CHRISTUS SPOHN Health System

CLINICAL LABORATORY – POLICY AND PROCEDURE
Christus Spohn Shoreline STAT Laboratory

Amylase using Abbott Architect ci4100

SOP Number:	HSL-0340.01	**Creation Date:**	8/24/18
Department:	STAT Lab	**Effective Date:**	8/24/18
Policy, Procedure, or Both:	Procedure	**Revision Date(s):**	
Author:	Kim Clark, MT (ASCP)	**Version:**	1

Applicable Standards	
Standard	Organization
COM.10000	CAP
Related Documents	

Version History		
Version	Effective Date	Retired Date
1	08/24/2018	

Review History (Up to the Last 15 Occurrences)			
Date	Version	Revision Type	Review By
8/22/18	1	**New Policy/Procedure**	System Laboratory Medical Director, Joe A. Lewis. M.D.. F.C.A.P.

Distribution
Christus Spohn Shoreline STAT Lab

TECHNICAL PROCEDURE MANUAL
CHRISTUS Spohn Hospital Corpus Christi Shoreline STAT Lab
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Intended Use
The Amylase assay is used for the quantitation of amylase in human serum, plasma, or urine.

Clinical Significance
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.

Principle

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: CNPG3 Substrate

Specimen Collection and Handling

Suitable Specimens
Serum, plasma, and urine are acceptable specimens.

• **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. Acceptable anticoagulants are lithium heparin (with or without gel barrier) and sodium heparin. Ensure centrifugation is adequate to remove platelets. Centrifuge according to tube manufacturer's instructions to ensure proper separation of plasma from blood cells.

• **Urine:** Collect random or timed urine specimens with no preservatives

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Specimen Storage

Serum, Plasma, and Urine

Temperature	Maximum Storage	
	Serum/Plasma	Urine
20 to 25°C	7 days	2 days
2 to 8°C	7 days	> 10 days
-20°C	1 year	> 3 weeks

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

7D58 Amylase 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.
The following warning and precaution apply to R1: Contains sodium azide and potassium thiocyanate.
EUH032 Contact with acids liberates very toxic gas.
This material and its container must be disposed of in a safe way.

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.

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Reagent Storage
Unopened reagents are stable until the expiration date when stored at 2 to 8°C.
Reagent stability is 19 days if the reagent is uncapped and onboard.

Reagent Preparation:

Amylase is supplied as a liquid, ready-to-use, reagent kit which contains: R1

Reactive Ingredients	Concentration
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: R1 contains sodium azide (< 0.1%) as a preservative.

Quality Control: Biorad Multiqual Controls Level 1, 2 and 3(697/698/699) Biorad Urine Controls Level1 and2 (397/398)

Calibration : Blank Calibration using on board deionized water.

Frequency:
Calibration is stable for 19 days (456 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 in the **Configure assay parameters** window, **Calibration** view.
An optional IFCC (International Federation of Clinical Chemistry) factor is provided. See note in Assay Parameters. The IFCC factor provides traceability of serum and plasma sample results to the IFCC reference method

Troubleshooting and Overall Acceptance Criteria Failure

See ARCHITECT Operations Manual for further calibration troubleshooting.

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Quality Control:

Controls are tested according to each location/site Quality Control Procedure.

- 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 Amylase 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 (Abbott Package Insert)

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

Urine

	Range (U/hour)
Timed	1 to 17

Serum/Plasma (this facility)

Critical Values : Refer to Critical Value Policy

Performance Characteristics

Linearity
Amylase is linear up to 3,010 U/L (3,338 U/L using IFCC factor).
Flex Rate Linearity is 6,554 U/L (7,270 U/L using IFCC factor). To use Flex Rate Linearity, the operator must edit the linear high value to 4,202 on the **Configure assay parameters** window, **Results** view.

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Dilution:

Serum, Plasma, and Urine: Specimens with amylase values exceeding 3,010 U/L (6,554 U/L for Flex Rate Linearity) are flagged and may be diluted by following either the Automated Dilution Protocol or the Manual Dilution Procedure.

Serum/Plasma Automated Dilution Protocol

If using the Automated Dilution Protocol, **the system performs a 1:2 dilution** of the specimen and automatically corrects the enzyme activity value by multiplying the result by the appropriate dilution factor.

Urine Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a dilution of the specimen and automatically corrects the enzyme activity value by multiplying the result by the appropriate dilution factor. To set up the automatic dilution feature, refer to *Section 2* of the **ARCHITECT System Operations Manual.**

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 Amylase is 2.4 U/L..

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

Limitation of Procedure:

N/A

Precision:

The imprecision of the Amylase assay is ≤ 4.6% Total CV.

Serum/Plasma:

Control		Level 1	Level 2
N		80	80
Mean (U/L)		46.9	476.4
Within Run	SD	0.53	2.79
	%CV	1.1	0.6
Between Run	SD	1.14	2.33
	%CV	2.4	0.5
Between Day	SD	1.17	9.47
	%CV	2.5	2.0
Total	SD	1.72	10.15
	%CV	3.7	2.1

Urine

Control		Level 1	Level 2
N		50	50
Mean (U/L)		40.9	179.0
Within Run	SD	0.65	1.03
	%CV	1.6	0.6
Between Run	SD	0.39	1.19
	%CV	1.0	0.7
Between Day	SD	0.24	1.61
	%CV	0.6	0.9
Total	SD	0.80	2.25
	%CV	2.0	1.3

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.

Interfering Substance	Interferent Concentration	N	Target (U/L)	Observed (% of Target)
Bilirubin	7.5 mg/dL (128 µmol/L)	4	95.9	107.3
	15 mg/dL (257 µmol/L)	4	95.9	114.1
Hemoglobin	125 mg/dL (1.25 g/L)	3	69.7	92.8
	250 mg/dL (2.50 g/L)	3	69.7	82.6
Intralipid	1,000 mg/dL (10.0 g/L)	3	83.2	98.4
	2,000 mg/dL (20.0 g/L)	3	83.2	96.6

References:

1. ABBOTT ARCHITECT Amylase package insert
   Abbott Laboratories
   Diagnostics Division
   Abbott Park, IL 60064
   Aug 2015 306719/R04
2. Abbott ARCHITECT Operator's Guide

Effective Date for this procedure:

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