May 23, 2018

DFI Co., Ltd.
% Ho Dong Yang, CEO
Onbix Corporation
#821 Samil Plaza, 14, Dogok-ro 1-Gil, Gangnam-gu
Seoul, 06523
Korea

Re: K181024
Trade/Device Name: DUS 2GP Reagent Strips, DUS 5 Reagent Strips, DUS 10 Reagent Strips
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIO, JIR, LJX, JMT, CDM, CEN, JRE, JIN, JJB
Dated: April 11, 2018
Received: April 18, 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,

Kellie B. Kelm -S

for 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)*
K181024

Device Name
DUS 2GP Reagent Strips, DUS 5 Reagent Strips, DUS 10 Reagent Strips

Indications for Use *(Describe)*

DUS 2GP Reagent Strips, DUS 5 Reagent Strips, DUS 10 Reagent Strips
This device is intended for the in vitro measurement of the following in urine: Leukocyte, Nitrite, Urobilinogen, Protein, pH, Blood, Specific gravity, Ketone, Bilirubin, Glucose. These strips are intended for prescription, in vitro diagnostic use only and they are visually read.

DUS 2GP reagent strips provide qualitative and semiquantitative measurements for protein, and glucose in urine specimens. Test results may provide information regarding the status of carbohydrate metabolism and kidney function.

DUS 5 reagent strips provide qualitative and semiquantitative measurements for leukocytes, nitrite, blood , protein, and glucose in urine specimens. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies and urinary tract infections.

DUS 10 reagent strips provide qualitative and semiquantitative measurements for specific gravity, pH, leukocytes, nitrite, protein, glucose, ketone, urobilinogen, bilirubin and blood in urine specimens. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function.

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 [K181024]

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

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Date Summary Prepared: May 17, 2018

Device Information:

Trade Name(s): DUS 2GP Reagent Strips, DUS 5 Reagent Strips, DUS 10 Reagent Strips
Common Name: urinary test system
Panel: clinical chemistry

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
Urinary Protein or Albumin (nonquantitative) test system	21 CFR 862.1645	JIR	I
Leukocyte peroxidase test	21 CFR 864.7675	LJX	I
Nitrite (nonquantitative) test system	21 CFR 862.1510	JMT	I
Urinary Urobilinogen (nonquantitative) test system	21 CFR 862.1785	CDM	I
Urinary pH (nonquantitative) test	21 CFR 862.1550	CEN	I
Specific Gravity	21CFR 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

Predicate Device Information:

K992257 / MULTISTIX 10 SG

Device Description:

DUS 2GP Reagent Strips, DUS 5 Reagent Strips, DUS 10 Reagent Strips
The DUS Series are urine test strips with different reagent pads for the determination of specific gravity, pH, leukocytes, nitrite, protein, glucose, ketone, urobilinogen, bilirubin and blood affixed onto plastic strips. of which leukocyte, nitrite, urobilinogen, protein, pH, blood, specific gravity, ketone, bilirubin and glucose reagent pads are affixed onto the plastic strips. The reagent pads react with analytes in the urine giving a visible color. Results are confirmed by comparison of the test strip with the color chart on the container. For each color result for each analyte, a semiquantitative value is available on the box label (e.g. bilirubin results include negative, 1, 2, and 4 mg/dL) and the associated qualitative result (e.g. bilirubin results include negative, +, ++, +++).

Indications for Use:

This device is intended for the in vitro measurement of the following in urine: Leukocyte, Nitrite, Urobilinogen, Protein, pH, Blood, Specific gravity, Ketone, Bilirubin, Glucose. These strips are intended for prescription, in vitro diagnostic use only and they are visually read.

DUS 2GP reagent strips provide qualitative and semiquantitative measurements for protein and glucose in urine specimens. Test results may provide information regarding the status of carbohydrate metabolism and kidney function.

DUS 5 reagent strips provide qualitative and semiquantitative measurements for leukocytes, nitrite, blood, protein, and glucose in urine specimens. These measurements are used to aid in the diagnosis of metabolic disorders and kidney function anomalies and urinary tract infections.

