May 10, 2021

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

Re: K193649
Trade/Device Name: Yumizen C1200 Creatinine PAP
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: JFY
Dated: October 7, 2020
Received: October 9, 2020

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.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193649

Device Name
Yumizen C1200 Creatinine PAP

Indications for Use *(Describe)*
Yumizen C1200 Creatinine PAP reagent is intended for the quantitative in vitro diagnostic determination of Creatinine in human serum, plasma and urine based on an enzymatic method using a multi- step approach ending with a photometric end-point reaction. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

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 K193649

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.

1- Date of Summary

Date submitted : October 07th, 2020

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 1843
Fax: + (33) 4 67 14 1517

4- Device Name and Classification

- **Devices Names and Intended Uses**

Device's names	Intended Use
Yumizen C1200 Creatinine PAP (1300023844/1300023843)	**Yumizen C1200 Creatinine PAP** reagent is intended for the quantitative in vitro diagnostic determination of Creatinine in human serum, plasma and urine based on an enzymatic method using a multi- step approach ending with a photometric end-point reaction. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

- **Devices Classification**

Trade/Proprietary Name: Yumizen C1200 Creatinine PAP
Device Class: Class II / 510(k) required
Classification Name: §862.1225: Creatinine test system
Product Code: JFY
Panel: Clinical Chemistry (75)

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5- 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 Creatinine PAP (Serum/Plasma and Urine applications)	ABX Pentra Enzymatic Creatinine CP (Serum/Plasma and Urine applications) On ABX Pentra 400 / Pentra C400	HORIBA ABX SAS	K110137

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

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b. Yumizen C1200 Creatinine PAP (Serum/Plasma and Urine applications)

i. Comparison with predicate Device : Similarities

Item	Predicate K110137	Candidate
Device Name	ABX Pentra Enzymatic Creatinine CP (A11A01907)	Yumizen C1200 Creatinine PAP (1300023843)
Intended Use	**ABX Pentra Enzymatic Creatinine CP** reagent is intended for the quantitative in vitro diagnostic determination of Creatinine in human serum, plasma and urine based on an enzymatic method using a multi-step approach ending with a photometric end-point reaction. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes	**Yumizen C1200 Creatinine PAP** reagent is intended for the quantitative in vitro diagnostic determination of Creatinine in human serum, plasma and urine based on an enzymatic method using a multi-step approach ending with a photometric end-point reaction. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes
Reagent format	Liquid	Same
Method	Enzymatic colorimetric test	Same
Measurement	Quantitative	Same
Manufactured by	HORIBA ABX SAS	Same
Product code	JFY	Same
Sample type	Serum, plasma and Urine	Serum, Lithium heparin plasma Urine
Sample Stability	Serum/Plasma : At 20-25°C :7 days At 4-8°C : 7 days At -20°C : 3 months Urine : At 20-25°C :2 days At 4-8°C : 6 days At -20°C : 6 months	Serum/Plasma : At 20-25°C :7 days At 4-8°C : 7 days At -20°C : 3 months Urine : At 20-25°C :2 days At 4-8°C : 6 days At -20°C : 6 months
Reagent Shelf-life	Stable up to expiry date on the label if stored at 2-8°C.	Stable up to expiry date on the label if stored at 2-8°C.Store protected from light.

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ii. Comparison with predicate Device: Differences

Item	Predicate K110137	Candidate
Device Name	ABX Pentra Enzymatic Creatinine CP (A11A01907)	Yumizen C1200 Creatinine PAP (1300023843)
Instrument	ABX Pentra 400	Yumizen C1200 Clinical chemistry Analyzer
Calibrators	ABX Pentra Multical (A11A01652)	Yumizen C1200 Multi Cal (1300023891/1300023890)
Controls	ABX Pentra N Control (A11A01653A) ABX Pentra P Control (A11A01654) ABX Pentra Urine Control L/H (A11A01674)	Yumizen C1200 N Multi Control (1300023938/1300023939) Yumizen C1200 P Multi Control (1300023940/130002394) Yumizen C1200 Urine Level 1 Control (1300023946) Yumizen C1200 Urine Level 2 Control (130002347)
Packaging	22 mL (R1) 8 mL (R2)	6x35 mL (R1) 6x19 mL (R2)
Analytical Range	**Measuring Range** <u>Serum/Plasma :</u> 0.11 - 16.95 mg/dL <u>Urine :</u> 3.56 - 282.5 mg/dL	**Measuring Range** <u>Serum/Plasma :</u> 0.11 - 16.95 mg/dL <u>Urine :</u> 3.56 - 175 mg/dL
Reagent On board Stability	30 days	6 weeks
Reference range	<u>Serum/Plasma :</u> Men : 0.62 - 1.10 mg/dL Women : 0.45 - 0.75 mg/dL <u>Urine :</u> Men :14 - 26 mg/kg/day Women :11 - 20 mg/kg/day	<u>Serum/plasma :</u> Men : 0.67 - 1.17 mg/dL Women : 0.51 - 0.95 mg/dL <u>Urine :</u> Men :14 - 26 mg/kg/day Women :11 - 20 mg/kg/day
Discussion on the analysis differences : 1.Instrument: Yumizen C1200 Creatinine PAP is used on Yumizen C1200 analyzer. 2. Calibrators&Controls: Yumizen C1200 Creatinine PAP uses Yumizen C1200 Multi Cal,		

