May 26, 2022

Magdalena Suszko
Manager, Regulatory Affairs
Lisnarnuck
Longford,
Ireland

Re: K210633
Trade/Device Name: Amylase2
Regulation Number: 21 CFR 862.1070
Regulation Name: Amylase Test System
Regulatory Class: Class II
Product Code: JFJ
Dated: March 29, 2022
Received: March 29, 2022

Dear Magdalena Suszko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210633

Device Name
Amylase2

Indications for Use *(Describe)*
The Amylase2 assay is used for the quantitation of amylase in human serum, plasma, or urine on the ARCHITECT c System. The Amylase2 assay is to be used primarily as an aid in the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. 510(k) Number

k210633

II. Applicant Name

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Lisnamuck, Longford
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Date Summary Prepared: March 28, 2022

III. Device Name

Amylase2

Reagents

Trade Name: Amylase2
Device Classification: Class II
Classification Name: Amylase test system
Governing Regulation Number: 21 CFR 862.1070
Product Code: JFJ

IV. Predicate Device

AMY (k981653)

V. Description of Device

A. 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

B. Reagents

The configuration of the Amylase2 reagent kit is described below.

	List Number
	04S8920
Tests per cartridge set	160
Number of cartridge sets per kit	4
Tests per kit	640
Reagent 1 (R1)	14.5 mL
Reagent 1 (R2)	13.4 mL

Reagent 1 Active ingredient: α-glucosidase 16.000 KU/L. Preservative: sodium azide.

Reagent 2 Active ingredient: Ethylidene-4-NP-G7 (EPS) 6.501 g/L. Preservative: sodium azide.

VI. Intended Use of the Device

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

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

VII. Comparison of Technological Characteristics

The Amylase2 assay (subject device) is an automated clinical chemistry assay for the quantitation of amylase in human serum, plasma, or urine on the ARCHITECT c System.

The similarities and differences between the subject device and the predicate device are presented in the following table.

Comparison of Subject Device (Amylase2) to Predicate Device (AMY)		
Characteristics	**Subject Device Amylase2 (List No. 04S89)**	**Predicate Device AMY (k981653; List No. 7D58)**
Platform	ARCHITECT c System	Same*
Intended Use and Indications for Use	The Amylase2 assay is used for the quantitation of amylase in human serum, plasma, or urine on the ARCHITECT c System. The Amylase2 assay is to be used primarily as an aid in the diagnosis and treatment of pancreatitis (inflammation of the pancreas).	The Amylase assay is used for the quantitation of amylase in human serum, plasma, or urine.
Methodology	Enzymatic/Colorimetric	Same (2-chloro-4-nitrophenyl-α-D-maltotrioside [CNPG3] Substrate)
Specimen Type	Human serum, plasma, urine	Same
Assay Principle / Principle of Procedure	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.	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.
Standardization	IRMM/IFCC†-456	Molar extinction coefficient of CNP (non-IFCC method) IFCC† reference method 2006‡
Use of Calibrators	Yes	No
Calibration Method	Calibration and Calibration Factor method	Factor method
Use of Controls	Yes	Same

* In accordance with FDA Guidance Document "Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagent for Automated Analyzers", issued June 10, 1996, the assay equivalency study on ARCHITECT c System vs. the original platform, AEROSET, was performed and submitted under k980367/A005 in May 2002.

† IFCC = International Federation of Clinical Chemistry and Laboratory Medicine; IRMM = Institute for Reference Materials and Measurement

‡ The assay was re-standardized against IFCC reference method 2006 in 2015.

Comparison of Subject Device (Amylase2) to Predicate Device (AMY) (Continued)		
Characteristics	**Subject Device Amylase2 (List No. 04S89)**	**Predicate Device AMY (k981653; List No. 7D58)**
Assay Range	Serum/Plasma: Analytical Measuring Interval: 3–3010 U/L Extended Measuring Interval: 3010–5959 U/L Reportable Interval: 2–5959 U/L Urine: Analytical Measuring Interval: 3–3010 U/L Extended Measuring Interval: 3010–8600 U/L Reportable Interval: 1–8600 U/L	Serum/Plasma/Urine: Analytical Measuring Interval: 3–3010 U/L Flex Rate Linearity: 6554 U/L
Precision	Serum/Plasma: Samples with amylase concentrations between 4 and 2629 U/L were evaluated. The samples demonstrated % coefficients of variation (%CV) ≤ 2.2% and standard deviations (SD) ≤ 0.5 U/L. Urine: Samples with amylase concentrations between 6 and 2625 U/L were evaluated. The samples demonstrated %CV ≤ 2.9% and SD ≤ 0.5 U/L.	Serum/Plasma: Samples with amylase concentrations between 46.9 and 476.4 U/L demonstrated %CV values ranging from 2.1% to 3.7%. Urine: Samples with amylase concentrations between 40.9 and 179.0 U/L demonstrated %CV values ranging from 1.3% to 2.0%.
Lower Limits of Measurement	Serum/Plasma: Limit of Blank: 0 U/L Limit of Detection: 2 U/L Limit of Quantitation: 2 U/L Urine: Limit of Blank: 0 U/L Limit of Detection: 1 U/L Limit of Quantitation: 3 U/L	Serum/Plasma/Urine: Limit of Detection: 2.0 U/L Limit of Quantitation: 2.4 U/L