DUS 10 reagent strips provide qualitative and semiquantitative measurements for specific gravity, pH, leukocytes, nitrite, protein, glucose, ketone, urobilinogen, bilirubin a n d blood in urine specimens. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function.

Comparison to Predicate Device(s):

This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

- indications for use
- technological characteristics
- performance properties

Summary of testing:

The performance characteristics of the candidate strips were verified by method comparison, precision, detection limit, interference and specificity studies.

Testing is summarized below.

1. Performance Characteristics

DUS 10 reagent strips were used for all analytical studies, because DUS 2GP and DUS 5 reagent strips contain subsets of the analytes in the DUS 10 reagent strips.

a) Precision/Reproducibility

Precision testing was done in accordance with CLSI EP5-A3.. The repeatability/ reproducibility were determined at three clinical sites, using commercially available control solutions. Studies were performed by medical technicians, using 2 levels of commercially available urine based control solutions. For within-run precision studies, 10 test strips from 3 different lots at 3 sites were tested (30 tests at each site = 90 replicates per level). For within-day precision studies, 1 test strip a day from 3 different lots was tested at 3 sites for 10 days (30 tests at each site = 90 replicates per level). The results are summarized below:

Level 1 control					
		Within-run (n=90)		**Within-day (n=90)**	
Item	**Test Results**	**Exact agreement (%)**	**Agreement within +/-one block(%)**	**Exact agreement (%)**	**Agreement within +/-one block(%)**
Urobilinogen	Normal	100	100	100	100
Glucose	Negative	100	100	100	100
Bilirubin	Negative	100	100	100	100
Ketones	Negative	100	100	100	100
SG	1.020	100	100	100	100
Blood	Negative	100	100	100	100
pH	6	100	100	100	100
Protein	Negative	100	100	100	100
Nitrite	Negative	100	100	100	100
Leukocytes	Negative	100	100	100	100

Level 2 control					
		Within-run (n=90)		**Within-day (n=90)**	
Item	**Test Results**	**Exact agreement (%)**	**Agreement within +/-one block(%)**	**Exact agreement (%)**	**Agreement within +/-one block(%)**
Urobilinogen	4mg/dL	100	100	100	100
Glucose	1000mg/dL	100	100	100	100
Bilirubin	4mg/dL	100	100	100	100
Ketones	40mg/dL	100	100	100	100
SG	1.020	98.9	100	100	100
Blood	200 RBC/uL	100	100	100	100
pH	7	100	100	98.9	100
Protein	100 mg/dL	100	100	100	100
Nitrite	Pos	100	100	100	100
Leukocytes	70 WBC/uL	100	100	100	100

b) *Linearity /assay reportable range.*

Linearity / assay reportable range was evaluated in-house. Samples were created by spiking known concentration of each standard material or by serial dilution of a high concentration urine sample with negative urine. Testing was performed by 3 medical technicians using 3 lots of test strips. Each concentration level was tested in 10 replicates with each lot of test strips. The results are summarized below:

Analyte	**Urine sample concentration**	**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	97.7 % (88/90)
	4 mg/dL	4 mg/dL	98.8 % (89/90)
	8 mg/dL	8 mg/dL	98.8 % (89/90)
Glucose	Negative	Neg.	100 % (90/90)
	100 mg/dL	±(100 mg/dL)	100 % (90/90)
	250 mg/dL	+(250 mg/dL)	97.7 % (88/90)
	500 mg/dL	++(500 mg/dL)	98.8 % (89/90)
	1000 mg/dL	+++(1000 mg/dL)	97.7 % (88/90)
	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	++	96.6 % (87/90)
	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)	97.7 % (88/90)
	40 mg/dL	++(40 mg/dL)	98.8 % (89/90)
	80 mg/dL	+++(80 mg/dL)	98.8 % (89/90)
	160 mg/dL	++++(160 mg/dL)	100 % (90/90)

