August 30, 2019

Horiba ABX SAS
Caroline Ferrer
Regulatory Affairs Manager
Parc Euromedecine
Montpellier Cedex 4, 341184
France

Re: K191245
Trade/Device Name: Yumizen C1200 ALP, Yumizen C1200 Albumin
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Code: CJE, CIX
Dated: July 18, 2019
Received: July 19, 2019

Dear Caroline Ferrer:

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,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k191245

Device Name
Yumizen C1200 ALP
Yumizen C1200 Albumin

Indications for Use *(Describe)*
Yumizen C1200 ALP reagent is intended for the quantitative in vitro diagnostic determination of alkaline phosphatase in human serum and plasma based on a kinetic photometric test using p-Nitrophenylphosphate. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

Yumizen C1200 Albumin reagent is intended for the quantitative in vitro diagnostic determination of albumin in human serum and plasma by colorimetry. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

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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510(k) Summary : k191245

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

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1- Date of Summary

Date submitted: 27th August, 2019

2- Company

HORIBA ABX SAS
HORIBA MEDICAL
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4
France

3- Contact person

Contact Person: Caroline Ferrer (caroline.ferrer@horiba.com)
Telephone: + (33) 4 67 14 18 43
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4- Product Name

Yumizen C1200 ALP (1300023830)
Yumizen C1200 Albumin (1300023798/1300023799)

5- Device Name and Classification

- **Intended use**

The devices involved by the 510(k) submission file are the following:

Device's names	Intended Use
Yumizen C1200 ALP	Yumizen C1200 ALP reagent is intended for the quantitative in vitro diagnostic determination of alkaline phosphatase in human serum and plasma based on a kinetic photometric test using p-Nitrophenylphosphate. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.
Yumizen C1200 Albumin	Yumizen C1200 Albumin reagent is intended for the quantitative in vitro diagnostic determination of albumin in human serum and plasma by colorimetry. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

- **Classification and Description**

Trade/Proprietary Name:	Yumizen C1200 ALP
Device Class:	Class II / 510(k) required
Classification Name:	§862.1050: Alkaline phosphatase or isoenzymes test system
Product Code:	CJE
Panel:	Clinical Chemistry (75)

Trade/Proprietary Name:	Yumizen C1200 Albumin
Device Class:	Class II / 510(k) required
Classification Name:	§862.1035: Albumin test system
Product Code:	CIX
Panel:	Clinical Chemistry (75)

6- Substantial Equivalence Information

The following tables show the similarities and differences and demonstrates substantial equivalence between the candidate device and its predicate device identified below.

a. Predicate Device Name and 510(k) number

Candidate device	Predicate device	Predicate Manufacturer	Predicate 510(k) number
Yumizen C1200 ALP	ALP IFCC Gen2	COBAS 8000/Roche Diagnostics	K171080
Yumizen C1200 Albumin	ABX Pentra Albumin CP	ABX Pentra 400/Pentra C400 / HORIBA ABX SAS	K060434

The following tables show the similarities and differences and demonstrates substantial equivalence between the candidate device and its predicate device identified below.

b. Yumizen C1200 ALP (1300023830)

i. Comparison with predicate Device : Similarities

Item	Predicate k171080	Candidate
Device Name	ALP IFCC Gen.2 (03333752/0333701)	Yumizen C1200 ALP (1300023830)
Intended Use	In vitro test for the quantitative determination of the catalytic activity of alkaline phosphatase in humain serum and plasma on COBAS INTEGRA systems	Diagnostic reagent for quantitative *in-vitro* determination of Alkaline Phosphatase (ALP) in serum or plasma by colorimetry
Sample type	Serum, plasma in lithium heparin	Same
Reagent format	Liquid	Same
Measurement	Quantitative	Same
method	Colorimetry	Same
Shelf-life	2-8°C – see expiration date on cobas c pack label	Stable up to the expiry date on the label if stored at 2-8°C.Store protected from light
Reference range	40-129 U/L (Men) 35-104 U/L (Women)	40-129 U/L (Men) 35-104 U/L (Women)

