May 7, 2019

Roche Diagnostics
Angela Clements
Regulatory Affairs Principal
9115 Hague Road
Indianapolis, IN 46250

Re: K183432
Trade/Device Name: cobas u 601 urinalysis test system
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIO, CDM, CEN, JIN, JIR, JJB, JMT, LJX, KQO
Dated: March 22, 2019
Received: March 25, 2019

Dear Angela Clements:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Office of In Vitro Diagnostics
and Radiological Health
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)*
k183432

Device Name
cobas u 601 urinalysis test system

Indications for Use *(Describe)*
The cobas u 601 urinalysis test system is comprised of the cobas u 601 urine analyzer and the cobas u pack.

The cobas u 601 urine analyzer when used with the cobas u pack is a fully automated urinalysis system intended for the in vitro qualitative or semi- quantitative determination of urine analytes, including pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, color and erythrocytes, as well as clarity. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. This system is intended to be used by trained operators in clinical laboratories.

The cobas u pack is a cassette loaded with cobas u 601 test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, color and erythrocytes in urine with the cobas u 601 urine analyzer. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders.

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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cobas u 601 Urinalysis Test System
510(k) Summary
k183432

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

In accordance with 21 CFR 807.87, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification 510(k).

The purpose of this Traditional 510(k) Premarket Notification is to obtain FDA review and clearance for the cobas u 601 Urinalysis Test System.

Submitter Name	Roche Diagnostics
Address	9115 Hague Road P.O. Box 50416 Indianapolis, IN 46250-0457
Contact	Angie Clements Phone: (317) 521-7338 FAX: (317) 521-2324 Email: angie.clements@roche.com Michael Leuther Phone: (317) 521-3930 FAX: (317) 521-2324 Email: Michael.leuther@roche.com
Date Prepared	December 10, 2018
Proprietary Name	**cobas u 601** Urinalysis Test System
Common Name	Automated urinalysis system Reagent strip for urinalysis
Product Codes, Regulation Numbers	See Table 1
Predicate Devices	**cobas u** 411 (k093555)
Establishment Registration	For the **cobas u** 601 Urinalysis Test System the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126. The establishment registration number for Roche Diagnostics in the United States is 1823260.

Table 1: Product Codes and Regulation Numbers

Device/Analyte	Product Code	Classification	Regulation	Panel
Automated urinalysis system	KQO	Class I	21 CFR 862.2900	75 Chemistry
Glucose, urinary, non-quantitative	JIL	Class II	21 CFR 862.1340	75 Chemistry
Blood, occult, colorimetric, in urine	JIO	Class II	21 CFR 864.6550	81 Hematology
Urobilinogen, urinary, non-quantitative	CDM	Class I	21 CFR 862.1785	75 Chemistry

Device/Analyte	Product Code	Classification	Regulation	Panel
pH, urinary, non-quantitative	CEN	Class I	21 CFR 862.1550	75 Chemistry
Ketones, non-quantitative	JIN	Class I	21 CFR 862.1435	75 Chemistry
Protein or albumin, urinary, non-quantitative	JIR	Class I	21 CFR 862.1645	75 Chemistry
Nitrite, non-quantitative	JMT	Class I	21 CFR 862.1510	75 Chemistry
Leukocyte, peroxidase test	LJX	Class I	21 CFR 864.7675	81 Hematology
Bilirubin and its conjugates, urinary, non-quantitative	JJB	Class I	21 CFR 862.1115	75 Chemistry
Color	No regulation			
Clarity	No regulation			

1. DEVICE DESCRIPTION

The cobas u 601 Urinalysis Test System consists of the following components:

- **cobas u** 601 urine analyzer
- **cobas u** pack

1.1. cobas u 601 urine analyzer

The **cobas u** 601 urine analyzer is a fully automated urine analysis system. It is optimized for high throughput workloads in the professional environment. The **cobas u** 601 urine analyzer performs a maximum theoretical throughput of up to 240 samples per hour.

The **cobas u** 601 analyzer consists of several major components:

- Rack transport system
- Liquid handling system
- Test strip cassette compartment
- Automated test strip processing area
- Photometer which is a 4 wavelength reflectance measuring unit based on a Complementary Metal Oxide Semiconductor chip used in digital cameras (CMOS sensor)
- Physical Measurement Cell (PMC): flow cell connected to an optical detector
- Touch Screen
- Inbuilt Computer

The functions of the **cobas u** 601 urine analyzer include:

- Sample loading and transport
- Sample identification
- Robotic pipetting of samples onto test pads on test strips

- Robotic aspiration of samples into the PMC
- Controlled incubation
- Photometric measurement of test strips
- Optical determination in the PMC
- Automatic disposal of used test strips
- Result readout
- Result memory
- Optional formats for data output including electronic result communication

The operating system will be a Microsoft Windows for embedded devices. The system will use a Postgres/SQL database.

The **cobas u** 601 urine analyzer is designed to be inter-connected mechanically and electronically with another urine sediment analyzer (**cobas u** 701) in order to create a urine work area (**cobas**® 6500).

1.2. cobas u pack

The **cobas u** pack is a cassette containing 400 tests strips. The **cobas u** 601 analyzer will use the **cobas u** pack to dispense single test strips for each sample.

Each test strip has ten individual test pads that are used to test for different substances or characteristics. The test strips are analyzed automatically through the analyzer. One test strip is used per sample. When a strip is dispensed for use by the **cobas u** 601, an aliquot of the urine sample is pipetted onto each of the test pads. The resulting color changes are measured photometrically.