Analyte	Urine sample concentration	Color block output	% Exact match
Specific gravity	1.000	1.000	100 % (90/90)
	1.005	1.005	94.4 % (85/90)
	1.010	1.010	100 % (90/90)
	1.015	1.015	96.6 % (87/90)
	1.020	1.020	97.7 % (88/90)
	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)	98.8 % (89/90)
	80 RBC/µL	++(80 RBC/µL)	100 % (90/90)
	200 RBC/µL	+++(200 RBC/µL)	100 % (90/90)
pH	5	5	100 % (90/90)
	6	6	98.8 % (89/90)
	6.5	6.5	98.8 % (89/90)
	7	7	97.7 % (88/90)
	7.5	7.5	97.7 % (88/90)
	8	8	98.8 % (89/90)
	8.5	8.5	100% (90/90)
Protein	Negative	Neg.	100 % (90/90)
	15 mg/dL	Trace	98.8 % (89/90)
	30 mg/dL	+(30 mg/dL)	98.8 % (89/90)
	100 mg/dL	++(100 mg/dL)	96.6 % (87/90)
	300 mg/dL	+++(300 mg/dL)	97.7 % (88/90)
	100 mg/dL	++++(1000 mg/dL	100 % (90/90)
Leukocytes	Negative	Neg.	100 % (90/90)
	15 WBC/µL	Trace	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)	100 % (90/90)

c) Detection limit

A sensitivity study was performed to evaluate the limits of detection for each of the analytes. Negative urine was spiked with standard materials to obtain 3 levels across the measuring range for each analyte concentration. 90 replicates were obtained for each concentration (each sample concentration was analyzed 30 times using 3 reagent strip lots). Sensitivity was defined as the cutoff for which ≥95% of the contrived pooled measurements were trace or the first positive result.

Urobilinogen			
Conc.	**Negative**	**Positive (+ 2mg/dL)**	**Positive Agreement (%)**
1.8 mg/dL	8	82	91.1%
2 mg/dL	0	90	100%
2.3 mg/dL	0	90	100%
Result cut off	2 mg/dL		

Glucose			
Conc.	**Negative**	**Positive (± 100mg/dL)**	**Positive Agreement (%)**
80 mg/dL	5	85	94.4%
100 mg/dL	0	90	100%
120 mg/dL	0	90	100%
Result cut off	100mg/dL		

Bilirubin			
Conc.	**Negative**	**Positive (+ 1.0mg/dL)**	**Positive Agreement (%)**
0.8 mg/dL	6	84	93.3%
1.0 mg/dL	0	90	100%
1.2 mg/dL	0	90	100%
Result cut off	1.0 mg/dL		

Ketones			
Conc.	**Negative**	**Positive (± 5mg/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			
Conc.	**Negative**	**Positive (±5 RBC/µL)**	**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			
Conc.	**Negative**	**Positive (±15 mg/dL)**	**Positive Agreement (%)**
12mg/dL	6	84	93.3%
15mg/dL	0	90	100%
18mg/dL	0	90	100%
Result cut off	15mg/dL		

Nitrite			
Conc.	**Negative**	**Positive (0.05 mg/dL)**	**Positive Agreement (%)**
0.04mg/dL	6	84	93.3%
0.05mg/dL	0	90	100%
0.06mg/dL	0	90	100%
Result cut off	0.05mg/dL		

Leukocytes			
Conc.	**Negative**	**Positive (Trace 15WBC/µL)**	**Positive Agreement (%)**
12 WBC/ µL	5	85	94.4%
15 WBC/ µL	0	90	100%
18WBC/ µL	0	90	100%
Result cut off	15 WBC/µL		

The reportable ranges for each analyte are summarized below:

Test	**Reportable Range**
Urobilinogen	Qualitative: normal to 3+ Semi-quantitative: 0.1 to 8 mg/dL
Glucose	Qualitative: Negative to 4+ Semi-quantitative : Negative to 2000 mg/dL
Bilirubin	Qualitative: Negative to 3+ Semi-quantitative : Negative to 4 mg/dL
Ketones	Qualitative: Negative to 4+ Semi-quantitative : Negative to 160 mg/dL
Specific Gravity	Semi-quantitative : 1.000 to 1.030
Blood	Qualitative: Negative to 3+ Semi-quantitative : Negative to 200 RBC/ µL
pH	Semi-quantitative : 5 to 8.5
Protein	Qualitative: Negative to 4+ Semi-quantitative : Negative to 1000 mg/dL
Nitrite	Qualitative: Negative to Pos Semi-quantitative : Negative to 10 mg/dL
Leukocytes	Qualitative: Negative to 3+ Semi-quantitative : Negative to 500 WBC/µL

d) Analytical specificity

Potential interferents and drugs were evaluated to assess their interfering effect on the performance of DUS 10 test strips. Urine sample pools prepared at 3 analyte concentrations (negative, low positive and high positive) were spiked with potential interfering substances at various interference concentrations and analyzed in 3 replicates using 3 lots of DUS 10 test strips. Interference was defined as change in output of ±1 color block between the spiked and unspiked control sample. 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
Nitrofurantoin	10 mg/dL
Oxalic acid	30 mg/dL
p-amino 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

The following table shows the substances that did interfere with one more of the analytes tested with the DUS 10 test strips. Results are expressed as the lowest concentration of interfering substances that exhibit interference and the resulting change in output of color block:

Analyte	Potential Interfering Substance	Concentration at which Interference was observed	Change in color block output
Urobilinogen	Azo gantrinsin (Sulfamethoxazol)	≥105mg/dL	+1
	Bilirubin	≥4mg/dL	+1
	Formaldehyde	≥150mg/dL	-1
	Nitrofurantoin	≥40mg/dL	+1
	p-Amino salicylic acid	≥750mg/dL	+1
	Phenazopyridine	≥37mg/dL	+1
	Riboflavin	≥25mg/dL	+1
	Selenium	≥220mg/dL	+1
Glucose	Ascorbic Acid	≥40mg/dL	-1
	Bilirubin	≥6mg/dL	+1
	Chlorine Bleach	≥1%	+1
	Formaldehyde	≥150mg/dL	+1
	Lithium	≥40mg/dL	-1
	NaCl (Specific gravity)	≤1.000	+1
Bilirubin	Ascorbic Acid	≥40mg/dL	-1
	p-Amino salicylic acid	≥1500mg/dL	+1
	Phenazopyridine	≥37mg/dL	+1
	Selenium	≥220mg/dL	+1
Ketones	Bilirubin	≥4mg/dL	+1
	Captopril	≥150mg/dL	+1
	NaCl (Specific gravity)	≥1.040	+1
Blood	Albumin	≥1000mg/dL	-1
	Ascorbic Acid	≥30mg/dL	-1
	Bilirubin	≥6mg/dL	+1
	Captopril	≥150mg/dL	-1
	Chlorine Bleach	≥0.5%	+1
	Formaldehyde	≥150mg/dL	+1
	NaCl (Specific gravity)	≥1.040	-1
	Nitrofurantoin	≥30mg/dL	+1
	Riboflavin	≥50mg/dL	+1
	Urobilinogen	≥20mg/dL	-1
pH	-	-	-
Specific Gravity	pH	≥8	+1

Protein	Acetaminophen	50mg/dL	+1
	Bilirubin	≥6mg/dL	+1
	Hemoglobin	≥5mg/dL	+1
	Nitrofurantoin	≥20mg/dL	+1
	Riboflavin	≥25mg/dL	-1
	Urobilinogen	≥20mg/dL	-1
	pH	≥9	+1
Nitrite	Ascorbic Acid	≥40mg/dL	-1
	Bilirubin	≥4mg/dL	+1
	Nitrofurantoin	≥20mg/dL	+1
	Phenazopyridine	≥37mg/dL	+1
	Riboflavin	≥50mg/dL	+1
	Selenium	≥300mg/dL	+1
	Urobilinogen	≥15mg/dL	+1
Leukocytes	Albumin	≥1000mg/dL	-1
	Bilirubin	≥4mg/dL	+1
	Captopril	≥150mg/dL	-1
	Chlorine Bleach	≥0.5%	+1
	Formaldehyde	≥150mg/dL	+1
	NaCl (Specific gravity)	≥1.040	-1
	Nitrofurantoin	≥30mg/dL	+1
	Oxalic Acid	≥45mg/dL	-1
	Glucose	≥1500mg/dL	-1
	Phenazopyridine	≥50mg/dL	+1
	Riboflavin	≥37mg/dL	+1
	Selenium	≥300mg/dL	+1
	Tetracycline	≥40mg/dL	-1
	Urobilinogen	≥15mg/dL	+1

