February 16, 2018

DFI CO., LTD.
% HO DONG YANG, CEO
ONBIX CORPORATION
#821 SAMIL PLAZA, 14, DOGOK-RO 1-GIL
GANGNAM-GU, SEOUL, KOREA 06523

Re: K171521
Trade/Device Name: DUS R-50S (Urine Chemistry system)
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIO, JFY, JIR, LJX, JMT, CDM, CEN, JRE, JIN, JJB, KQO
Dated: December 27, 2017
Received: January 10, 2018

Dear Ho Dong Yang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k171521

Device Name
DUS R-50S (Urine Chemistry system)

Indications for Use *(Describe)*
The DUS R-50S System provides a qualitative and semi-quantitative measurements for specific gravity, pH, leukocytes, nitrite, protein, glucose, ketone, urobilinogen, bilirubin, blood, microalbumin and creatinine in urine specimens. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function. The system is intended for prescription, in vitro diagnostic use only.

The DUS R-50S System consists of the following:
DUS R-50S Analyzer
DUS 10 Reagent Strips for urinalysis include test pads for leukocytes, nitrite, urobilinogen, protein, pH, blood, specific gravity, ketone(acetoacetic acid), bilirubin and glucose.
DUS 2AC Reagent Strips for urinalysis include test pads for microalbumin and creatinine.

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 [K171521]

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

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Date Summary Prepared: Feb 15, 2018

Device Information:

Trade Name(s): DUS R-50S (Urine Chemistry system)

Common Name: Automated urinalysis system

Regulatory information:

Name	Regulation	Product code	Device class
Urinary Glucose (non-quantitative) test system	21 CFR § 862.1340	JIL	II
Occult Blood test	21 CFR 864.6550	JIO	II
Creatinine test system	21 CFR 862.1225	JFY	II
Urinary Protein or Albumin (nonquantitative) test system	21 CFR 862.1645	JIR	I
Leukocyte peroxidase	21 CFR 864.7675	LJX	I
Nitrite (nonquantitative) test system	21 CFR 862.1510	JMT	I
Urinary Urobilinogen	21 CFR 862.1785	CDM	I

(nonquantitative) test system			
Urinary pH (nonquantitative) test	21 CFR 862.1550	CEN	I
Specific Gravity	21 CFR 862.2800	JRE	I
Ketones (nonquantitative) test system	21 CFR 862.1435	JIN	I
Urinary Bilirubin and its conjugates (nonquantitative) test system	21 CFR 862.1115	JJB	I
Automated Urinalysis System	21 CFR 862.2900	KQO	I

Predicate Device Information:

K091216 / Clinitek Status+

Device Description:

The DUS R-50S (Urine Chemistry system) is a portable analyzer. It is designed to read only DUS Series for urinalysis. This analyzer reports semi-quantitatively assays for 12 urine analytes [Leukocyte, Nitrite, Urobilinogen, Protein, pH, Blood, Specific gravity, Ketone, Bilirubin, Glucose, Microalbumin, Creatinine]. Reagent strip results are automatically displayed on the screen. The DUS R-50S is intended for in vitro diagnostic use only

Indications for Use:

The DUS R-50S (Urine Chemistry System) provides a qualitative and semi-quantitative measurements for specific gravity, pH, leukocytes, nitrite, protein, glucose, ketone, urobilinogen, bilirubin, blood, microalbumin and creatinine in urine specimens. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function. The system is intended for prescription, in vitro diagnostic use only.

The DUS R-50S (Urine Chemistry System) consists of the following:

- DUS R-50S Analyzer
- DUS 10 Reagent Strips for urinalysis include test pads for leukocytes, nitrite, urobilinogen, protein, pH, blood, specific gravity, ketone (acetoacetic acid), bilirubin and glucose.
- DUS 2AC Reagent Strips for urinalysis include test pads for microalbumin and creatinine.

Comparison to Predicate Device(s):

The DUS R-50S (Urine Chemistry System) is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* technological characteristics
* performance properties

Summary of testing:

To be in compliance with electromagnetic safety and compatibility, appropriate study has been applied to the new device.

