Abbott
CLINICAL CHEMISTRY

ARCHITECT® / AEROSET®

AMYLASE

This package insert contains information to run the Amylase assay on the ARCHITECT *c* Systems™ and the AEROSET System.

NOTE: Changes Highlighted

NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Support

United States:	**1-877-4ABBOTT**
Canada:	**1-800-387-8378 (English speaking customers)**
	1-800-465-2675 (French speaking customers)
International:	**Call your local Abbott representative**

Symbols in Product Labeling

CONC	Concentration	REF	Catalog number/List number
EC REP	Authorized Representative in the European Community	SN	Serial number
INGRED	Ingredients		Consult instructions for use
IVD	In vitro diagnostic medical device		Manufacturer
LOT	Batch code/Lot number	°C °C	Temperature limitation
R1	Reagent 1		Use by/Expiration date

ABBOTT LABORATORIES
Abbott Park, IL 60064, USA

EC REP ABBOTT
Max-Planck-Ring 2
65205 Wiesbaden
Germany
+49-6122-580

Abbott
Diagnostics

February 2007

NAME

AMYLASE

INTENDED USE

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

SUMMARY AND EXPLANATION OF 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 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: CNPG3 Substrate

REAGENTS

Reagent Kit

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

REF **7D58-20**

R1 10 x 53 mL

Estimated tests per kit: 2,244*

REF **7D58-30**

R1 4 x 53 mL

Estimated tests per kit: 898*

*Calculation is based on the minimum reagent fill volume per kit.

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
Sodium Azide	< 0.1%

REAGENT HANDLING AND STORAGE

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.

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.

WARNINGS AND PRECAUTIONS

Precautions for Users

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.
4. This product contains potassium thiocyanate. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.
5. **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.[1] Biosafety Level 2[2] or other appropriate biosafety practices[3,4] should be used for materials that contain or are suspected of containing infectious agents.

NOTE: Refer to *Section 8* of the instrument-specific operations manual for proper handling and disposal of reagents containing sodium azide.

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. Separate serum from red blood cells or gel as soon after collection as possible.

  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. Separate plasma from red blood cells or gel as soon after collection as possible.
- **Urine:** Collect random or timed urine specimens with no preservatives.[5,6]

Refer to the specimen collection tube manufacturer's instructions for processing and handling requirements.

For total sample volume requirements, refer to the instrument-specific ASSAY PARAMETERS section of this package insert and *Section 5* of the instrument-specific operations manual.

Specimen Storage

Serum, plasma, and urine

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

Guder et al.[7] suggest storage of frozen specimens at -20˚C for no longer than the time intervals cited above. However, limitations of laboratory equipment make it necessary in practice for clinical laboratories to establish a range around -20˚C for specimen storage. This temperature range may be established from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

PROCEDURE

Materials Provided

REF 7D58-20 or 7D58-30 Amylase Reagent Kit

Materials Required but not Provided

- Control Material
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

Assay Procedure

For a detailed description of how to run an assay, refer to *Section 5* of the instrument-specific operations manual.

Specimen Dilution Procedures

The ARCHITECT *c* Systems and the AEROSET System have automatic dilution features; refer to *Section 2* of the instrument-specific operations manual for additional information.

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 using 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 instrument-specific operations manual for additional information.

Manual Dilution Procedure

Manual dilutions should be performed as follows:

- Use saline (0.85% to 0.90% NaCl) to dilute the sample.
- The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the enzyme activity value by multiplying the result by the entered factor.
- If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

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 instrument-specific operations manual.

CALIBRATION

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

A calibration factor must be entered.

- ARCHITECT *c* Systems—**Configure assay parameters** window, **Calibration** view
- AEROSET System—**Assay Configuration** screen, **Calibration** page

For a detailed description of how to calibrate an assay, refer to *Section 6* of the instrument-specific operations manual.

QUALITY CONTROL

The following is the recommendation of Abbott Laboratories for quality control. As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) 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, 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 lot.

RESULTS

Refer to the instrument-specific operations manual for information on results calculations.

- **ARCHITECT System Operations Manual**—*Appendix C*
- **AEROSET System Operations Manual**—*Appendix A*

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. Results obtained in individual laboratories may vary.

LIMITATIONS OF THE PROCEDURE

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

EXPECTED VALUES

Reference Range

Serum/Plasma[9]

	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 Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS C28-A.[10] From this study, 95% of all specimens fell within 23 to 96 U/L, with samples ranging from 19 to 129 U/L.