The test strip in the **cobas u** pack cassette ("cassette test strip") is a multi-parameter urine analysis test strip, with test pads for blood (Erythrocytes), Leukocytes, Nitrite, Proteins, Glucose, Ketones, Bilirubin, Urobilinogen, Color and pH.

The **cobas u** pack is technically identical to the marketed Urisys 2400 Cassette with 400 test strips (cleared under K012397) with the following modifications:

- Added RFID-tag (ISO15693; 13.56 MHz)
- own labeling and own Id. No.
- different brand

The RFID-tag is used for storing test strip related information to improve the safety and the convenience of the system. The following data is stored on the RFID-Tag:

- generic product data
- strip cassette data
- test strip related data
- cassette number
- lot number
- expiry date
- load date
- check sum

The on-board time is checked by the instrument and an alarm is triggered if the on-board time of a strip cassette (identified through its RFID-tag) exceeds its specified on-board stability.

2. INDICATIONS FOR USE

The cobas u 601 urinalysis test system is comprised of the cobas u 601 urine analyzer and the cobas u pack. The cobas u 601 urine analyzer when used with the cobas u pack is a fully automated urinalysis system intended for the in vitro qualitative or semi-quantitative determination of urine analytes, including pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, color and erythrocytes, as well as clarity. These

measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. This system is intended to be used by trained operators in clinical laboratories.

The **cobas u** pack is a cassette loaded with **cobas u** 601 test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, color and erythrocytes in urine with the **cobas u** 601 urine analyzer. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders.

3. TECHNOLOGICAL CHARACTERISTICS

The following tables compare the **cobas u** 601 Urinalysis Test System with its predicate device, **cobas u** 411 (k093555).

Table 2: Similarities and Differences between the cobas u 601 Urinalysis Test System and the cobas u411 System

Feature	cobas u 411 (Predicate Device)	cobas u 601 Urinalysis Test System (proposed device)
Intended Use	The **cobas u** 411 urine analyzer is a semi-automated, benchtop analyzer which is designed to read the Chemstrip 10 UA (Combur10 Test M) test strips for urinalysis for the measurement of bilirubin, blood, glucose, ketone, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen and color (if selected). These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Tests performed using the **cobas u** 411 are intended for prescription, *in vitro* diagnostic use only.	The **cobas u** 601 urine analyzer when used with the cobas u pack is a fully automated urinalysis system intended for the *in vitro* qualitative or semi-quantitative determination of urine analytes, including pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, color and erythrocytes, as well as clarity. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. This system is intended to be used by trained operators in professional laboratories.
Submission	K093555	N/A

Feature	cobas u 411 (Predicate Device)	cobas u 601 Urinalysis Test System (proposed device)
Automation	Semi-Automated	Fully Automated
Specimen	Urine	same
Analyzer Technology	Reflectance photometry	Reflectance photometry for • pH, • Leukocytes, • Nitrite, • Protein, • Glucose, • Ketones, • Urobilinogen, • Bilirubin, and • Erythrocytes (blood).
Reagent Strip Format	Chemstrip 10 UA test strip	**cobas u** pack loaded with cobas u 601 test strips
	Width: 5.0 mm	Width: 4.2 mm
	Length: 121 mm (with handle area)	Length: 104.9 mm (no handle area)
	Number of pads: 11	Number of pads: 10 (without specific gravity) Same distance between pads
	Sequence of pads: 1. specific gravity, 2. pH, 3. leukocytes, 4. nitrite, 5. protein, 6. glucose, 7. ketone, 8. urobilinogen, 9. bilirubin, 10. blood, 11. color pH pad: no underlying paper	Sequence of pads: 1. Blood, 2. leukocytes, 3. nitrite, 4. ketone, 5. glucose, 6. protein, 7. urobilinogen, 8. bilirubin, 9. color, 10. pH (no specific gravity) pH pad: underlying paper (different height)
	leukocytes: 1x underlying paper	Leukocytes: no underlying paper (different height)

Feature	cobas u 411 (Predicate Device)	cobas u 601 Urinalysis Test System (proposed device)
	nitrite: 1x underlying paper	nitrite: no underlying paper (different height)
	protein: 2 x protein layer	protein: 1 x protein layer (different color density)
	Glucose	Same format
	Ketone	Same format
	Urobilinogen	Same format
	Bilirubin	Same format
	Blood	Same format
	Color	Same format
Strip Delivery	Measurement of single strips, insert manually into the instrument out of a vial	Automated test strip delivery from cassette
Test Principles	**pH:** color change with the indicators methyl red, phenolphthalein and bromothymol blue.	Same
	Leukocytes: esterases cleave an indoxyl ester, and the indoxyl reacts with a diazonium salt to produce a purple color. Nitrite: based on the principle of the Griess test. Nitrite, if present, reacts with an aromatic amine to give a diazonium salt, which yields a red-violet azo dye.	Same
	Protein: based on the "protein error of pH indicators" involving tetrachlorophenoltetrabromosulfophthalein	Same
	Glucose: based on the specific glucose oxidase/peroxidase reaction (GOD/POD method).	Same
	Ketone: based on the principle of Legal's test involving use of sodium nitroprusside.	Same
	Urobilinogen: Urobilinogen is coupled with 4-methoxybenzene-diazonium-tetrafluoroborate in an acid medium to form a red azo dye.	Same