ii. Comparison with predicate Device: Differences

Item	Predicate k171080	Candidate
Device Name	ALP IFCC Gen.2 (03333752/0333701)	Yumizen C1200 ALP (1300023830)
Manufactured by	Roche Diagnostics	HORIBA ABX SAS
Instrument	COBAS INTEGRA systems	Yumizen C1200 Clinical chemistry analyzer
Calibrators	Calibrator f.a.s	Yumizen C1200 Multical
Controls	PreciControl ClinChem Multi 1	Yumizen C1200 N Multi Control
		Yumizen C1200 P Multi Control
Packaging &Number of tests	200 tests (ALP IFCC Gen.2 Small) 400 tests (ALP IFCC Gen.2 Large)	6x220 tests
Reagent On board Stability	On-board in use at 10-15°C : 4 weeks	Once opened, the reagent cassette placed in the refrigerated compartment is stable

Item	Predicate k171080	Candidate
		for 1 week
Analytic Range	Measuring Range 3.0-1200 U/L	Measuring Range 6.0-1200 U/L
	Automatic post-dilution: Results from samples diluted using the rerun function are automatically multiplied by a factor of 5.	Automatic post-dilution: 6 to 1200 U/L, until 4800 U/L with the automatic post-dilution. A post-dilution (factor N = 4) will be realized in case of sample concentration higher than 1200 U/L
Discussion on the analysis differences : 1. Manufacturer is different because of the choice of predicate 2. Instrument: Yumizen C1200 ALP is used on Yumizen C1200 (See 2.) 3. Packaging: Yumizen C1200 ALP has one packaging. Its predicate has two packagings, one is smaller and the other is larger. 4. Reagent stability: the on board stability of Yumizen C1200 ALP is shorter. Stability depend on reagent composition and cassette capacity. 5. Analytic Range: LOQ is 6.0 U/L and this value is not clinically critical value.		

c. Yumizen C1200 Albumin (1300023798/1300023799)

i. Comparison with predicate Device : Similarities

Item	Predicate K060434	Candidate
Device Name	ABX Pentra Albumin CP (A11A01664)	Yumizen C1200 Albumin (1300023798/1300023799)
Intended Use	Diagnostic reagent for quantitative *in-vitro* determination of Albumin in serum and plasma by colorimetry.	Yumizen C1200 Albumin reagent is intended for the quantitative in vitro diagnostic determination of albumin in human serum and plasma by colorimetry. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.
Manufactured by	HORIBA ABX SAS	HORIBA ABX SAS
Sample type	Serum, plasma in lithium heparin	Same
Reagent format	Liquid	Same
Measurement	Quantitative	Same

Item	Predicate K060434	Candidate
method	Colorimetry	Same
Calibrators	ABX Pentra Multical	Yumizen C1200 Multical
Shelf-life	In onopened cassettes, stable up to the expiry date on the label if stored at 2-8°C	Stable up to the expiry date on the label if stored at 2-8°C. Store protected from light.
Analytic Range	Measuring Range 0.46-5.60 g/dL	Measuring Range 0.46-5.60 g/dL (= 4.6 to 56 g/L)
	Automatic post-dilution: Up to 11.20 g/dL	Automatic post-dilution: Up to 11.20 g/dL (Up to 112 g/L)
Reference range	0 - 4 days: 28 - 44 g/L 4 days - 14 years: 38 - 54 g/L 14 - 18 years: 32 - 45 g/L 20 - 60 years: 35 - 52 g/L 60 - 90 years: 32 - 46 g/L > 90 years: 29 - 45 g/L.	0 - 4 days: 28 - 44 g/L 4 days - 14 years: 38 - 54 g/L 14 - 18 years: 32 - 45 g/L 20 - 60 years: 35 - 52 g/L 60 - 90 years: 32 - 46 g/L > 90 years: 29 - 45 g/L.