Urine[9]

	Range (U/hour)
Timed	1 to 17

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

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)

$$\text{Timed amylase excretion} = [(V \times a) \div (t \times 1000)] \text{ U/hour}$$

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity

Amylase is linear up to 3,010 U/L.

Flex Rate Linearity is 6,554 U/L. To use Flex Rate Linearity, the operator must edit the linear high value to 6,554 on the appropriate screen.

- ARCHITECT *c* Systems—**Configure assay parameters** screen, **Results** view
- AEROSET System—**Assay Configuration** screen, **Outline** page

Linearity was verified using CLSI protocol NCCLS EP6-P.[11]

Limit of Detection (LOD)

The LOD for Amylase is 2.0 U/L. The LOD is the mean concentration of an analyte-free sample + 2 SD, where SD = the pooled, within-run standard deviation of the analyte-free sample. A study performed on an ARCHITECT *c* System and an AEROSET System produced an LOD for Amylase of 0.9 U/L.

Limit of Quantitation (LOQ)

The LOQ for Amylase is 2.4 U/L. The LOQ is the analyte concentration at which the CV = 20%.

SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)

Interfering Substances[12]

Interference studies were conducted using CLSI protocol NCCLS EP7-P.[13] 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

Bilirubin solutions at the above concentrations were prepared by addition of a bilirubin stock to human serum pools. Hemoglobin solutions at the above concentrations were prepared by addition of hemolysate to human serum pools. Intralipid solutions at the above concentrations were prepared by addition of Intralipid to human serum pools.

For the urine application, glucose up to 1,000 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 (8.5N), hydrochloric acid (6N), nitric acid, and sodium carbonate demonstrated greater than 10% interference.

Precision

The imprecision of the Amylase assay is ≤ 4.6% Total CV. Representative data from studies using CLSI protocol NCCLS EP5-A[14] are summarized below.

Serum

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

Representative data from studies using CLSI protocol NCCLS EP10-A[15] are summarized below.

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

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A.[16]

Serum and urine results from the Amylase assay on the AEROSET System were compared with those from a commercially available ethylidene-G7PNP methodology.

Serum and urine results from the Amylase assay on an ARCHITECT *c* System were compared with the Amylase assay on an AEROSET System.

Serum

	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	77	97
Y - Intercept	-1.232	-2.663
Correlation Coefficient	0.999	1.000
Slope	1.237	1.029
Range (U/L)*	23.7 to 1,223.2	20.54 to 5,760.40

*AEROSET Range

Urine

	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	54	66
Y - Intercept	3.720	-25.402
Correlation Coefficient	0.997	0.999
Slope	1.039	1.040
Range (U/L)*	3.8 to 1,160.0	38.70 to 5,730.20

*AEROSET Range

BIBLIOGRAPHY

1. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030, *Occupational Exposure to Bloodborne Pathogens*.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories.* HHS Publication (CDC), 4th ed. Washington, DC: US Government Printing Office, May 1999.
3. World Health Organization. *Laboratory Biosafety Manual*. Geneva: World Health Organization, 2004.
4. Sewell DL, Bove KE, Callihan DR, et al. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Third Edition (M29-A3)*. Wayne, PA: Clinical and Laboratory Standards Institute, 2005.
5. Kaplan LA, Pesce AJ, editors. *Clinical Chemistry Theory, Analysis, and Correlation*, 2nd ed. St Louis, MO: CV Mosby; 1989:908.
6. Jacobs DS, Oxley DK, editors. *Laboratory Test Handbook*, 5th ed. Hudson, OH: Lexi-Comp; 2001:104.
7. Guder WG, da Fonseca-Wollheim F, Heil W, et al. *The Quality of Diagnostic Samples*. Darmstadt, Germany: GIT Verlag; 2001:16–7, 50–1.
8. US Pharmacopeial Convention, Inc. General notices. In: *US Pharmacopeia National Formulary*, 1995 ed. (USP 23/NF 18). Rockville, MD: The US Pharmacopeial Convention, Inc; 1994:11.
9. Burtis CA, Ashwood ER, editors. *Tietz Textbook of Clinical Chemistry*, 2nd ed. Philadelphia, PA: WB Saunders; 1994:2178.
10. Sasse EA, Aziz KJ, Harris EK, et al. *How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline (C28-A)*. Villanova, PA: The National Committee for Clinical Laboratory Standards, 1995.
11. Passey RB, Bee DE, Caffo A, et al. *Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline (EP6-P)*. Villanova, PA: The National Committee for Clinical Laboratory Standards, 1986.
12. Young DS. *Effects of Drugs on Clinical Laboratory Tests*, 4th ed. Washington, DC: AACC Press; 1995:3-43–3-46.
13. Powers DM, Boyd JC, Glick MR, et al. *Interference Testing in Clinical Chemistry; Proposed Guideline (EP7-P)*. Villanova, PA: The National Committee for Clinical Laboratory Standards, 1986.
14. Kennedy JW, Carey RN, Coolen RB, et al. *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline (EP5-A)*. Wayne, PA: The National Committee for Clinical Laboratory Standards, 1999.
15. Krouwer JS, Castaneda-Mendez K, Dawson JM, et al. *Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline (EP10-A)*. Wayne, PA: The National Committee for Clinical Laboratory Standards, 1998.
16. Kennedy JW, Carey RN, Coolen RB, et al. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (EP9-A)*. Wayne, PA: The National Committee for Clinical Laboratory Standards, 1995.