Feature	cobas u 411 (Predicate Device)	cobas u 601 Urinalysis Test System (proposed device)
	Bilirubin: based on the, coupling of bilirubin with a diazonium salt.	Same
	Blood: The peroxidase-like action of hgb and myoglobin catalyzes the oxidation of the indicator by the organic peroxide.	Same
Light sources	LEDs	LEDs
Wavelengths	Light Emitting Diodes (LEDs) Wavelength: Orange: 620 nm Green: 555 nm Blue: 470 nm	Light Emitting Diodes (LEDs) Wavelength: Red: 615 nm Green: 560 nm True Green: 525 nm Blue: 465 nm
Remission Sensor	11 wide range photo sensors	Camera with CMOS (Complementary Metal Oxide Semiconductor) sensor
Sample Preparation	1. Remove the test strip from the vial and close the vial 2. Dip all test pads of the test strip completely in the sample and wipe off excessive urine on the edge of the sample tube. 3. Position the test strip on the test strip tray for analysis	1. Preparation of sample racks and tubes 2. Loading the rack(s) onto the analyzer 3. Start (automatic) analysis of samples
Sample application	Manually dip of the strip	Robotic pipetting of samples onto test pads on test strips
Calibration method	Calibration strips with specific reflectance values for calibration.	Same
Intrinsic color compensation	Area not impregnated with reagents, allows instrumental compensation for the intrinsic color of the urine while testing	Same

Feature	cobas u 411 (Predicate Device)	cobas u 601 Urinalysis Test System (proposed device)
Output values	The operator can view the concentration ranges for each test parameter.	Same
	Units: conventional, SI, Arbitrary, SI & Arbitrary Conventional & Arbitrary	Same
	ERY neg / 10 / 25 / 50 / 150 / 250 p/µl	Same
	LEU neg / 25 / 100 / 500 p/µl	Same
	NIT neg / pos	Same
	PRO neg / 15 / 30 / 100 / 500 mg/dl	Same
	GLU norm / 50 / 100 / 250 / 1000 mg/dl	Same
	KET neg / 5 / 15 / 50 / 150 mg/dl	Same
	BIL neg / 1 / 3 / 6 mg/dl	Same
	pH 5 / 6 / 6.5 / 7 / 8 / 9	Same
	UBG norm / 1 / 4 / 8 / 12 mg/dl	Same
Strip Detector	Two strip detectors	Automatic strip transportation system
Strip packaging	In vials of 100 strips	In cassette of 400 strips

Feature	cobas u 411 (Predicate Device)	cobas u 601 Urinalysis Test System (proposed device)
Strip storage	Store at 20°C - 30°C. Close vial immediately after use.	Store at 20°C - 30°C. After loading the cassette into the analyzer, the test strips are stable within the tightly closed cassette compartment for 14 days. After this period, the cassette has to be replaced by a new one.
Operating Conditions	Temperature: operational: 15 -32 °C storage: -25 – 60 °C Humidity: operational: 30 - 80% storage: 10 -95%	Temperature: operational: 15 -32 °C storage: 5 – 40 °C Humidity: operational: 30 - 80% storage: 10 -85%
Storage Medium	USB stick	USB stick
Sample identification	Sample identification with optional external barcode scanner	Internal barcode reader for rack ID and sample ID recognition
Printer	Integrated thermal paper	Optional external printer
Controlled incubation	Controlled incubation period after placing the wet strip on the test strip tray	Controlled incubation period after sample pipetting onto test pads on test strips
Result Memory	Memory for 1000 entries (pending samples and results)	Result memory is available

4. NON-CLINICAL PERFORMANCE EVALUATION

4.1. Linearity/Reportable Results

The reportable results are determined by the analytical sensitivity and method comparison studies (Sections 4.2 and 5.1.3).

The results of those studies support the following reportable results:

Table 3: Reportable Results for each Parameter

Parameter	Unit of Measure	Reportable Results
NIT	NA	Neg/Pos
GLU	mg/dL	Norm to 1000
KET	mg/dL	Neg to 150
BIL	mg/dL	Neg to 6
UBG	mg/dL	Norm to 12
PRO	mg/dL albumin	Neg to 500
ERY	ERY/µL	Neg to 250
LEU	LEU/ µL	Neg to 500
pH	NA	5 to 9
COL	NA	Pale yellow, yellow, amber, brown, orange, red, green, others
SG	g/cm^3	1.000 to 1.050
Clarity	NA	Clear, light turbid, turbid

4.2. Analytical Sensitivity

The sensitivity study was performed to determine the concentration at which the analyte on the **cobas u** pack changed from negative to the lowest positive color range. Samples were prepared by spiking the negative urine pool with the appropriate agent to yield the desired concentrations of analyte. Multiple samples were tested for each analyte. Each sample was measured 20 times on each of the 3 instruments using 3 reagent test strip lots. Sensitivity is defined as the lowest concentration where ≥90% of the overall results are positive.

The results summary and labeling claims are listed below.

Table 4: Summary and Labeling Claims for Analytical Sensitivity

Parameter	Analytical Sensitivity Claim for cobas u pack	Point at which sensitivity meets criteria of ≥90% detection
LEU	10-30 Leu/µL	10 Leu/µL
NIT	0.03 – 0.07 mg/dL	0.045 mg/dL
PRO	7 - 13 mg/dL albumin	9 mg/dL albumin
GLU	25 – 45 mg/dL	25 mg/dL
KET	3 – 7 mg/dL	4 mg/dL

Parameter	Analytical Sensitivity Claim for cobas u pack	Point at which sensitivity meets criteria of ≥90% detection
BIL	0.4 – 0.6 mg/dL	0.6 mg/dL
UBG	1.0 – 1.6 mg/dL	1.15 mg/dL
ERY	5-15 Ery/µL	7 Ery/µL

4.3. Drug and Endogenous Interferences

Interference studies were performed to assess the interfering effect of various therapeutic drugs and endogenous substances. Each analyte was tested in the normal/negative range and in the first positive range. A urine pool was prepared using fresh normal/negative urine and urine samples spiked with analytes in the first positive range. Each urine pool was tested at 2 concentrations of the pharmaceutical compounds/endogenous substances. The pharmaceutical compound solutions were prepared at a multiple of the maximum daily dosage and at the therapeutic concentration (maximal daily dosage). The endogenous substances were tested at a high pathological concentration and an intermediate concentration. Multiple replicates of the urine pool and the spiked interferent samples were measured. Testing was performed with two **cobas u** 601 urine analyzers. In the case of interference, further interferent concentrations were tested to evaluate the maximum interferent concentration which shows no influence on the measurement results.