The labeling includes the following limitations to address the interferences observed:

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 cannot 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 negatives. The test is not reliable method for the detection of porphobilinogen.

Glucose: Ascorbic acid (≥40 mg/dL) may cause false negative results at low levels (100 mg/dL) of glucose. Ketones reduce the sensitivity of the test. Moderately high ketone levels (≥40 mg/dL) may cause false negatives for specimens containing a small amount of glucose (100 mg/dL). Chlorine Bleach (≥1%), low SG (≤1.000) and formaldehyde (≥150 mg/dL) may cause false positive results.

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

Ketones: Low level false positive reactions may be seen in highly concentrated urine specimens (SG≥1.004) or in specimens containing large amounts of levodopa drug metabolites 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 excessive urine remains on the strip because of improper test procedure, it is possible that the acidic buffer in the protein pad comes out and affects the neighboring pH pad, decreasing the measured pH. This phenomenon is called "run-over effect."

Blood: Elevated specific gravity (≥1.040) or protein in urine (≥1000 mg/dL) may reduce the sensitivity of the blood test pad leading to lower results. Microbial peroxidase associated with urinary tract infections may cause false positive results. Ascorbic acid concentrations (≥30 mg/dl) may cause false negatives at trace levels of blood. Substances that cause abnormal urine color, such as drugs 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**):** Alkaline urine (pH≥8) may cause false positive results.

Protein: False positive results may be found in strongly basic urine (pH≥9). Protein testing should not be performed using turbid urine specimens. Metabolites of drugs such as acetaminophen may cause false positives. Hemoglobin may also cause false positives.

Pigments such as bilirubin and azo-containing compounds cause false positive results.

Nitrite: Ascorbic acid (≥40mg/dL) may cause false negative results with urine containing low levels of nitrite (≤0.05mg/dL). The negative result does not always mean that the patient is free from bacteriuria. Pink spots or pink edges should not be interpreted as positive results. Medications such as phenazopyridine or other azo-containing compounds or other dyes cause false positive results.

Leukocyte: The test results may not always be consistent with the leukocyte cell number by the microscopic examination. Strong oxidizing agents such as chlorine bleach (≥0.5%) and formaldehyde (≥150 mg/dL) may cause false positive results. Falsely low results may be seen with elevated glucose (≥1500 mg/dL), high SG (≥1.040), oxalic acid (≥45 mg/dL) and high level of albumin (≥1000 mg/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.

2. Method Comparison study

The method comparison study was conducted at three clinical sites with a total of867 samples. Three medical technicians performed the testing at each site. Fresh urine samples were obtained at each medical facility and the samples were processed within 4 hours. The results from the DUS 10 test strips were compared to the predicate device (Multistix 10SG). The results of the method comparison study for the combines sites are shown in the tables below:

Results for urinary urobilinogen (URO):

URO (Total)	**Predicate device (mg/mL)**				
New device (mg/mL)	**Norm**	**1**	**2**	**4**	**8**
8				5	39
4			4	83	2
2		4	112	2	
1		80	1		
Norm	535				
Total	535	84	117	90	41
Exact agreement	100%	95%	96%	92%	95%
Within 1 block	100%	100%	100%	100%	100%

Results for urinary glucose (GLU):

GLU (Total)	Predicate device (mg/mL)					
New device (mg/mL)	**Neg**	**100**	**250**	**500**	**1000**	**2000**
2000					1	23
1000				2	38	1
500			2	58	2	
250		2	70	3		
100		70	1			
Neg	594					
Total	594	72	73	63	41	24
Exact agreement	100%	97%	96%	92%	93%	96%
Within 1 block	100%	100%	100%	100%	100%	100%