TRADEMARKS

ARCHITECT®

Amylase Serum/Plasma—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **Amy** Type: **Photometric** Version: **1**
Number: **1028**

● Reaction definition O Reagent / Sample O Validity checks

Reaction mode: **Rate up**

	Primary		Secondary		Read times
Wavelength:	**404**	/	**476**	Main:	**4 – 7**
Last required read:	**7**			Flex:	**2 – 5**

Absorbance range: **0.0000 – 2.8000** Color correction: ___ – ___
Sample blank type: **None**

O Reaction definition ● Reagent / Sample O Validity checks

R1

Reagent: **AMY00** Reagent volume: **200**
Diluent: **Saline** Water volume: ___
Diluent dispense mode: **Type 0** Dispense mode: **Type 0**

Dilution name	Sample	Diluted sample	Diluent	Water		Dilution factor	Default dilution
STANDARD :	**4.8**	___	___	___	=	**1:1.00**	●
1:2 :	**2.4**	___	___	___	=	**1:1.98**	O
_____ :	___	___	___	___	=		O

O Reaction definition O Reagent / Sample ● Validity checks

Reaction check: **None**

Rate linearity %: **10**

Configure assay parameters — Calibration

O General ● Calibration O SmartWash O Results O Interpretation

Assay: **Amy** Calibration method: **Factor**
Factor: **3431.0000**

● Calibrators O Volumes O Intervals O Validity checks

Calibrator set: **None** Calibrator level: **Blank:** **Water** Concentration: **0**

Replicates: **3** [Range 1 – 3]

O Calibrators ● Volumes O Intervals O Validity checks

Calibrator:

	Calibrator level	Sample	Diluted sample	Diluent	Water
Blank:	**Water**	**4.8**	___	___	___

O Calibrators O Volumes ● Intervals O Validity checks

Calibration intervals:
Full interval: **456** (hours)

O Calibrators O Volumes O Intervals ● Validity checks

Blank absorbance range: _____ – _____

Configure assay parameters — SmartWash

O General O Calibration ● SmartWash O Results O Interpretation

Assay: **Amy**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
Cuvette	**Trig**	**10% Detergent B*** **	**345**	

*** Select "**Detergent B**" for software prior to Version 2.2.

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **Amy** Result units: **U/L**
Assay defaults:
Low-Linearity: **3**†
High-Linearity: **3010**
Gender and age specific ranges:

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**25 – 125**	

Configure result units

Assay: **Amy**
Version: **1**
Result units: **U/L**
Decimal places: **0** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

† The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

ARCHITECT®

Amylase Urine—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **Amy-U** Type: **Photometric** Version: **1**
Number: **1043**

● Reaction definition O Reagent / Sample O Validity checks

Reaction mode: **Rate up**

	Primary		Secondary		Read times
Wavelength:	**404**	/	**476**	Main:	**4 – 7**
Last required read:	**7**			Flex:	**2 – 5**
Absorbance range:	**0.0000 – 2.8000**			Color correction:	___ – ___
Sample blank type:	**None**				

O Reaction definition ● Reagent / Sample O Validity checks

R1

Reagent: **AMY00** Reagent volume: **200**
Diluent: **Saline** Water volume: ___
Diluent dispense mode: **Type 0** Dispense mode: **Type 0**