Summaries and labeling claims are listed in the tables below.

Table 5: Analyte Concentrations of Samples Tested

Parameter	Unit	Concentration Tested	
		Negative/Normal	1st Positive Range
ERY	Ery/µL	Negative	10
LEU	Leu/µL	Negative	25
NIT	mg/dL	Negative	0.1
PRO	mg/dL	Negative	15
GLU	mg/dL	Normal	50
KET	mg/dL	Negative	5
UBG	mg/dL	Normal	1
BIL	mg/dL	Negative	1

Table 6: Potentially Interfering Therapeutic Drug Substances and Initial Test Concentrations

Therapeutic drug	Interferent c1: a multiple of the maximal daily dosage [mg/L]	Interferent c2: Maximal daily dosage under medication [mg/L]
Acetaminophen	3000	500
Amoxicillin	13333	2667
Ascorbic acid	4000	400
Biotin	1000	200
Cefoxitin	12000	2000
Furosemide	2000	400
Gabapentin	12000	2400
Gentamycin Sulfate	400	80
Ibuprofen	2500	500
Levodopa	1250	250
Lisinopril	267	53.4
Metformin	8500	1700
Methyldopa	2000	200
Methenamine + Methylene blue	400 + 66.5	80 + 13.3
N-Acetyl-Cysteine	200	100
Ofloxacin	900	100
Phenazopyridine	300	50
Salicyluric acid	6000	100
Tetracycline	500	100

Table 7: Potentially Interfering Endogenous Substances and Initial Test Concentrations

Endogenous substances	Interferent c1: High pathological dosage [mg/L]	Interferent c2: Intermediate dosage [mg/L]
3-Hydroxybutyrate	4500	150
Ammonium chloride	25000	5000
Bilirubin	800	80
Calcium chloride	3000	600
Creatinine	15000	3000
Glucose	100000	70000
Hemoglobin	830 ≙ 25000 ERY/µl	330 ≙ 10000 ERY/µl

Endogenous substances	Interferent c1: High pathological dosage [mg/L]	Interferent c2: Intermediate dosage [mg/L]
human IgG	5000	1000
Nitrite	110	2
Urea	200000	40000
Uric acid	1550	550
Urobilinogen	3000	120
pH: 4.5; 5.5; 6.5; 7.5; 8.5; 9.0		

Table 8: Summary and Labeling Claims

The following substances showed no interference at tested concentrations :

Cefoxitin

ß-3-Hydroxybutyrat

Gentamycin Sulfate

Human IgG

Lisinopril

Uric acid

Metformin

Ofloxacin

Salicyluric acid

Tetracycline

The following table, which is included in the **cobas u** Pack method sheet, lists the therapeutic drugs which produced significant interference. Elevated positive result means that reference result = 1+ and spiking of interferent leads to results of 2+ or 3+.

Table 9: Interfering Therapeutic Drugs Listed in cobas u pack Method Sheet

Parameter	Therapeutic drug	No Interference up to	Effect above stated concentration
ERY	Ascorbic Acid	750 mg/L	At 1125 mg/L decreased from 10 Ery/µL / 1+ to negative (False negative results)

Parameter	Therapeutic drug	No Interference up to	Effect above stated concentration
	Furosemide	1800 mg/L	At 2000 mg/L decreased from 10 Ery/µL / 1+ to negative (False negative results)
	Ibuprofen	750 mg/L	At 1250 mg/L decreased from 10 Ery/µL / 1+ to negative (False negative results)
	Levodopa	625 mg/L	At 937.5 mg/L increased from negative / neg to pos 1 and from positive / pos 1 to pos 2 (False positive and elevated positive result)
	Methyldopa	800 mg/L	At 2000 mg/L increased from negative / neg to pos 1 and from positive / pos 1 to pos 2 and at 1200 mg/L increased from positive / pos 1 to pos 2 (False positive and elevated positive result)
	Methenamine and Methylene blue	8 mg/L Methenamine 1.3 mg/L Methylene blue	At 16 mg/L Methenamine and 2.7 mg/L Methylene blue increased from negative / neg to pos 1 and from positive/pos 1 to pos 2 (False positive and Elevated positive results)
LEU	Amoxicillin	10667 mg/L	At 12000 mg/L decreased from 25 Leu/µL / 1+ to negative (False negative result)
	Ibuprofen	200 mg/L	At 500 mg/L decreased from 25 Leu/µL / 1+ to negative (False negative result)
	Methenamine and Methylene blue	40 mg/L Methenamine 6.7 mg/L Methylene blue	At 80 mg/L Methenamine and 13.3 mg/L Methylene blue increased from negative / neg to pos 1 (False positive results)
NIT	Ascorbic Acid	1500 mg/L	At 2000 mg/L decreased from positive / pos to neg (False negative results)
	Methenamine and Methylene blue	28 mg/L Methenamine 4.7 mg/L Methylene blue	At 40 mg/L Methenamine and 6.7 mg/L Methylene blue increased from negative / neg to pos (False positive results)
	Phenazopyridine	120 mg/L	At 300 mg/L increased from negative / neg to pos 1 (False positive results)