The performance characteristic of the DUS R-50S (Urine Chemistry System) were verified by method comparison, precision, detection limit, interference, specificity, shelf life and stress studies.
Testing is summarized below.

Performance Characteristics

a. Precision/Reproducibility

The repeatability / reproducibility precisions were tested at three Clinical sites, using commercially Quantimetrix Dipper Urine Dipstick Control Level 1 and Level 2. The agreements of results are shown above 95%.

Level 1 control					
		Within-run (90)		Within-day (90)	
Item	Test Results	Agreement (%)	Agreement within	Agreement (%)	Agreement within +/-1block (%)
Urobilinogen	Normal	90/90	90/90 (100%)	90/90 (100%)	90/90 (100%)
Glucose	Negative	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Bilirubin	Negative	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Ketones	Negative	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
SG	1.020	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Blood	Negative	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
pH	6	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Protein	Negative	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Nitrite	Negative	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Leukocytes	Negative	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Creatinine	10mg/dL	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Microalbumin	10mg/L	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)

Level 2 control					
		Within-run (90)		Within-day (90)	
Item	Test Results	Agreement (%)	Agreement within	Agreement (%)	Agreement within +/-1 block (%)
Urobilinogen	4 mg/dL	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Glucose	1000	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Bilirubin	4 mg/dL	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Ketones	40 mg/dL	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
SG	1.020	89/90 (98.9%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Blood	120	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
PH	7	90/90 (100%)	90/90 (100%)	89/90 (98.9%)	90/90 (100%)
Protein	100 mg/dL	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Nitrite	Positive	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Leukocytes	70	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Creatinine	200mg/d	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Microalbumin	150mg/L	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)

b. Linearity /assay reportable range.

Linearity / assay reportable range were tested at DFI Clinical center. Samples were created by spiking known concentration of each standard material or by serial dilution of a high concentration with negative urine. Test results indicated that there was no significant difference between the samples of known concentration result and result of DUS R-50s.

Results of summarized below:

Analyte	Urine sample concentration tested	Color block output	% Exact match
Urobilinogen	Negative/Norm	0.1	100% (90/90)
	1 mg/dL	1 mg/dL	100% (90/90)
	2 mg/dL	2 mg/dL	98.8% (89/90)
	4 mg/dL	4 mg/dL	98.8% (89/90)
	8 mg/dL	8 mg/dL	100% (90/90)
Glucose	Negative	Neg.	100% (90/90)
	100 mg/dL	± (100 mg/dL)	100% (90/90)
	250 mg/dL	+250 mg/dL	98.8% (89/90)
	500 mg/dL	++500 mg/dL	96.6% (87/90)
	1000 mg/dL	+++ 1000 mg/dL	98.8% (89/90)
	2000 mg/dL	++++2000 mg/dL	100% (90/90)
Bilirubin	Negative	Neg.	100% (90/90)
	1 mg/dL	+	98.8% (89/90)
	2 mg/dL	++	98.8% (89/90)
	4 mg/dL	+++	100% (90/90)
Ketones	Negative	Neg.	100% (90/90)
	5 mg/dL	± 5 mg/dL	100% (90/90)
	15 mg/dL	+ 15 mg/dL	96.6% (87/90)
	40 mg/dL	++ 40 mg/dL	98.8% (89/90)
	80 mg/dL	+++ 80 mg/dL	97.7% (88/90)
	160 mg/dL	++++ 160 mg/dL	100% (90/90)
Specific gravity	1.000	1.000	100% (90/90)
	1.005	1.005	98.8% (89/90)
	1.010	1.010	97.7% (88/90)
	1.015	1.015	96.6% (87/90)
	1.020	1.020	98.8% (89/90)
	1.025	1.025	96.6% (87/90)
	1.030	1.030	100% (90/90)
Nitrite	Negative	Neg.	100% (90/90)
	0.05 mg/dL	Trace	100% (90/90)
	10 mg/dL	Pos	100% (90/90)
Blood	Negative	Neg	100% (90/90)
	10 RBC/µL	Trace	100% (90/90)
	25 RBC/µL	+ 25 RBC/µL	100% (90/90)
	80 RBC/µL	++ 80 RBC/µL	98.8% (89/90)
	200 RBC/µL	+++ 200 RBC/µL	97.7% (88/90)
pH	5	5	100% (90/90)
	6	6	98.8% (89/90)
	6.5	6.5	98.8% (89/90)
	7	7	98.8% (89/90)
	7.5	7.5	97.7% (88/90)
	8	8	100% (90/90)
	8.5	8.5	100% (90/90)