ii. Comparison with predicate Device: Differences

Item	Predicate K060434	Candidate
Device Name	ABX Pentra Albumin CP (A11A01664)	Yumizen C1200 Albumin (1300023798/1300023799)
Instrument	ABX Pentra 400 Clinical Chemistry Analyzer	Yumizen C1200 Clinical chemistry analyzer
Controls	ABX Pentra N Control	Yumizen C1200 N Multi Control
	ABX Pentra P Control	Yumizen C1200 P Multi Control
Number of tests	327 tests	4x245 / 6x250 tests
Packaging	Cassette of 99 ml	Cassette of 90 ml
Sample Volume	2µl	1µl/test
Reagent On board Stability	One opened, the reagent cassette placed in the refrigerated ABX Pentra 400 compartment is stable: 83 days (11 weeks)	Once opened, the reagent cassette placed in the refrigerator compartment is stable for 6 weeks.
Calibration Stability	The reagent is calibrated on Day 0. The calibration stability is checked by testing 2	6 weeks

Item	Predicate K060434	Candidate
	control specimens. The calibration stability is at least 14 days.	
Discussion on the analysis differences : 1. Instrument: Yumizen C1200 Albumin is used on Yumizen C1200 2. Packaging: Yumizen C1200 Albumin has two packaging on, one is smaller and the other is larger. 3. Number of test depends on packaging and cassette capacity. 4. Reagent stability: the on board stability of Yumizen C1200 Albumin is shorter. Stability depend on reagent composition and cassette capacity.		

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7- Special Control/Guidance Document Referenced

a. Standards Followed

The following standards & FDA guidance documents have been used to support this submission:

CLSI Guidelines:

- **CLSI EP05-A3:**Evaluation of Precision of Quantitative Measurement Procedures– Third Edition - October 2014
- **CLSI EP17-A2:** Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures – Second Edition - June 2012
- **CLSI EP09-A3:** Measurement Procedure Comparison and Biais Estimation Using Patient Samples– Third Edition -August 2013
- **CLSI EP06-A:** Evaluation of the Linearity of Quantitative measurement Procedures A Statistical Approach – First Edition – April 2003
- **CLSI C28-A3:** Defining, Establishing, and Verifying Reference Intervals in the Clinical laboratory- Third Edition – November 2008
- **CLSI EP25-A** : Evaluation of Stability of In Vitro Diagnostic reagents

b. FDA Guidances Followed

- Guidance for Industry and FDA Staff : Format for Traditional and Abbreviated 510(k)s – 2005
- Refuse To Accept (RTA) Policy for 510(k) – Guidance for Industry and Food and Drug Administration Staff Document issued on: February 21, 2019.
- Guidance for Industry and FDA Staff : eCopy Program for Medical Device Submissions – 2015

c. Others Guidances followed

- Valtec guideline (Vassault et al., Ann. Biol. Clin., 1986, (44), 686-745)

d. Declaration of conformity

Please see the declaration of conformity in section 009

8- Analytical Performance Characteristics

8.1 Measuring Range

The limit of detection and quantitation was determined according to the CLSI guideline EP17-A2.
The reagent linearity was determined according to CLSI guideline EP06-A.
The limit of quantitation and the linearity studies showed that claimed measuring range is appropriated
Results

- **Yumizen C1200 ALP :**

	Limit of detection	Limit of quantitation	Linearity	Measuring range
Serum / plasma	LoD = 1.40U/L	5.85 U/L	0 to 1620 U/L	6 to 1200 U/L
Post-dilution	NA	NA	up to 4800 U/L	up to 4800 U/L

- **Yumizen C1200 Albumin :**

	Limit of detection	Limit of quantitation	Linearity	Measuring range
Serum / plasma	LoD = 0.57 g/L	3.34 g/L	0 to 60.2 g/L	4.6 to 56 g/L
Post-dilution	NA	NA	Up to 112 g/L	up to 112 g/L.