Parameter	Therapeutic drug	No Interference up to	Effect above stated concentration
PRO	Gabapentin	2400 mg/L	At 3600 mg/L increased from positive / pos 1 to pos 2 (Elevated positive results)
	Ibuprofen	2250 mg/L	At 2500 mg/L decreased from positive / pos 1 to neg (False negative results)
	Methenamine and Methylene blue	2 mg/L Methenamine 0.33 mg/L Methylene blue	At 80 mg/L Methenamine and 13.3. mg/L Methylene blue increased from neg to pos 3 and from positive / pos 1 to pos 3 and at 8 mg/L Methenamine and 1.3 mg/L Methylene blue increased from positive / pos 1 to pos 2 (False positive and elevated positive results)
	Phenazopyridine	120 mg/L	At 300 mg/L increased from negative / neg to pos 1 and from positive / pos 1 to pos 2 and at 240 mg/L increased from positive / pos 1 to pos 2 (False positive and elevated positive results)
GLU	Ascorbic Acid	200 mg/L	At 400 mg/L decreased from positive / pos 1 to norm (False normal results)
	Methenamine and Methylene blue	120mg/L Methenamine 20 mg/L Methylene blue	At 160 mg/L Methenamine and 26.6 mg/L Methylene blue decreased from positive / pos 1 to norm (False normal results)
KET	N-Acetylcysteine	30 mg/L	At 50 mg/L increased from Negative / neg to pos 1 and from positive / pos 1 to pos 2 (False positive and elevated positive results)
	Levodopa	1000 mg/L	At 1250 mg/L increased from positive / pos 1 to pos 2 (Elevated positive results)
	Methyldopa	1200 mg/L	At 2000 mg/L increased from negative / neg to pos 1 and from positive / pos 1 to pos 2 and at 1600 mg/L increased from positive / pos 1 to pos 2 (False positive and elevated positive results)

Parameter	Therapeutic drug	No Interference up to	Effect above stated concentration
	Methenamine and Methylene blue	160 mg/L Methenamine 26.6 mg/L Methylene blue	At 208 mg/L Methenamine and 35 mg/L Methylene blue decreased from positive / pos 1 to neg (False negative results)
UBG	Acetaminophen	240 mg/L	At 420 mg/L increased from positive / pos 1 to pos 2 (Elevated positive results)
	Gabapentin	10800 mg/L	At 12000 mg/L decreased from positive / pos 1 to norm (False normal results)
	Methenamine and Methylene blue	24 mg/L Methenamine 4 mg/L Methylene blue	At 48 mg/L Methenamine and 8 mg/L Methylene blue increased from positive / pos 1 to pos 2 (Elevated positive results)
	Phenazopyridine	120mg/L	At 300 mg/L increased from normal / norm to pos 1 and from positive / pos 1 to pos 2 and at 210 mg/L increased from positive / pos 1 to pos 2 (False positive and elevated positive results)
BIL	Ascorbic Acid	2000 mg/L	At 4000 mg/L decreased from positive / pos 1 to neg (False negative results)
	Biotin	800 mg/L	At 1000 mg/L increased from positive / pos 1 to pos 2 (Elevated positive results)
	Methenamine and Methylene blue	140 mg/L Methenamine 23.3 mg/L Methylene blue	At 160 mg/L Methenamine and 26.6 mg/L Methylene blue decreased from positive / pos 1 to neg (False negative results)
	Phenazopyridine	120 mg/L	At 240 mg/L increased from positive / pos 1 to pos 2 (Elevated positive results)

The following table, which is included in the **cobas u** Pack Method Sheet, lists the endogenous substances which produced significant interference. Elevated positive result means that reference result = 1+ and spiking of interferent leads to results of 2+ or 3+.

Table 10: Interfering Endogenous Substances Listed in the cobas u pack Method Sheet

Parameter	Endogenous substance	No Interference up to	Effect above stated concentration
ERY	Calcium chloride	2430 mg/L	At 3000 mg/L increased from positive / pos 1 to pos 2 (Elevated positive result)
	Nitrite	40 mg/L	At 80 mg/L decreased from positive / pos 1 to neg (False negative results)
	Urobilinogen	480 mg/L	At 3000 mg/L increased from negative / neg to pos 2 and from positive / pos 1 to pos 2 and at 1200 mg/L increased from negative / neg to pos 1 (False positive and elevated positive results)
LEU	Calcium chloride	2430 mg/L	At 3000 mg/L decreased from positive / pos 1 to neg (False negative result)
	Glucose	10.000 mg/L	At 20.000 mg/L decreased from positive / pos 1 to neg (False negative results)
	Hemoglobin	750 mg/L	At 830 mg/L increased from negative / neg to pos 1 (False positive results)
	pH	< pH 5.5	At pH 4.5 decreased from positive / pos 1 to neg (False negative results)
	Bilirubin	400 mg/L	At 800 mg/L increased from negative / neg to pos 1 (False positive results)
	Urobilinogen	120 mg/L	At 3000 mg/L decreased from positive / pos 1 to neg and at 150 mg/L increased from negative / neg to pos 1 (False positive results and false negative results)
	SG	1.030	At SG 1.040 decreased from positive / pos 1 to neg (False negative results)
NIT	Bilirubin	400 mg/L	At 800 mg/L decreased from positive / pos 1 to neg (False negative results)
	Urobilinogen	90 mg/L	At 105 mg/L increased from negative / neg to pos 1 (False positive results)