Protein	Negative	Neg.	100% (90/90)
	15 mg/dL	Trace	98.8% (89/90)
	30mg/dL	(+) 30 mg/dL	97.7% (88/90)
	100 mg/dL	(++) 100 mg/dL	97.7% (88/90)
	300 mg/dL	(+++) 300 mg/dL	97.7% (88/90)
	1000 mg/dL	(++++) 1000 mg/dL	100% (90/90)
Leukocytes	Negative	Negative	100% (90/90)
	15 WBC/µL	15 WBC/µL	100% (90/90)
	70 WBC/µL	70 WBC/µL	97.7% (88/90)
	125 WBC/µL	125 WBC/µL	97.7% (88/90)
	500 WBC/µL	500 WBC/µL	98.8% (89/90)
Microalbumin	10 mg/dL	10 mg/dL	100% (90/90)
	30 mg/dL	30 mg/dL	98.8% (89/90
	80 mg/dL	80 mg/dL	97.7% (88/90))
	150 mg/dL	150 mg/dL	98.8% (89/90
Creatinine	10 mg/dL	10 mg/dL	100% (90/90)
	50 mg/dL	50 mg/dL	100% (90/90)
	100 mg/dL	100 mg/dL	98.8% (89/90
	200 mg/dL	200 mg/dL	96.6% (87/90)
	300 mg/dL	300 mg/dL	197.7% (88/90)

The report ranges for the DUS 10 reagent strips are of each analyte are summarized below:

Test	Reportable Range
Urobilinogen	Qualitative: normal to 3+ Semi-quantitative: 0.1 – 8 mg/dL
Glucose	Qualitative: Negative to 4+ Semi-quantitative: Neg – 2000 mg/dL
Bilirubin	Qualitative: normal to 3+ Semi-quantitative: Neg – 4 mg/dL

Ketones	Qualitative: Negative to 4+ Semi-quantitative: Neg – 160 mg/dL
Specific Gravity	1.000 – 1.030
Blood	Qualitative: normal to 3+ Semi-quantitative: Neg – 200 RBC/ μL
pH	5 – 8.5
Protein	Qualitative: Negative to 4+ Semi-quantitative: Neg – 1000 mg/dL
Nitrite	Semi-quantitative: Neg – 10 mg/dL
Leukocytes	Qualitative: normal to 3+ Semi-quantitative: Neg - 500 WBC/μL
Microalbumin	Semi-quantitative: 10 – 150 mg/L
Creatinine	Semi-quantitative: 10 – 300 mg/dL

The reportable ranges for DUS 2AC reagent strips are:

Microalbumin	Semi-quantitative: 10 – 150 mg/L
Creatinine	Semi-quantitative: 10 – 300 mg/dL

c. Detection limit

A sensitivity study was performed to evaluate the lower limits of detection for each the analytes on the DUS strips (DUS 10, DUS 2AC) utilizing the DUS R-50S analyzer. Negative urine was spiked with standard materials to obtain the desired concentrations. 90 replicates were obtained for each concentration. Sensitivity was defined as the cutoff in which ≥95% of the contrived pooled measurements were trace or the first positive result. The pH, specific gravity and creatinine were not evaluated for the lower limits of sensitivity.