Comparison of Subject Device (Amylase2) to Predicate Device (AMY) (Continued)		
Characteristics	**Subject Device Amylase2 (List No. 04S89)**	**Predicate Device AMY (k981653; List No. 7D58)**
Tube Types	Serum: - Serum tubes - Serum separator tubes Plasma: - Lithium heparin tubes - Lithium heparin separator tubes - Sodium heparin tubes	Serum: - Glass or plastic tubes with or without gel barrier Plasma: - Glass or plastic lithium heparin tubes with or without gel barrier - Glass or plastic sodium heparin tubes

VIII. Summary of Nonclinical Performance

A. Reportable Interval

Based on the limit of detection (LoD), limit of quantitation (LoQ), precision, and linearity, the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.*

Serum/Plasma

	U/L
Analytical Measuring Interval (AMI)[a]	3–3010
Extended Measuring Interval (EMI)[b]	3010–5959
Reportable Interval[c]	2–5959

[a] AMI: The AMI is determined by the range of values in U/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.

Urine

	U/L
Analytical Measuring Interval (AMI)[a]	3–3010
Extended Measuring Interval (EMI)[b]	3010–8600
Reportable Interval[c]	1–8600

[a] AMI: The is determined by the range of values in U/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.

* Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking. 1st ed*. CLSI Document EP34. Wayne, PA: CLSI; 2018.

B. Within-Laboratory Precision

Within-Laboratory Precision - Serum/Plasma

A study was performed based on guidance from CLSI EP05-A3.* 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.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

Within-Laboratory Precision - Urine

A study was performed based on guidance from CLSI EP05-A3.* 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.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

System Reproducibility - Serum/Plasma

A study was performed based on guidance from CLSI EP05-A3.* 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
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.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

System Reproducibility - Urine

A study was performed based on guidance from CLSI EP05-A3.* 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.

			Repeatability		**Within-Laboratory[a]**		**Reproducibility[b]**	
Sample	**n**	**Mean (U/L)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%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.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

C. 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 1 instrument. The bias was within ± 2.4%.

Calibration Factor method

Testing was conducted using 3 lots of the Amylase2 reagent and 1 instrument. The bias was within ± 3.1%.

D. Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.* 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
LoB[a]	0
LoD[b]	2
LoQ[c]	2

Urine

	U/L
LoB[a]	0
LoD[b]	1
LoQ[c]	3

[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.

E. Linearity

A study was performed based on guidance from CLSI EP06-A.† This assay demonstrated linearity across the analytical measuring interval of 3 to 3010 U/L for both serum and urine applications.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

† Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. CLSI Document EP06-A. Wayne, PA: CLSI; 2003.

F. Potentially Interfering Endogenous and Exogenous Substances

Serum/Plasma

A study was performed based on guidance from CLSI EP07, 3rd ed.* 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

Potentially Interfering Substance	Interferent Level
Bilirubin - conjugated	60 mg/dL
Bilirubin - unconjugated	60 mg/dL
Hemoglobin	1000 mg/dL
Total protein	15 g/dL
Triglycerides	1500 mg/dL

Potentially Interfering Exogenous Substances

Potentially Interfering Substance	Interferent Level
Acetaminophen	160 mg/L
Acetylcysteine	150 mg/L
Acetylsalicylic acid	30 mg/L
Ampicillin-Na	80 mg/L
Ascorbic acid	60 mg/L
Biotin	4250 ng/mL
Ca-dobesilate	60 mg/L
Cefotaxime	53 mg/dL
Cefoxitin	6600 mg/L
Cyclosporine	2 mg/L
Doxycycline	20 mg/L