Parameter	Endogenous substance	No Interference up to	Effect above stated concentration
PRO	Ammonium chloride	1725 mg/L	At 5000 mg/L decreased from positive / pos 1 to neg (False negative results)
	Calcium chloride	2430 mg/L	At 3000 mg/L decreased from positive / pos 1 to neg (False negative results)
	Creatinine	2850 mg/L	At 15000 mg/L increased from negative / neg to pos 1 and from positive / pos 1 to pos 2 and at 4200 mg/L increased from positive / pos 1 to pos 2 (False positive and elevated positive result)
	Hemoglobin	66 mg/L	At 130 mg/L increased from positive / pos 1 to pos 2 (False positive and false elevated results due to unspecific protein detection may occur)
	Urea	52000 mg/L	At 200000 mg/L increased from negative / neg to pos 2 and from positive / pos 1 to pos 2 and at 89000 mg/L increased from positive / pos 1 to pos 2 (False positive and elevated positive result)
	Urobilinogen	120 mg/L	At 3000 mg/L increased from negative / neg to pos 3 and from positive / pos 1 to pos 3 and at 240 mg/L increased from positive / pos 1 to pos 2 (False positive and elevated positive result)
	Bilirubin	400 mg/L	At 600 mg/L increased form negative / neg to pos 1 (False positive results)
GLU	Ammonium chloride	10300 mg/L	At 15200 mg/L decreased from positive / pos 1 to norm (False normal results)
	Urea	89000 mg/L	At 126000 mg/L increased from positive / pos 1 to norm (False normal results)
	Bilirubin	400 mg/L	At 800 mg/L decreased from positive / pos 1 to norm (False normal results)
	Urobilinogen	1250 mg/L	At 1500 mg/L decreased from positive / pos 1 to norm (False normal results)
KET	Bilirubin	400 mg/L	At 800 mg/L decreased from positive / pos 1 to neg (False negative results)

Parameter	Endogenous substance	No Interference up to	Effect above stated concentration
	Urobilinogen	900 mg/L	At 3000 mg/L decreased from positive / pos 1 to neg (False negative results)
UBG	Nitrite	7 mg/L	At 14 mg/L decreased from positive / pos 1 to norm (False normal results)
	Bilirubin	400 mg/L	At 600 mg/L decreased from positive / pos 1 to norm (False normal results)
BIL	Nitrite	7 mg/L	At 14 mg/L decreased from positive / pos 1 to neg (False negative results)
	Urobilinogen	60 mg/L	At 120 mg/L increased from negative / neg to pos 2 and from positive / pos 1 to pos 2 and at 70 mg/L increased from positive / pos 1 to pos 2 (False positive and elevated positive results)

4.4. Color Interference

The purpose of this study was to verify the color compensation functionality of the **cobas u** 601 urine analyzer.

Two analyte solutions per parameter were prepared, a negative/normal solution and a solution in a color block that uses color compensation.

Each of the test solutions prepared above were spiked with the following concentrations of interferent to produce a red, orange or brown color:

Table 11: Interferent Concentration

Interferent	0	c1	c2
ERY (red color)	0 Ery/µL (~67% REM)	15050 Ery/µL (~58% REM)	3550 Ery/µL (~65% REM)
BIL (orange color)	0 mg/dL (~67% REM)	31 mg/dL (~58% REM)	8 mg/dL (~65% REM)
UGB (brown color)	0 mg/dL (~67% REM)	100 mg/dL (~58% REM)	12 mg/dL (~65% REM)

Interferent	0	c1	c2
Color compensation active	No	Yes	No

The following concentrations of interferent were tested for LEU (red, orange and brown), NIT (brown) and UBG (brown):

Table 12: Interferent Concentration

Interferent	0	c1	c2
Hemoglobin (red color)	0 Ery/µL (~67% REM)	750 mg/L 25,000 Ery/ µL (~58% REM)	300 mg/L 10,000 Ery/µL (~65% REM)
SunsetYellow (orange color)	0 mg/dL (~67% REM)	312.5 mg/L (~58% REM)	150 mg/L (~66% REM)
Lignin (brown color)	0 mg/L (~67% REM)	1 mg/L (~58% REM)	0.4 mg/L (~66% REM)
Color compensation active	No	Yes	No

For the red colored urine two further concentrations were measured. One at pathological concentration level (c3 = 500 ERY/µL ≙ 15 mg/L hemoglobin, including 66 % safety margin) and one at physiological concentration level (c4 = 30 ERY/µL ≙ 0.9 mg/L hemoglobin).

The final test solutions were tested in a 10-fold determination for each parameter.