Analyte	Concentration	Negative result	Positive (+ 2 mg/dL)	Positive Agreement (%)
Urobilinogen	1.8 EU/dL	8	82	91.1%
	2 EU/dL	0	90	100%
	2.3 EU/dL	0	90	100%
Result cut-off	2 Eu/dL			
Glucose	Concentration	Negative	Positive	Positive Agreement

		result	(±100 mg/dL)	(%)
	80 mg/dL	5	85	94.4%
	100 mg/dL	0	90	100%
	120 mg/dL	0	90	100%
Result cut-off	100 mg/dL			
Bilirubin	Concentration	Negative result	Positive (+1.0 mg/dL)	Positive Agreement (%)
	0.8 mg/dL	6	84	93.3%
	1.0	0	90	100%
	1.2	0	90	100%
Result cut-off	1.0 mg/dL			
Ketone	Concentration	Negative result	Positive (± 5 mg/dL)	Positive Agreement (%)
	4 mg/dL	5	85	94.4%
	5 mg/dL	0	90	100%
	6 mg/dL	0	90	100%
Result cut-off	5 mg/dL			
Blood	Concentration	Negative result	Positive (± 5 mg/dL)	Positive Agreement (%)
	8 RBC/µL	7	83	92.2%
	10 RBC/µL	0	90	100%
	12 RBC/µL	0	90	100%
Result cut-off	10 RBC/µL			
Protein	Concentration	Negative result	Positive (±15 mg/dL)	Positive Agreement (%)
	12 mg/dL	6	84	93.3%
	15 mg/dL	0	90	100%
	18 mg/dL	0	90	100%
Result cut-off	15 mg/dL			
Nitrite	Concentration	Negative result	Positive (0.05 mg/dL)	Positive Agreement (%)
	0.04 mg/dL	6	84	93.3%
	0.05 mg/dL	0	90	100%
	0.06 mg/dL	0	90	100%
Result cut-off	0.05 mg/dL			
Leukocytes	Concentration	Negative result	Positive (15 WBC/µL)	Positive Agreement (%)
	12 WBC/µL	5	85	94.4%
	15 WBC/µL	0	90	100%
	18 WBC/µL	0	90	100%
Result cut-off	15 WBC/µL			

	Concentration	Negative result	Positive (3 mg/dL)	Positive Agreement (%)
Microalbumin	2 mg/dL	8	82	91.1%
	3 mg/dL	0	90	100%
	4 mg/dL	0	90	100%
Result cut-off	3 mg/dL			

d. Analytical specificity:

No interference was observed for the following compounds at the concentrations evaluated below:

Potential Interfering Substance	Highest concentration at which no interference was observed
Albumin (protein)	750 mg/dL
Ascorbic acid	15 mg/dL
Acetaminophen	25 mg/dL
Azo gantrinsin (Sulfamethoxazol)	140 mg/dL
Bilirubin	3 mg/dL
Captropril	100 mg/dL
Sodium hypochlorite	0.1%
Creatinine	800 mg/dL
Nitrofurantion	10 mg/dL
Oxalic acid	30 mg/dL
p-amno Salicylic acid	375 mg/dL
β-D-Glucose (Glucose)	1000 mg/dL
Phenazopyridine	25 mg/dL
Riboflavin	12 mg/dL
Selenium	150 mg/dL
Forrmaldehyde	100 mg/dL
Hemoglobin	3 mg/dL
Lithium acetoacetate (ketones)	20 mg/dL
Tetracycline	20 mg/dL
Urobilinogen	10 mg/dL
pH	7
Specific gravity	1.030

e. Analytical specificity / Limitation

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result of method. Substances that cause abnormal urine color may affect the readability of test pads in urinalysis reagent strips. Urinary ascorbic acid concentrations as low as 40mg/dl can cause interference in specimens with low concentrations of glucose, blood, nitrite and bilirubin.