Potentially Interfering Substance	Interferent Level
Ibuprofen	220 mg/L
Icodextrin	3.6 mg/dL
Levodopa	8 mg/L
Methyldopa	25 mg/L
Metronidazole	130 mg/L
Pancreozymin	314 pg/mL
Phenylbutazone	330 mg/L
Rifampicin	50 mg/L
Sodium heparin	4 U/mL
Theophylline	60 mg/L

* Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

Urine

A study was performed based on guidance from CLSI EP07, 3rd ed.* 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

Potentially Interfering Substance	**Interferent Level**
Ascorbate	150 mg/dL
Glucose	1000 mg/dL
Protein	50 mg/dL

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

Potentially Interfering Substance	**Interferent Level**	**Analyte Level**	**% Interference (95% CI)**
Ascorbate	200 mg/dL	450 U/L	-21% (-21%, -20%)
Ascorbate	200 mg/dL	1400 U/L	-18% (-19%, -17%)

Potentially Interfering Exogenous Substances

Potentially Interfering Substance	**Interferent Level**
Acetaminophen	16 mg/dL
Acetylcysteine	15 mg/dL
Biotin	4250 ng/mL
Boric acid	250 mg/dL
Ibuprofen	22 mg/dL
Sodium carbonate	1.25 g/dL
Sodium fluoride	400 mg/dL
Sodium oxalate	60 mg/dL

* Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

G. Method Comparison

A study was performed based on guidance from CLSI EP09-A3* using the Passing-Bablok regression method. The study compared the Amylase2 assay to the Amylase assay (List Number 7D58).

Amylase2 vs Amylase on the ARCHITECT c System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	124	U/L	1.00	-1	0.98	6–2788
Urine	103	U/L	1.00	-1	0.93	4–2916

H. Tube Type

A study was performed to evaluate the suitability of specific blood collection tube types for use with the Amylase2 assay. Samples were collected from a minimum of 40 donors and evaluated across tube types. The following blood collection tube types were determined to be acceptable for use with the Amylase2 assay:

Serum

- Serum tubes
- Serum separator tubes

Plasma

- Lithium heparin tubes
- Lithium heparin separator tubes
- Sodium heparin tubes

* Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. CLSI Document EP09-A3. Wayne, PA: CLSI; 2013.

I. Dilution Verification

Serum/Plasma

A study was performed to evaluate the performance of the Amylase2 automated dilution protocol relative to the manual dilution procedure on the ARCHITECT c System. Five human serum samples were created by spiking α-amylase from porcine pancreas stock solution into a serum pool to target concentration values of 3800, 4500, 5200, 5900, and 6600 U/L. Each sample was divided into multiple aliquots. An aliquot of each sample was tested using the 1:2 automated dilution protocol on the ARCHITECT c System. The additional aliquots were divided such that 2 technicians prepared 3 manual dilutions (1:2 dilution with saline) of each sample. Each sample preparation from a given technician was tested in a separate run.

The samples were tested in replicates of 5 using 1 lot each of reagents, calibrators, and controls on the ARCHITECT c System. The difference values of -0.1% to 0.2% of the Amylase2 automated dilution protocol relative to the manual dilution procedure demonstrated acceptable performance.

Urine

A study was performed to evaluate the performance of the Amylase2 automated dilution protocol relative to the manual dilution procedure on the ARCHITECT c System. Five urine samples were created by spiking α-amylase from porcine pancreas stock solution into a urine pool to target concentration values of 3800, 4500, 5200, 5900, and 6600 U/L. Each sample was divided into multiple aliquots. An aliquot of each sample was tested using the 1:3 automated dilution protocol on the ARCHITECT c System. The additional aliquots were divided such that 2 technicians prepared 3 manual dilutions (1:3 dilution with saline) of each sample. Each sample preparation from a given technician was tested in a separate run.

The samples were tested in replicates of 5 using 1 lot each of reagents, calibrators, and controls on the ARCHITECT c System. The difference values of -3.0% to -1.9% of the Amylase2 automated dilution protocol relative to the manual dilution procedure demonstrated acceptable performance.

IX. Summary of Clinical Performance

This section does not apply.

X. Conclusion Drawn from Nonclinical Laboratory Studies

The similarities and differences between the subject device and predicate device are presented in Section 5-VII. The results presented in this 510(k) provide reasonable assurance that the subject device Amylase2 is safe and effective for the stated intended use. Any differences between the subject device and the predicate device shown in the tables do not raise different questions of safety and effectiveness.

There is no known potential adverse effect to the operator when using this *in vitro* device according to the Amylase2 reagent package insert instructions.