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8.2 Precision

Repeatability (within-run precision) and Reproducibility (total precision)

- **Yumizen C1200 ALP**

  - **Single site : 20x2x2**

Within run : CV limit accepted, for the low, middle and high level are respectively 4.5 %, 4.5 % and 3.8 % for serum and plasma.
Total precision : CV limit accepted, for the low, middle and high level are respectively 6 %, 6 % and 5 % for serum and plasma

Sample	N	Mean (U/L)	Within-Run (%CV)	Between-Run (%CV)	Between-Day (%CV)	Between-Instrument (%CV)	Total (%CV)
Yumizen C1200 N Multi Control	240	**81.98**	**0.8**	2.7	3.2	3.7	**5.6**
Yumizen C1200 P Multi Control	240	**201.77**	**0.5**	2.4	3.1	3.5	**5.2**
Sample 1	240	**11.71**	**3.3**	3.1	3.4	4.4	**7.2**
Sample 2	240	**21.58**	**1.8**	2.4	3.3	4.0	**6.0**
Sample 3	240	**56.27**	**1.0**	3.7	3.9	4.1	**6.8**
Sample 4	240	**428.89**	**0.6**	2.5	3.6	1.6	**4.7**
Sample 5	240	**1042.42**	**0.5**	1.1	1.3	1.7	**2.5**

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- **Multi site : 3x5x2x3**

Within run : CV limit accepted, for the low, middle and high level are respectively 4.5 %, 4.5 % and 3.8 % for serum and plasma.
Total precision : CV limit accepted, for the low, middle and high level are respectively 6 %, 6 % and 5 % for serum and plasma.

Sample	N	Mean (U/L)	Within-Day (%CV)	Between-Day (%CV)	Within-Lot (%CV)	Between-Lot (%CV)	Total (%CV)
Yumizen C1200 N Multi Control	90	**74.44**	**0.7**	2.7	2.8	0.0	**2.8**
Yumizen C1200 P Multi Control	90	**165.83**	**0.7**	2.8	2.9	0.0	**2.9**
Sample 1	90	**10.24**	**2.7**	2.2	3.5	1.6	**3.9**
Sample 2	90	**21.76**	**1.3**	3.3	3.5	0.0	**3.5**
Sample 3	90	**46.50**	**1.3**	2.1	2.5	0.0	**2.5**
Sample 4	90	**438.24**	**1.5**	2.8	3.2	0.0	**3.2**
Sample 5	90	**1112.95**	**2.0**	3.0	3.6	0.0	**3.6**

The results are within the specifications.

- **Yumizen C1200 Albumin**

  - **Single site : 20x2x2**

Within run : CV limit, for the low, middle and high level are respectively 4.5 %, 3.8 % and 3.0 % for serum and plasma

Total precision: CV limit, for the low, middle and high level are respectively 6.0 %, 5.0 % and 4.0 % for serum and plasma.

Sample	N	Mean (g/L)	Within-Run (%CV)	Between-Run (%CV)	Between-Day (%CV)	Between-Instrument (%CV)	Total (%CV)
Yumizen C1200 N Multi Control	240	**37.8**	**0.4**	2.4	1.8	0.3	**3.0**
Yumizen C1200 P Multi Control	240	**47.1**	**0.3**	0.8	1.8	0.0	**2.0**
Sample L	240	**20.1**	**0.7**	3.2	0.8	0.0	**3.3**
Sample M	240	**39.3**	**0.4**	1.4	1.8	0.3	**2.3**
Sample H	240	**54.2**	**0.4**	1.3	1.6	0.0	**2.1**

The results are within the specifications.

  - **Multi site : 3x5x2x3**

Within run : CV limit, for the low, middle and high level are respectively 4.5 %, 3.8 % and 3.0 %

Total precision: CV limit, for the low, middle and high level are respectively 6.0 %, 5.0 % and 4.0 %

Sample	N	Mean (g/L)	Within-Day (%CV)	Between-Day (%CV)	Within-Lot (%CV)	Between-Lot (%CV)	Total (%CV)
Yumizen C1200 N Multi Control	90	**37.67**	**1.0**	0.5	1.1	0.0	**1.1**
Yumizen C1200 P Multi Control	90	**53.24**	**0.9**	0.5	1.0	0.0	**1.0**
Sample 1	90	**22.07**	**2.2**	2.5	3.4	0.0	**3.4**
Sample 2	90	**43.41**	**1.4**	1.0	1.7	0.5	**1.8**
Sample 3	90	**53.52**	**0.6**	0.5	0.8	0.2	**0.8**

The results are within the specifications.