Urobilinogen: The absence of urobilinogen in the specimen can't be determined. The test area will react with interfering substances known to react with Ehrlich's reagent, such as p- aminosalicylic acid. Drugs containing azo gantrisin (sulfamethoxazol) or high Bilirubin may give a masking golden color. Preservative Formaldehyde may cause false negative. The test is not reliable method for the detection of porphobilinogen.

Glucose: Ascorbic acid (more than 40mg/dl) may cause false negative result at the low level of glucose. Ketones reduce the sensitivity of the test. Moderately high ketone level (> 40mg/dl) may cause a false negative for specimen containing small amount of glucose (100mg/dl). Chlorine Bleach (≥1%), low SG and formaldehyde urine may cause false positive result at the low level.

Bilirubin: Metabolites of drugs, such as selenium(≥220mg/dL), phenazopyridine(≥37mg/dL) may cause false positives. p-Amino salicylic acid(≥1500mg/dL) can produce a yellow-orange to red color response, which may interfere with the interpretation of false positive bilirubin readings. Ascorbic acid (≥40mg/dL) may cause false negative.

Ketones: Low level false positive reactions may be seen in highly concentrated urine specimens (high specific gravity) or in specimens containing large amounts of levodopa metabolites drug such as captopril. The uroprotective drug mesna (sodium 2-mercaptoethane sulfonate) and other free-sulfhydryl compounds produce false-positive results in ketone methods that are based on the Legal reaction (alkaline sodium nitroprusside).

pH: If the excessive urine remains on the strip because of improper test procedure, it is possible that the acidic buffer in protein portion comes out and affect the pH portion, then pH result may be decreased than the actual. This phenomenon is called" run-over effect."

Blood: Elevated specific gravity or protein in urine may reduce the reactivity of the blood test portion. Microbial peroxidase associated with urinary tract infection may cause false positive results. Ascorbic acid concentrations (>30 mg/dl) may cause

false negatives at the low level of blood. Substances that cause abnormal urine color, such as drug containing azo dyes, nitrofurantoin and riboflavin may cause false positive result. Strong oxidizing cleaning agents such as chlorine bleach cause false positive results.

Specific Gravity (SG): High-buffered alkaline urine may cause diminished result, whereas high- buffered acidic urine may cause slightly elevated result.

Protein: False positive results may be found in strongly basic urine (pH 9). The interpretation of results is also difficult in turbid urine specimens. Metabolites of drugs, such as acetaminophen, hemoglobin may cause false positives. Pigments such as bilirubin and azo-containing compounds cause false result with the color reaction.

Nitrite: Ascorbic acid (>40mg/dL) may cause false negative result with low level of nitrite containing (<0.03mg) urine. The negative result does not always mean that the patient is free from bacteriuria. Pink spots or pink edges should not be interpreted as a positive result. Medication such as phenazopyridine or other azo-containing compounds or other dyes cause false positive results.

Leukocyte: The test result may not always be consistent with the leukocyte cell number by the microscopic examination. Strong oxidizing agents such as chlorine bleach and formaldehyde may cause positive reactions. Decreased results may be seen with elevated glucose (≥1500mg /dl), high specific gravity, oxalic acid and high level of albumin(≥1000mg/dL). Drugs causing decreased or false negative results include tetracycline, captopril. Substance that color urine, such as a nitrofurantoin, riboflavin, selenium and bilirubin, may cause false positive results.

Microalbumin: The following substances may cause false positive results; a large amount of hemoglobin(≥5mg/dl), visibly bloody urine, highly alkaline urine(pH≥9), disinfectant including quaternary ammonium compound. Substances that cause abnormal urine color, such as drug containing nitrofurantoin, riboflavin may affect the results (false positives).

Creatinine: Nitrofurantoin(≥200mg/L), Riboflavin(≥50mg/L) and a large amount of hemoglobin(≥5mg/dl) cause false positive results. Visibly dark brown color urine may affect the results (false positives). Substances that cause abnormal urine color, such as drug containing nitrofurantoin, riboflavin may affect the results (false positives).