Table 13: Summary of Color Interference Testing

Parameter	Parameter concentration	Orange coloring		Red Coloring		Brown Coloring	
		Bilirubin concentration	Result[a]	Erythrocyte Concentration	Result[a]	Urobilinogen Concentration	Result[a]
Nitrite	Neg	Neg	100	Neg	100	---	---
	Neg	31 mg/dL	100	15050 Ery/µL	100	---	---
	Neg	8 mg/dL	100	3550 Ery/ µL	100	---	---
	0.1 mg/dL	Neg	100	Neg	100	---	---
	0.1 mg/dL	31 mg/dL	100	15050 Ery/µL	100	---	---
	0.1 mg/dL	8 mg/dL	100	3550 Ery/ µL	100	---	---
Ketone	Neg	Neg	100	Neg	100	Neg	100
	Neg	31 mg/dL	100	15050 Ery/µL	100	100 mg/dL	100
	Neg	8 mg/dL	100	3550 Ery/ µL	100	12 mg/dL	100
	4 mg/dL	Neg	100	Neg	100	Neg	100
	4 mg/dL	31 mg/dL	100	15050 Ery/µL	100	100 mg/dL	100
	4 mg/dL	8 mg/dL	100	3550 Ery/ µL	100	12 mg/dL	100
Glucose	Normal	Neg	100	Neg	100	Neg	100
	Normal	31 mg/dL	100	15050 Ery/µL	100	100 mg/dL	100
	Normal	8 mg/dL	100	3550 Ery/ µL	100	12 mg/dL	100
	50 mg/dL	Neg	100	Neg	100	Neg	100
	50 mg/dL	31 mg/dL	100	15050 Ery/µL	100	100 mg/dL	100
	50 mg/dL	8 mg/dL	100	3550 Ery/ µL	100	12 mg/dL	100
Bilirubin	Neg	---	---	Neg	100	---	---
	Neg	---	---	15050 Ery/µL	100	---	---
	Neg	---	---	3550 Ery/ µL	100	---	---
	1 mg/dL	---	---	Neg	100	---	---
	1 mg/dL	---	---	15050 Ery/µL	100	---	---
	1 mg/dL	---	---	3550 Ery/ µL	100	---	---
Urobilinogen	Normal	Neg	100	Neg	100	---	---
	Normal	31 mg/dL	100	15050 Ery/µL	100	---	---
	Normal	8 mg/dL	100	3550 Ery/ µL	100	---	---
	1.6 mg/dL	Neg	100	Neg	100	---	---
	1.6 mg/dL	31 mg/dL	100	15050 Ery/µL	100	---	---
	1.6 mg/dL	8 mg/dL	100	3550 Ery/ µL	100	---	---
Erythrocytes	Neg	Neg	100	---	---	Neg	100
	Neg	31 mg/dL	100	---	---	100 mg/dL	100
	Neg	8 mg/dL	100	---	---	12 mg/dL	100

Parameter	Parameter concentration	Orange coloring		Red Coloring		Brown Coloring	
		Bilirubin concentration	Result[a]	Erythrocyte Concentration	Result[a]	Urobilinogen Concentration	Result[a]
	75 Ery/µL	Neg	100	---	---	Neg	100
	75 Ery/µL	31 mg/dL	100	---	---	100 mg/dL	100
	75 Ery/µL	8 mg/dL	100	---	---	12 mg/dL	100

[a]Results: For each negative parameter concentration: the results expressed as % negative results

For each positive parameter concentration: the results expressed as % exact agreement

Table 14: Summary of Color Interference Testing

Parameter	Parameter concentration	Orange coloring		Red Coloring		Brown Coloring	
		Sunset Yellow Concentration	Result[a]	Hemoglobin Concentration	Result[a]	Lignin Concentration	Result[a]
Nitrite	Neg	---	---	---	---	Neg	100
	Neg	---	---	---	---	1 mg/L	100
	Neg	---	---	---	---	0.4 mg/L	100
	0.1 mg/dL	---	---	---	---	Neg	100
	0.1 mg/dL	---	---	---	---	0.1 mg/L	100
	0.1 mg/dL	---	---	---	---	0.4 mg/L	100
Bilirubin	Neg	---	---	---	---	Neg	100
	Neg	---	---	---	---	1 mg/L	100
	Neg	---	---	---	---	0.4 mg/L	100
	1 mg/dL	---	---	---	---	Neg	100
	1 mg/dL	---	---	---	---	0.1 mg/L	100
	1 mg/dL	---	---	---	---	0.4 mg/L	100
Leukocytes	Neg	Neg	100	Neg	100	Neg	100
	Neg	312.5 mg/L	100	750 mg/L	90	100 mg/dL	100
	Neg	150 mg/L	100	300 mg/L	100	12 mg/dL	100
	40 Leu/µL	Neg	100	Neg	100	Neg	100
	40 Leu/µL	312.5 mg/L	20	750 mg/L	100	100 mg/dL	100
	40 Leu/µL	150 mg/L	100	300 mg/L	100	12 mg/dL	100

[a]Results: For each negative parameter concentration: the results expressed as % negative results

For each positive parameter concentration: the results expressed as % exact agreement

4.5. Stability

Shelf-life (real-time) and on-board stability of the **cobas u** pack were determined on **cobas u** 601.

Real-time stability of the **cobas u** pack on the **cobas u** 601 urine analyzer was determined using two analyzers and three lots of **cobas u** pack. Stability testing was performed at time 0 (after manufacturing), and 3, 13 and 16 months after storage.

For each testing point a fresh cassette was placed on the calibrated urine analyzer and a defined set of samples was measured. Those sample materials include native urine, artificial urine, urine spiked with low analyte concentration and urine with high analyte concentration (for the qualitative parameters NIT only three, and for pH only two different urine sample materials were tested). All samples were measured with n=10 determinations.

The **cobas u** pack is stable at room temperature for 15 months.

On-board stability of the **cobas u** pack on the **cobas u** 601 urine analyzer was determined using one lot of **cobas u** pack on one analyzer. The **cobas u** pack, which contains 400 reagent test strips in a single cassette, was stored on the **cobas u** 601 urine analyzer over a period of 15 days at 32°C and 80% relative humidity. Parameters were tested at 11 different time points with a total of 400 tests over the period of 15 days from a single cassette. Native and artificial urine samples at abnormal concentration were used for the on board stability study.

The **cobas u** pack is stable up to 14 days during operation on the system.

4.6. Expected Values

The expected values are listed in the table below:

Table 15: Expected Values

Analyte	Expected Value
Erythrocytes	0-5 Ery/µL
Leukocytes	< 10 Leu/µL
Nitrite	Negative
Ketone	< 5 mg/dL
Glucose	< 30 mg/dL
Protein	< 10 mg/dL
Bilirubin	< 0.2 mg/dL
Urobilinogen	< 1 mg/dL
pH	4.8 – 7.4

5. CLINICAL PERFORMANCE DATA

5.1. Precision

Precision was comprised of experiments for repeatability and Intermediate precision.