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8.3 Interferences

The Interferences were determined according to the CLSI guideline EP07-A2.
The acceptable bias is defined at +/-10% of the value without interfering substances.
These data in the following table represent the highest values for which no interferences higher than 10% have been observed.

- **Yumizen C1200 ALP**

Serum/plasma		
Hemoglobin	290 µmol/L	500 mg/dL
Triglycerides	5.77 mmol/l	504.88 mg/dL
Total Bilirubin	493 µmol/L	28.84 mg/dL
Direct Bilirubin	451 µmol/L	26.36 mg/dL
Acetylsalicylic Acid	3.62 mmol/L	65.16 mg/dL
Ascorbic Acid	340 µmol/L	5.98 mg/dL
Ibuprofen	2.43 mmol/L	50.10 mg/dL
Acetaminophen	1324 µmol/L	20 mg/dL

- **Yumizen C1200 Albumin**

Serum/Plasma		
Hemoglobin	218 µmol/L	375 mg/dL
Triglycerides	5.3 mmol/l	463.75 mg/dL
Total Bilirubin	537 µmol/L	31.39 mg/dL
Direct Bilirubin	449 µmol/L	26.27mg/dL
Acetylsalicylic Acid	3.62 mmol/L	65.16 mg/dL
Ascorbic Acid	340 µmol/L	5.98 mg/dL
Ibuprofen	2.43 mmol/L	50.10 mg/dL
Acetaminophen	1324 µmol/L	20 mg/dL

8.4 Method comparison with a predicate device

- **Yumizen C1200 ALP**

This study has been carried out using recommendations found in the CLSI EP-9A3 guidance.
Correlation of the ALP assay with the Yumizen C1200 ALP on the Yumizen C1200.
165 native serum samples have been assayed in duplicate, in ascendant order and descendant order on 5 working days.
The equation for the regression line using Passing Bablok was obtained.

Passing Bablok	N	Min	Max	Intercept	Slope	Correlation – r^2
ALP (U/L)	165	17.80	920.29	+3.907	0.940	0.993

- **Yumizen C1200 Albumin**

This study has been carried out using recommendations found in the CLSI EP-9A3 guidance.
Correlation of the Albumin assay with the Yumizen C1200 Albumin on the Yumizen C1200.
111 native samples have been assayed in duplicate, in ascendant order and descendant order on 5 working days.
The equation for the regression line using Passing Bablok was obtained.

Passing Bablok	N	Min	Max	Intercept	Slope	Correlation – r^2
Albumin (g/L)	111	7.2	54.8	+0.421	0.963	0.990

Conclusion : Results are within predefined acceptance criteria.

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8.5 Matrix comparison on predicate device

- **Yumizen C1200 ALP**

Study materials :

Anticoagulant : heparin-lithium
Samples: individual donors

Description :

40 lithium-heparin plasma samples were evaluated on Yumizen C1200 analyzer using Yumizen C1200 ALP reagent and with the US market predicate device as reference : Cobas800 with c502 module analyzer and reagent from Roche.

Passing Bablok	N	Min	Max	Intercept	Slope	Correlation
ALP (U/L)	40	20.39	116.67	0.3709	+1.013	0.993

- **Yumizen C1200 Albumin**

Study materials :

Anticoagulant : heparin-lithium
Samples: individual donors

Description:

70 lithium-heparin plasma samples were evaluated on Yumizen C1200 analyzer using Yumizen C1200 Albumin reagent and with the Pentra C400 analyzer with HORIBA Albumin reagent (Predicate device).

Passing Bablok	N	Min	Max	Intercept	Slope	Correlation
Albumin (g/L)	70	14.21	55.53	0.769	+1.009	0.988

Conclusion :

This study shows that heparin lithium plsama samples are validated for these applications.

8.6 Reagent Stability

8.6.1 Closed stability

The closed stability was determined according to the CLSI guideline EP25-A.

Stability before opening:
Stable up to the expiry date on the label if stored at 2-8°C. Store protected from light.

- **ALP :**
  The shelf life claim for HORIBA MEDICAL reagent will be 15 months in Yumizen C1200 container.

- **Albumin :**
  The shelf life claim for HORIBA MEDICAL reagent will be 24 months in Yumizen C1200 container.