Microalbumin to Creatinine Ratio: A low microalbumin result(10mg/L) in combination with strongly diluted urine (creatinine result of 10mg/dl) could indicate a microalbumin concentration below the sensitivity limit. In that case, consider testing a new specimen, preferably a first morning collection, for greater confidence in the result.

f. Method Comparison study

The method comparison study was conducted at three clinical sites with a total of 867 samples. The results from the DUS R-50S urine chemistry system (DUS R-50S instrument, DUS10 and DUS2AC reagent strips) was compared to the predicate device (Siemens Clinitek Status + urine chemistry instrument using Multistix 10SG and CLINITEK Microalbumin 2 test strips). The results of the method comparison study for combined sites are shown in the tables below:

URO (Total)		Predicate device (mg/dl)				
New device (mg/dl)	8				3	41
	4			2	86	
	2			115	1	
	1		84			
	Norm	535				
		Norm	1	2	4	8
Total		535	84	117	90	41
Exact agreement		100%	100%	98%	96%	100%
Within One Block		100%	100%	100%	100%	100%

GLU (Total)		Predicate device (mg/dl)					
New device (mg/dl)	2000						24
	1000				1	41	
	500			2	59		
	250		1	71	3		
	100		71				
	NEG	594					
		NEG	100	250	500	1000	2000
Total		594	72	73	63	41	24
Exact agreement		100%	99%	97%	94%	100%	100%
Within One Block		100%	100%	100%	100%	100%	100%

BIL (Total)		Predicate device (mg/dl)			
New device (mg/dl)	4				46
	2		4	87	1
	1		82	3	
	NEG	644			
		NEG	1	2	4
Total		644	86	90	47
Exact agreement		100%	95%	97%	98%
Within One Block		100%	100%	100%	100%

KET (Total)		Predicate device (mg/dl)					
New device (mg/dl)	160						9
	80				3	39	
	40				60		
	15			86	1		
	5		60	7			
	NEG	602					
		NEG	5	15	40	80	160
Total		602	60	93	64	39	9
Exact agreement		100%	100%	92%	94%	100%	100%
Within One Block		100%	100%	100%	100%	100%	100%

BLD (Total)		Predicate device (RBC/ul)				
New device (RBC/ul)	200				4	159
	80			8	150	1
	25		7	143	5	
	10		159	1		
	NEG	228				
		NEG	10	25	80	200
Total		228	166	154	159	160
Exact agreement		100%	96%	94%	94%	99%
Within One Block		100%	100%	100%	100%	100%

PRO (Total)		Predicate device (mg/dl)					
New device (mg/dl)	1000					1	17
	300				4	51	
	100			5	104		
	30		4	125	1		
	15		133	2			
	NEG	419					
		NEG	15	30	100	300	1000
Total		419	137	133	109	52	17
Exact agreement		100%	97%	95%	95%	98%	100%
Within One Block		100%	100%	100%	100%	100%	100%

NIT (Total)		Predicate device		
New device	Pos			311
	Trace		125	4
	NEG	427		
		NEG	Trace	Pos
Total		427	125	315
Exact agreement		100%	100%	99%
Within One Block		100%	100%	100%

LEU (Total)		Predicate device(WBC/ul)				
New device (WBC/ul)	500				2	108
	125			3	136	6
	70			122	4	
	15		105	2		
	NEG	379				
		NEG	15	70	125	500
Total		379	105	127	142	114
Exact agreement		100%	100%	96%	96%	95%
Within One Block		100%	100%	100%	100%	100%

PH (Total)		Predicate device						
New device	8.5						5	42
	8					5	103	
	7.5				7	106	3	
	7			3	151	5		
	6.5		5	182	2			
	6	1	143	7				
	5	91	6					
		5	6	6.5	7	7.5	8	8.5
Total		92	154	192	160	116	111	42
Exact agreement		99%	93%	95%	94%	91%	93%	100%
Within One Block		100%	100%	100%	100%	100%	100%	100%