5.1.1. Repeatability

Controls were measured for the within-run precision study of the test strip parameters. Controls with negative / normal and positive analyte concentrations were measured in 2 runs, 21 determinations each, thereby producing n = 42 results per control.

Table 16: Repeatability

Parameter	Control	Result	Exact Agreement
pH	Level 1	6	100%
	Level 2	7	100%
ERY	Level 1	Neg	100%
	Level 2	250 Ery/µL	100%
LEU	Level 1	Neg	100%
	Level 2	500 Ery/µL	100%
PRO	Level 1	Neg	100%
	Level 2	100 mg/dL	100%
GLU	Level 1	Norm	100%
	Level 2	1000 mg/dL	100%
KET	Level 1	Neg	100%
	Level 2	150 mg/dL	100%
UBG	Level 1	Norm	100%
	Level 2	8 mg/dL	100%
BIL	Level 1	Neg	100%
	Level 2	6 mg/dL	100%
COL	Level 1	Yellow	100%
	Level 2	Brown	100%

5.1.2. Intermediate Precision

Controls were measured for the intermediate study of the test strip parameters. Controls with negative / normal and positive analyte concentrations were measured in 21 days with 2 runs per day and duplicate measurements per control, thereby producing n = 84 results per control.

Table 17: Intermediate Precision

Parameter	Control	Result	Exact Agreement
pH	Level 1	6	100%
	Level 2	7	100%
ERY	Level 1	Neg	100%
	Level 2	250 Ery/µL	100%
LEU	Level 1	Neg	100%
	Level 2	500 Ery/µL	95.2%
PRO	Level 1	Neg	100%
	Level 2	100 mg/dL	100%
GLU	Level 1	Norm	100%
	Level 2	1000 mg/dL	100%
KET	Level 1	Neg	100%
	Level 2	150 mg/dL	100%
UBG	Level 1	Norm	100%
	Level 2	8 mg/dL	100%
BIL	Level 1	Neg	100%
	Level 2	6 mg/dL	100%
COL	Level 1	Yellow	100%
	Level 2	Brown	100%

5.1.3. Method Comparison versus Reference System

Method comparison studies were conducted to evaluate the performance of the **cobas u** 601 urinalysis test system. The **cobas u** 411 is the predicate for pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, and erythrocytes. The Urisys 2400 is the predicate for specific gravity, color and clarity. Testing was performed externally using fresh samples in order to cover the claimed ranges.

Table 18: Summary of comparison to cobas u 411

Summary Method comparison							
Test Strip Parameter		exact agreement (100% fit)		exact agreement (fit ± 1 block)	Overall agreement (%)	Specificity (%)	Sensitivity (%)
		Ranges passed	agreement rates (%)				
ERY	Ery/µL	6 / 6	85 - 100	100	99	99	99
LEU	Leu/µL	4 / 4	88 - 99	100	99	99	97
NIT	-	2 / 2	99 - 100	100	100	99	100
KET	mg/dL	5 / 5	88 - 99	100	99	99	97
GLUC	mg/dL	5 / 5	86 - 100	100	99	99	100
PRO	mg/dL	5 / 5	87 - 98	100	99	98	100
BIL	mg/dL	4 / 4	91 - 100	100	99	100	98
UBG	mg/dL	5 / 5	87 - 99	100	99	99	98
pH (pH 5+6)	-	2 / 2	87 - 90	100	98		
pH (pH 8+9)	-	2 / 2	86 - 97	100	98		
pH	-	6 / 6	70 - 97	100	95		

Table 19: Summary of comparison to Urisys 2400 for Color

COL		Urisys 2400						
cobas u 601		Pale yellow	Yellow	Amber	Brown	Orange	Red	
	Pale yellow	**126**	7	0	0	0	0	**133**
	Yellow	23	**85**	2				**110**
	Amber	1	29	**58**	0	0	0	**88**
	Brown	0	0	24	**50**	0	0	**74**

	Orange	5	0	5	7	**15**	3	**35**
	Red	0	0	0	0	7	**31**	**38**
	Σ	**155**	**121**	**89**	**57**	**22**	**34**	**478**

Agreement Rate (%):	**81**	**70**	**65**	**88**	**68**	**91**
	87					

Table 20: Summary of Comparison to Urysis 2400 for Clarity

Clarity		**URISYS 2400**			
cobas u 601		**clear**	**light turbid**	**turbid**	**Σ**
	clear	**921**	23	0	**944**
	light turbid	114	**173**	18	**305**
	turbid	2	21	**92**	**115**
	Σ	**1037**	**217**	**110**	**1364**

Exact agreement (%)	89%	80%	84%
agreement ± 1 color block	100%	100%	100%

5.2. Sample Carryover

Sample carryover studies were performed to assess the amount of sample carried over by the **cobas u** 601 from one specimen reaction into the subsequent specimen reactions. This consisted of testing low concentration/negative samples and high concentration samples. The negative pool was tested to determine a baseline value (reference). Then, the samples were tested by alternate pipetting of the low concentration/negative sample and high concentration samples. Carryover effects were assessed by comparing the baseline (reference) results to the results of the low concentration/negative samples when tested after the high concentration samples.

The results obtained for BIL, GLU, KET, LEU, ERY, NIT, PRO, UBG, pH, COL and SG met the pre-defined acceptance criteria. Deviations were observed for Clarity but there will be no risk for patient safety because of the low medical relevance of this parameter.

6. CONCLUSION

The information provided in this premarket notification 510(k) will support a determination of substantial equivalence for the **cobas u** 601 Urinalysis Test System as compared to the predicate devices.