8.6.2 Open stability

On board reagent Stability:

- The Reagent stability claim for the Yumizen C1200 ALP is 1 week
- The Albumin reagent stability On Board claimed is 6 weeks.

8.7 Reference range

The Reference Range was determined according to the CLSI guideline EP28-A3.

- **ALP**

➢ Adults data (bibliographic reference and study-see below):

44 “women normal samples” and 44 “men normal samples” from blood bank have been assayed with the method in evaluation. Each sample is assayed in duplicate.
The mean of the duplicate results for each subject was compared against reference ranges cited in literature. The verification studies support in the following reference ranges which were established through literature

Adults (37°C):	Men	40-129 U/L	(0.67-2.15 µkat/L)
	Women	35-104 U/L	(0.58-1.74 µkat/L)

Reference:
Abicht K, El-Samalouti V, Junge W, et al. Multicenter evaluation of new GGT and ALP reagents with new reference standardization and determination of 37 °C reference intervals. Clin Chem Lab Med 2001;39:Special Supplement pp S 346.

➢ Children data are based on bibliographic references.

Children (37°C):

Boys	0 – 14 days	83-248 U/L	(1.39-4.14 µkat/L)
	15 days – < 1 year	122-469 U/L	(2.04-7.83 µkat/L)
	1 – < 10 years	142-335 U/L	(2.37-5.59 µkat/L)
	10 – < 13 years	129-417 U/L	(2.15-6.96 µkat/L)
	13 – < 15 years	116-468 U/L	(1.94-7.82 µkat/L)
	15 – < 17 years	82-331 U/L	(1.37-5.53 µkat/L)
	17 – < 19 years	55-149 U/L	(0.92-2.49 µkat/L)
Girls	0 – 14 days	83-248 U/L	(1.39-4.14 µkat/L)
	15 days – < 1 year	122-469 U/L	(2.04-7.83 µkat/L)
	1 – < 10 years	142-335 U/L	(2.37-5.59 µkat/L)
	10 – < 13 years	129-417 U/L	(2.15-6.96 µkat/L)
	13 – < 15 years	57-254 U/L	(0.95-4.24 µkat/L)
	15 – < 17 years	50-117 U/L	(0.84-1.95 µkat/L)
	17 – < 19 years	45-87 U/L	(0.75-1.45 µkat/L)

Reference:

Estey MP, Cohen AH, Colantonio DA, et al. CLSI-based transference of the CALIPER database of pediatric reference intervals from Abbott to Beckman, Ortho, Roche and Siemens Clinical Chemistry Assays: Direct validation using reference samples from the CALIPER cohort. Clin Biochem 2013;46:1197–1219.

- **Albumin**

➢ Adults data (bibliographic reference and study-see below):

125 “normal samples” from blood bank have been assayed with the method in evaluation. Each sample is assayed in duplicate.

Normal range study for the albumin assay with the Yumizen C1200 Albumin reagent on the Yumizen C1200.
Transference of the normal range from literature.

Adults: 35 – 52 g/L (3.5 – 5.2 g/dL)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Normal Range Albumin

20 - 60 years:	35 - 52 g/L

Reference:
Roberts WL, McMillin GA, Burtis CA, Bruns DE. Reference Information for the Clinical Laboratory. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., Burtis CA, Ashwood ER, Bruns DE. (Elsevier Saunders eds. St Louis USA) (2006): 2254.

➢ Children data are based on bibliographic references.

0 - 4 days:	28 - 44 g/L
4 days - 14 years:	38 - 54 g/L
14 - 18 years:	32 - 45 g/L

Reference:
Roberts WL, McMillin GA, Burtis CA, Bruns DE. Reference Information for the Clinical Laboratory. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., Burtis CA, Ashwood ER, Bruns DE. (Elsevier Saunders eds. St Louis USA) (2006): 2254.

8.8 Proposed Labeling

The labeling is written as per the recommendations given in standard EN18113-2.
It takes into account the requirements of 21 CFR Part 809.10.

8.9 Conclusions for Performance Testing

The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that each device is substantially equivalent to its predicate device.