Item	Predicate K110137	Candidate
Yumizen C1200 N Multi Control, Yumizen C1200 P Multi Control, Yumizen C1200 Urine Level 1 Control, and Yumizen C1200 Urine Level 2 Control whereas the predicate uses its own brand calibrator and controls. 3. Packaging is different: depends on cassette capacity. 4. Analytical range: The measuring ranges in urine for Yumizen C1200 Creatinine PAP is reduced when compared to the predicate's. But both allow to cover the reference range of values. 5. On board stability: The on board stability of Yumizen C1200 Creatinine PAP is longer. Stability depends on the reagent composition and cassette capacity. 6. The reference range for serum/plasma is similar.		

6- 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- First Edition- September 2009

b. FDA Guidances Followed

- Guidance for Industry and FDA Staff : Format for Traditional and Abbreviated 510(k)s – 2019
- Refuse To Accept (RTA) Policy for 510(k) – Guidance for Industry and Food and Drug Administration Staff Document issued on: September 13, 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)

7- Analytical Performance Characteristics

8.1 Measuring Range

- **Yumizen C1200 Creatinine PAP**

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 appropriate.

- Results :

	Limit of detection	Limit of quantitation	Linearity	Measuring range
Serum	0.03 mg/dL	0.11 mg/dL	0.04 - 19.93 mg/dL	0.11 - 16.95 mg/dL
Serum Post-dilution	NA	NA	NA	until 50.85 mg/dL with the automatic post-dilution
Urine	0.16 mg/dL	1.13 mg/dL	0.00 - 327.60 mg/dL	3.56 - 175 mg/dL
Urine Post-dilution	NA	NA	NA	until 525 mg/dL with the automatic post-dilution

8.2 Accuracy and Precision

- **Yumizen C1200 Creatinine PAP**

Serum/Plasma :

- Instrument variability: 20x2x2

Within run precision: CV limits, for the low, middle and high level are respectively 4.5 %, 3.4 % and 1.8 % for serum or plasma.
Total precision: CV limits, for the low, middle and high level are respectively 6.0 %, 4.5 % and 2.4 % for serum and plasma.

Sample	N	Mean (µmol/L)	Mean (mg/dL)	Within-Run (%CV)	Between-Run (%CV)	Between-Day (%CV)	Between-Instrument (%CV)	Total (%CV)
Yumizen C1200 N Multi Control	240	**132.88**	**1.50**	**0.5**	0.7	0.8	0.9	**1.5**
Yumizen C1200 P Multi Control	240	**396.10**	**4.48**	**0.3**	0.8	0.5	0.9	**1.3**
Sample 1	240	**38.35**	**0.43**	**1.4**	1.2	2.2	0.6	**2.9**
Sample 2	240	**80.09**	**0.91**	**0.5**	1.2	1.3	0.8	**2.0**
Sample 3	240	**786.32**	**8.89**	**0.3**	0.6	0.6	1.0	**1.3**

The results are within the specifications.

- Lot to lot variability: 3x5x2x3

Within run precision: CV limits, for the low, middle and high level are respectively 4.5 %, 3.4 % and 1.8 % for serum or plasma.
Total precision: CV limits, for the low, middle and high level are respectively 6.0 %, 4.5 % and 2.4 % for serum or plasma.

Sample	N	Mean (µmol/L)	Mean (mg/dL)	Within-Day (%CV)	Between-Day (%CV)	Within-Lot (%CV)	Between-Lot (%CV)	Total (%CV)
Yumizen C1200 N Multi Control	90	**136.04**	**1.54**	**0.6**	0.6	0.9	0.0	**0.9**
Yumizen C1200 P Multi Control	90	**401.67**	**4.54**	**0.4**	0.4	0.6	0.0	**0.6**
Sample 1	90	**18.92**	**0.21**	**1.7**	4.3	4.6	0.0	**4.6**
Sample 2	90	**48.92**	**0.55**	**0.9**	1.7	2.0	0.0	**2.0**
Sample 3	90	**158.80**	**1.79**	**0.4**	0.6	0.7	0.0	**0.7**
Sample 4	90	**632.51**	**7.15**	**0.4**	0.3	0.5	0.0	**0.5**

The results are within the specifications.