Dilution name	Sample	Diluted sample	Diluent	Water		Dilution factor	Default dilution
STANDARD :	**4.8**	___	___	___	=	**1:1.00**	●
_____ :	___	___	___	___	=		O
_____ :	___	___	___	___	=		O

O Reaction definition O Reagent / Sample ● Validity checks

Reaction check: **None**

Rate linearity %: **10**

Configure assay parameters — Calibration

O General ● Calibration O SmartWash O Results O Interpretation

Assay: **Amy-U** Calibration method: **Use Cal Factor/Blank**
Use Cal factor from: **Amy**

Configure assay parameters — SmartWash

O General O Calibration ● SmartWash O Results O Interpretation

Assay: **AMY-U**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
Cuvette	**Trig**	**10% Detergent B*** **	**345**	

*** Select "**Detergent B**" for software prior to Version 2.2.

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **Amy-U** Result units: **U/L**
Assay defaults:
Low-Linearity: **3**†
High-Linearity: **3010**
Gender and age specific ranges:

GENDER	AGE (UNITS)	NORMAL	EXTREME

Configure result units

Assay: **Amy-U**
Version: **1**
Result units: **U/L**
Decimal places: **0** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

† The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

AEROSET®

Amylase Serum/Plasma—Conventional and SI Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
Amy	28	B-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H	Panic-H	Max	Max Text
*	0.0*	0.0	25 – 125	0.0	0.0*	*
	3**	L-Linear Range-H	3010			

Reference Ranges*

Age	Male	Female
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	Linearity %
RATE UP	404 / 476	4 – 7 / 2 – 5	10
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
_____ (___)	0 – 0	0 – 0	0.0 – 2.8

	S.Vol	DS.Vol	D.Vol	W.Vol		Rgt Name/Pos
Standard	4.8	0.0	0	0		
Dil 1	2.4	0.0	0	0	Diluent:	_____ _–__*
Dil 2	4.8	0.0	0	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	AMY0051 – ___*	200	0	0

Reaction Check	Read Time – A/B	Range	Minimum
_____	1 – 1 / 1 – 1	0.0 – 0.0	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	0	U/L

Assay Configuration: Calibration Page

Calib Mode	Factor	Interval (H)
Factor	3431.0	456
Blank/Calib Replicates	**Span**	**Span Abs Range**
3 / 0	BLK – 1	0.0 – 0.0

	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	BLK Abs Range
BLK	Water	4.8	0.0	0	0	0.0 – 0.0
C1		2.0	0.0	0	0	Cal Deviation
C2		2.0	0.0	0	0	0.0

Assay Configuration: SmartWash Page

Rgt Probe	Reagent	Wash	Vol
	—	—	—

Cuvette	Assay Name	Wash	Vol
	—	—	—

Sample Probe	Wash
	—

Amylase Urine—Conventional and SI Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
Amy-U	43	B-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H	Panic-H	Max	Max Text
*	0.0*	0.0	0 – 0	0.0	0.0*	*
	3**	L-Linear Range-H	3010			

Reference Ranges*

Age	Male	Female
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	Linearity %
RATE UP	404 / 476	4 – 7 / 2 – 5	10
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
_____ (___)	0 – 0	0 – 0	0.0 – 2.8

	S.Vol	DS.Vol	D.Vol	W.Vol		Rgt Name/Pos
Standard	4.8	0.0	0	0		
Dil 1	4.8	0.0	0	0	Diluent:	_____ _–__*
Dil 2	4.8	0.0	0	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	AMY0051 – ___*	200	0	0

Reaction Check	Read Time – A/B	Range	Minimum
_____	1 – 1 / 1 – 1	0.0 – 0.0	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	0	U/L

Assay Configuration: Calibration Page

Calib Mode	Use Cal Factor from	Interval (H)
UseFac/Blk	AMY (28)	0
Blank/Calib Replicates	**Span**	**Span Abs Range**
0 / 0	BLK – 1	0.0 – 0.0

	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	BLK Abs Range
BLK		2.0	0.0	0	0	0.0 – 0.0
C1		2.0	0.0	0	0	Cal Deviation
C2		2.0	0.0	0	0	0.0

Assay Configuration: SmartWash Page

Rgt Probe	Reagent	Wash	Vol
	—	—	—

Cuvette	Assay Name	Wash	Vol
	—	—	—

Sample Probe	Wash
	—

Refer to **Assay Configuration** in *Section 2* of the **AEROSET System Operations Manual** for information regarding assay parameters.

* User defined or instrument defined.

** The linear low value (L-Linear Range) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.