration Factor method**

Testing was conducted using 3 lots of the Amylase2 reagent and 3 instruments. The bias ranged from -3.1% to 0.1% across all instruments and reagent lots.

## Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[25] Testing was conducted using 3 lots of the Amylase2 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.

**Serum/Plasma**

| | U/L | µkat/L |
|---|---|---|
| LoB[a] | 0 | 0.00 |
| LoD[b] | 2 | 0.03 |
| LoQ[c] | 3 | 0.05 |

**Urine**

| | U/L | µkat/L |
|---|---|---|
| LoB[a] | 0 | 0.00 |
| LoD[b] | 1 | 0.02 |
| LoQ[c] | 3 | 0.05 |

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

## Linearity

A study was performed based on guidance from CLSI EP06-A.[26] This assay is linear across the analytical measuring interval of 3 to 3009 U/L (0.05 to 50.16 µkat/L) for both serum and urine applications.

## Analytical Specificity

**Interference**

**Serum/Plasma**

A study was performed based on guidance from CLSI EP07, 3rd ed.[27] Each substance was tested at 2 levels of the analyte (approximately 50 U/L and 200 U/L).

**No significant interference (interference within ± 10%)** was observed at the following concentrations.

Potentially Interfering Endogenous Substances

| No Significant Interference (Interference within ± 10%) | | |
|---|---|---|
| | Interferent Level | |
| Potentially Interfering Substance | Default Units | Alternate Units |
| Bilirubin - conjugated | 60 mg/dL | 712 µmol/L |
| Bilirubin - unconjugated | 60 mg/dL | 1026 µmol/L |
| Hemoglobin | 1000 mg/dL | 10 g/L |
| Total protein | 15 g/dL | 150 g/L |
| Triglycerides | 1500 mg/dL | 17 mmol/L |

Potentially Interfering Exogenous Substances

| No Significant Interference (Interference within ± 10%) | | |
|---|---|---|
| | Interferent Level | |
| Potentially Interfering Substance | Default Units | Alternate Units |
| Acetaminophen | 160 mg/L | 1059 µmol/L |
| Acetylcysteine | 150 mg/L | 920 µmol/L |
| Acetylsalicylic acid | 30 mg/L | 166.5 µmol/L |
| Ampicillin-Na | 80 mg/L | 215 µmol/L |
| Ascorbic acid | 60 mg/L | 341 µmol/L |
| Biotin | 4250 ng/mL | 17 µmol/L |
| Ca-dobesilate | 60 mg/L | 143 µmol/L |
| Cefotaxime | 53 mg/dL | 1166 µmol/L |
| Cefoxitin | 6600 mg/L | 15 444 µmol/L |
| Cyclosporine | 2 mg/L | 2 µmol/L |
| Doxycycline | 20 mg/L | 45 µmol/L |
| Ibuprofen | 220 mg/L | 1067 µmol/L |
| Levodopa | 8 mg/L | 41 µmol/L |
| Methyldopa | 25 mg/L | 118 µmol/L |
| Metronidazole | 130 mg/L | 759 µmol/L |
| Pancreozymin | 314 pg/mL | 314 ng/L |
| Phenylbutazone | 330 mg/L | 1069 µmol/L |
| Rifampicin | 50 mg/L | 61 µmol/L |
| Sodium heparin | 4 U/mL | N/A* |
| Theophylline | 60 mg/L | 333 µmol/L |

*N/A = Not applicable

**Urine**

A study was performed based on guidance from CLSI EP07, 3rd ed.[27] Each substance was tested at 2 levels of the analyte (approximately 450 U/L and 1400 U/L).

**No significant interference (interference within ± 10%)** was observed at the following concentrations.

Potentially Interfering Endogenous Substances

| No Significant Interference (Interference within ± 10%) | | |
|---|---|---|
| | Interferent Level | |
| Potentially Interfering Substance | Default Units | Alternate Units |
| Ascorbate | 150 mg/dL | 8520 µmol/L |
| Glucose | 1000 mg/dL | 55.5 mmol/L |
| Protein | 50 mg/dL | 0.5 g/L |

**Interference beyond ± 10% [based on 95% Confidence Interval (CI)]** was observed at the concentrations shown below for the following substances.

| Interference Beyond ± 10% (Based on 95% CI) | | | | | |
|---|---|---|---|---|---|
| Potentially Interfering Substance | Interferent Level | | Analyte Level | | % Interference (95% CI) |
| | Default Units | Alternate Units | Default Units | Alternate Units | |
| Ascorbate | 200 mg/dL | 11 360 µmol/L | 450 U/L | 7.50 µkat/L | -21% (-21%, -20%) |
| Ascorbate | 200 mg/dL | 11 360 µmol/L | 1400 U/L | 23.34 µkat/L | -18% (-19%, -17%) |

Potentially Interfering Exogenous Substances

| No Significant Interference (Interference within ± 10%) | | |
|---|---|---|
| | Interferent Level | |
| Potentially Interfering Substance | Default Units | Alternate Units |
| Acetaminophen | 16 mg/dL | 1059 µmol/L |
| Acetylcysteine | 15 mg/dL | 920 µmol/L |
| Biotin | 4250 ng/mL | 17 µmol/L |
| Boric acid | 250 mg/dL | 40 mmol/L |
| Ibuprofen | 22 mg/dL | 1067 µmol/L |
| Sodium carbonate | 1.25 g/dL | 117 875 µmol/L |
| Sodium fluoride | 400 mg/dL | 95 mmol/L |
| Sodium oxalate | 60 mg/dL | 4478 µmol/L |

Interferences from medication or endogenous substances may affect results.[28]

### Method Comparison

A study was performed based on guidance from CLSI EP09-A3[29] using the Passing-Bablok regression method.

| Amylase2 vs Amylase on the ARCHITECT c System | | | | | | |
|---|---|---|---|---|---|---|
| | n | Units | Correlation Coefficient | Intercept | Slope | Concentration Range |
| Serum | 124 | U/L | 1.00 | -1.36 | 0.98 | 6 - 2788 |
| | | (µkat/L) | | (-0.02) | | (0.10 - 46.47) |
| Urine | 103 | U/L | 1.00 | -0.80 | 0.96 | 4 - 2916 |
| | | (µkat/L) | | (-0.02) | | (0.07 - 48.61) |

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## Key to Symbols

| ISO 15223 Symbols | |
|---|---|
|  | Consult instructions for use |
|  | Manufacturer |
|  | Sufficient for |
|  | Temperature limitation |
|  | Use by/Expiration date |
| IVD | *In Vitro* Diagnostic Medical Device |
| LOT | Lot Number |
| REF | List Number |
| SN | Serial number |

| Other Symbols | |
|---|---|
| CONTAINS: AZIDE | Contains Sodium Azide. Contact with acids liberates very toxic gas. |
| DISTRIBUTED IN THE USA BY | Distributed in the USA by |
| FOR USE WITH | Identifies products to be used together |
| INFORMATION FOR USA ONLY | Information needed for United States of America only |
| PRODUCT OF IRELAND | Product of Ireland |
| R1 | Reagent 1 |
| R2 | Reagent 2 |
| Rx ONLY | For use by or on the order of a physician only (applicable to USA classification only). |

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

The ARCHITECT c System family of instruments consists of c4000, c8000, and c16000 instruments.



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