SG (Total)		Predicate device						
New device	1.030						5	82
	1.025					5	107	
	1.020				8	167	2	
	1.015			5	166	7		
	1.010		5	147	5			
	1.005		104	4				
	1.000	50						
		1.000	1.005	1.010	1.015	1.020	1.025	1.030
Total		50	109	156	177	179	114	82
Exact agreement		100%	95%	94%	94%	93%	94%	100%
Within One Block		100%	100%	100%	100%	100%	100%	100%

CRE(Total)		Predicate device(mg/dl)				
New device (mg/dl)	300				7	188
	200			7	191	11
	100		9	198	9	
	50		151	6		
	10	90				
		10	50	100	200	300
Total		90	160	211	207	199
Exact agreement		100%	94%	94%	92%	94%
Within One Block		100%	100%	100%	100%	100%

MA(Total)		Predicate device(mg/L)			
New device (mg/dl)	15				445
	8		3	98	3
	3		72	8	
	1	238			
		1	3	8	15
Total		238	75	106	448
Exact agreement		100%	96%	92%	99%
Within One Block		100%	100%	100%	100%

All of the coefficient of correlation estimated among (MultiStix 10SG vs DUS10 / CLINITEK Microalbumin 2 Vs DUS 2AC) is statistically significant at 1% level. A comparison results between DUS R-50S and CLINITEK Status urinalysis analyzer revealed a very high concordance of between 90-100%. It results were obtained by 867 samples at 3 hospitals.
The majority of analysis display 90-100 % concordance over all blocks on comparing the results of primary diagnosis. When the results, which fall between neighboring blocks, are taken into account, concordance increases to around 95-100%.

Analyte	Exact agreement (%)	Within one block (%)
Urobilinogen	99.3	100
Glucose	99.2	100
Bilirubin	99	100
Ketones	98.7	100
Blood	97	100
Protein	98	100
Nitrite	99.5	100
Leukocytes	98	100
pH	94.3	100
Specific Gravity	94.9	100
Creatinine	94.3	100
Microalbumin	98.4	100

G. Expected values/Reference range:

Urobilinogen: The normal urobilinogen range is 0.1 to 1.0 Ehrlich unit /dl. If results exceed the concentration of 2.0 mg/dl, the patient and the urine specimen should be evaluated further.

Glucose: The kidney normally excretes small amounts of glucose. Concentrations of 100mg/dl may be considered as abnormal if found consistently.
Bilirubin: Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation.

Ketones: Ketone bodies should not be detected in normal urine specimens with this reagent.

pH: Urine values generally range from pH 4.5 - 8.

Blood: Normally, no hemoglobin is detectable in urine. When hemoglobin appears in urine it may indicate kidney disease or a urinary tract disorder. Blood may often be found in the urine of menstruating females.

Specific Gravity (SG): The normal SG of urine ranges from 1.001 to 1.035.

Protein: Normal urine specimens ordinarily contain some protein (<20mg/dL) therefore only persistent elevated levels of urine protein indicate kidney or urinary tract disease. The persistent results of trace level or over indicate significance proteinuria and thus further clinical testing is needed to evaluate the significant of results.

Nitrite: Normally no nitrite is detectable in urine.

Leukocyte: Normally no leukocytes are detectable in urine.

Microalbumin: Normal albumin excretion in urine is under 30 mg/day.

Microalbuminuria is indicated with results of > 30 mg/day.

Creatinine: The urine of healthy individuals contains creatinine. Generally, healthy individuals excrete 1g creatinine per day. Very low creatinine results can be caused by adulteration of the urine specimen or by severe renal failure.

Microalbumin to Creatinine Ratio: Microalbumin is normally present in urine at concentrations of less than 30mg albumin/g creatinine. Microalbuminuria is indicated

-*Levey AS, Coresh J, Balk E, et al. National Kidney Foundation practice guidelines for chronic kidney disease: evaluation, classification, stratification.* Ann Intern Med. 139:137-147; 2003

Conclusion

DUS R-50S (Urine Chemistry System) has the same device characteristics as the predicate device. The results of the testing show that the new device is substantially equivalent to the predicate device.