Results for urinary Bilirubin (BIL):

BIL (Total)	Predicate device (mg/mL)			
New device (mg/mL)	**Neg**	**1**	**2**	**4**
4			3	44
2		4	83	3
1		82	4	
Neg	644			
Total	644	86	90	47
Exact agreement	100%	95%	92%	94%
Within 1 block	100%	100%	100%	100%

Results for urinary Ketones (KET):

KET (Total)	Predicate device (mg/mL)					
New device (mg/mL)	**Neg**	**5**	**15**	**40**	**80**	**160**
160						9
80				4	37	
40				59	2	
15		2	85			
5		58	8			
Neg	602					
Total	602	60	93	63	39	9
Exact agreement	100%	97%	91%	94%	95%	100%
Within 1 block	100%	100%	100%	100%	100%	100%

Results for urinary Blood (BLD):

BLD (Total)	Predicate device (mg/mL)				
New device (mg/mL)	**Neg**	**10**	**25**	**80**	**200**
200				8	153
480			8	146	7
225		9	141	5	
10		157	5		
Neg	228				
Total	228	166	154	159	160
Exact agreement	100%	95%	92%	92%	96%
Within 1 block	100%	100%	100%	100%	100%

Results for urinary Protein (PRO):

PRO (Total)	Predicate device (mg/mL)					
New device (mg/mL)	**Neg**	**15**	**30**	**100**	**300**	**1000**
1000					2	16
300				5	49	1
100			6	101	1	
30		2	125	3		
15		125	2			
Neg	419					
Total	419	137	133	109	52	17
Exact agreement	100%	91%	94%	93%	94%	94%
Within 1 block	100%	100%	100%	100%	100%	100%

Results for urinary Nitrite (NIT):

NIT (Total)	Predicate device (mg/mL)		
New device (mg/mL)	**Neg**	**Trace**	**Pos**
Pos		4	309
Trace		121	6
Neg	427		
Total	427	125	315
Exact agreement	100%	97%	98%
Within 1 block	100%	100%	100%

Results for urinary Leukocytes (LEU):

LEU (Total)	**Predicate device (mg/mL)**				
New device (mg/mL)	**Neg**	**15**	**70**	**125**	**500**
500				4	106
125			5	131	8
70		6	119	6	
15		100	3		
Neg	379				
Total	379	106	127	141	114
Exact agreement	100%	94%	94%	93%	93%
Within 1 block	100%	100%	100%	100%	100%

Results for urinary pH (pH):

pH (Total)	**Predicate device (mg/mL)**						
New device (mg/mL)	**5**	**6**	**6.5**	**7**	**7.5**	**8**	**8.5**
8.5						5	39
8					5	102	3
7.5				9	106	4	
7			6	148	5		
6.5		8	176	3			
6	3	140	10				
5	89	6					
Total	92	154	192	160	116	111	42
Exact agreement	97%	91%	92%	93%	91%	92%	93%
Within 1 block	100%	100%	100%	100%	100%	100%	100%

Results for urinary Specific Gravity (SG):

SG (Total)	Predicate device (mg/mL)						
New device (mg/mL)	**1.000**	**1.005**	**1.010**	**1.015**	**1.020**	**1.025**	**1.030**
1.030						6	77
1.025					6	105	5
1.020				9	166	3	
1.015			7	161	7		
1.010		9	144	7			
1.005	1	100	5				
1.000	49	0					
Total	50	109	156	177	179	114	82
Exact agreement	98%	92%	92%	91%	93%	92%	94%
Within 1 block	100%	100%	100%	100%	100%	100%	100%

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 greater indicate significance proteinuria and thus further clinical testing is needed to evaluate the significance of results.

Nitrite: Normally no nitrite is detectable in urine.

Leukocyte: Normally no leukocytes are detectable in urine.

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

The new device (DUS 2GP Reagent Strips, DUS 5 Reagent Strips, DUS 10 Reagent Strips) 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.