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Urine :

- Instruments variability: 20x2x2

Within run precision: CV limits, for the low, middle and high level are respectively 4.5 %, 3.8 % and 3.8 % for urine.
Total precision: CV limits, for the low, middle and high level are respectively 6.0 %, 5.0 % and 5.0 % for urine.

Sample	N	Mean (µmol/L)	Mean (mg/dL)	Within-Run (%CV)	Between-Run (%CV)	Between-Day (%CV)	Between-Instrument (%CV)	Total (%CV)
Yumizen C1200 Urine Level 1 Control	240	**6415.65**	**72.50**	**0.8**	2.0	2.1	2.3	**3.8**
Yumizen C1200 Urine Level 2 Control	240	**13808.68**	**156.04**	**1.0**	2.4	1.3	2.1	**3.6**
Sample 1	240	**638.30**	**7.21**	**1.2**	1.9	2.1	2.8	**4.2**
Sample 2	240	**1049.59**	**11.86**	**0.8**	2.2	1.7	3.2	**4.3**
Sample 3	240	**8422.53**	**95.18**	**0.8**	2.2	1.3	2.8	**3.9**
Sample 4	240	**12762.06**	**144.21**	**1.2**	2.0	1.4	2.3	**3.6**

The results are within the specifications.

- Lot to Lot Variability: 3x5x2x3

Within run precision: CV limits, for the low, middle and high level are respectively 4.5 %, 3.8 % and 3.8 % for urine.
Total precision: CV limits, for the low, middle and high level are respectively 6.0 %, 5.0 % and 5.0 % for urine.

Sample	N	Mean (µmol/L)	Mean (mg/dL)	Within-Day (%CV)	Between-Day (%CV)	Within-Lot (%CV)	Between-Lot (%CV)	Total (%CV)
Yumizen C1200 Urine Level 1 Control	90	**6525.73**	**73.74**	**0.8**	0.6	1.0	0.0	**1.0**
Yumizen C1200 Urine Level 2 Control	90	**13490.94**	**152.45**	**0.8**	0.4	0.9	0.2	**0.9**
Sample 1	90	**497.31**	**5.62**	**1.1**	1.8	2.1	0.0	**2.1**
Sample 2	90	**1013.67**	**11.45**	**0.9**	1.0	1.3	0.0	**1.3**
Sample 3	90	**8328.21**	**94.11**	**0.9**	0.4	0.9	0.0	**0.9**
Sample 4	90	**12770.44**	**144.31**	**0.7**	0.5	0.8	0.0	**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.
The data in the following table represent the highest values for which no interferences higher than +/-10% have been observed.

- **Yumizen C1200 Creatinine PAP**

Serum/Plasma		
Hemoglobin	290 µmol/L	500 mg/dL
Triglycerides	5.33 mmol/L	466.38 mg/dL
Total Bilirubin	351 µmol/L	20.54 mg/dL
Direct Bilirubin	202 µmol/L	11.80 mg/dL
Ascorbic Acid	340 µmol/L	5.98 mg/dL
Acetylsalicylic Acid	3.62 mmol/L	65.16 mg/dL
Ibuprofen	2.43 mmol/L	50.10 mg/dL
Acetaminophen	1324 µmol/L	20 mg/dL
N-Acetylcystein	275 µmol/L	27.5 mg/dL
Glucose	55 mmol/L	985 mg/dL
Total Protein	from 1 to 133 g/L.	
Methyldopa	21.29 µmol/L	0.45 mg/dL
L-Dopa	20.28 µmol/L	0.40 mg/dL
Calcium Dobesilate	23.9 µmol/L	1.00 mg/dL

Urine		
Hemoglobin	290 µmol/L	500 mg/dL
Triglycerides	4.84 mmol/L	423.33 mg/dL
Direct Bilirubin	502 µmol/L	29.35 mg/dL
Ascorbic acid	340 µmol/L	5.98 mg/dL
N-Acetylcystein	1100 mmol/L	110 mg/dL
pH	Acidification or alcalinisation do not interfere with this test.	

8.4 Matrix comparison Serum /Lithium Heparin Plasma: Yumizen C1200 Creatinine PAP

Scope of Study
Study of the coagulation effect on the creatinine measurement with the Yumizen C1200 Creatinine PAP reagent.
The goal of this study is to show that coagulation process does not change the creatinine concentration and that the anticoagulant has no interfering action.

Description:
84 paired samples were evaluated on Yumizen C1200 analyser using Yumizen C1200 Creatinine PAP reagent.
For this study, each paired sample (serum and lithium heparin plasma) has been obtained from single donor.
The equation for the regression line using mean square regression was obtained.

Mean square regression	N	Min	Max	Intercept	Slope	r^2
Creatinine PAP Serum (mg/dL)	84	0.32	13.94	-0.0281	1.0008	0.995
Creatinine PAP Plasma (mg/dL)		0.33	14.77			

Conclusion:
The results show there is no significant difference between serum specimens and plasma with heparin specimens ➔ coagulation does not have impact on creatinine determination with Yumizen C1200 Creatinine PAP reagent.

8.5 Method comparison with a predicate device

- **Yumizen C1200 Creatinine PAP**

Serum/Plasma:

This study has been carried out using recommendations found in the CLSI EP-9A3 guidance.
Samples: Anonymous remnants of human serum specimens collected from CHU Nîmes (University Hospital Center). These samples are in the candidate measuring range and predicate measuring range.

103 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
Creatinine (mg/dL)	103	0.22	15.02	-0.0107	0.9611	0.997

Urine:

This study has been carried out using recommendations found in the CLSI EP-9A3 guidance.
Samples: Anonymous remnants of human urine specimens collected from routine clinical laboratory. These samples are in the candidate measuring range and predicate measuring range.
129 native samples have been assayed in duplicate, in ascendant order and descendant order on 6 working days.
The equation for the regression line using Passing Bablok was obtained.

Passing Bablok	N	Min	Max	Intercept	Slope	Correlation – r^2
Creatinine (mg/dL)	129	4.19	164.34	0.2296	0.9772	0.994

8.6 Reagent Stability

8.6.1 Closed stability

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

- **Yumizen C1200 Creatinine PAP**

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

The Shelf Life of Yumizen C1200 Creatinine PAP is 12 months.

8.6.2 Open stability

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

On board reagent Stability:

- Yumizen C1200 Creatinine PAP : The stability claim after opening, on-Board, is 6 weeks

8.7 Reference range

The Reference Ranges were verified according to the CLSI guideline EP28-A3.

- **Yumizen C1200 Creatinine PAP**

Serum/Plasma:

- **Men**

45 "normal samples" from blood bank have been assayed with the method in evaluation. Each sample is assayed in duplicates.
Study was performed on 2 different working days.
The first replicate result for each subject was compared against reference ranges cited in literature.
The verification studies support the following reference ranges which were established through literature.

Normal range
59 -104 µmol/L / 0.67 -1.17 mg/dL.

Reference:
Mazzachi BC, Peake MJ, Ehrhard V. Reference range and method comparison studies for enzymatic and Jaffe creatinine assays in plasma and serum and early morning urine. Clin. Lab. (2000) 46: 53-55.

- **Women**

41 "normal samples" from blood bank have been assayed with the method in evaluation. Each sample is assayed in duplicates.
Study was performed on 2 different working days. The first replicate result for each subject was compared against reference ranges cited in literature.
The verification studies support the following reference ranges which were established through literature.

Normal range
45 - 84 µmol/L / 0.51 - 0.95 mg/dL.

Reference:
Mazzachi BC, Peake MJ, Ehrhard V. Reference range and method comparison studies for enzymatic and Jaffe creatinine assays in plasma and serum and early morning urine. Clin. Lab. (2000) 46: 53-55.

- **Children**

Verification of normal values in pediatric samples could not be made due to lack of availability of samples from healthy pediatric patients.
Each laboratory should establish its own reference ranges.

Normal range

Children	*mg/dL*	*µmol/L*
0 – 7 days	0.6 – 1.1	53 – 97

1 week – 1 month	0.3 – 0.7	27 – 62
1 – 6 month(s)	0.2 – 0.4	18 – 35
7 – 12 months	0.2 – 0.4	18 – 35
1 – 18 year(s)	0.2 – 0.7	18 – 62

Reference:
Schlebusch Soldin SJ, HicksJM. Pediatric reference ranges. Washington: AACC Press, 1995:50.

Urine:
Verification of normal values in urine could not be made due to lack of availability of urine samples from healthy people.
Each laboratory should establish its own reference ranges.

Normal range Creatinine - Urine (24 hours):

Men	Women
14 - 26 mg/kg/day	11 – 20 mg/kg/day
124 - 230 µmol/kg/day	97 – 177 µmol/kg/day

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): 2264

9. 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.

10. Conclusions for Performance Testing

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