510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k171521

B. Purpose for Submission:

New Device

C. Measurand:

Measurement of the following analytes in urine: glucose, blood, creatinine, microalbumin, leukocytes, nitrites, urobilinogen, protein, pH, specific gravity, ketones, bilirubin

D. Type of Test:

Qualitative and semi-quantitative urinalysis

E. Applicant:

DFI Co., Ltd.

F. Proprietary and Established Names:

DUS R-50S (Urine Chemistry System)

G. Regulatory Information:

1. Regulation section:

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 (nonquantitative) test system	21 CFR 862.1785	CDM	I
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

2. Panel:

   Chemistry (75)

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   See indications for use statement below.

2. Indication(s) for use:

   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.

3. Special conditions for use statement(s):

   For prescription use only.

   For in vitro diagnostic use only.

4. Special instrument requirements:

   DUS R-50S Analyzer

   Device Description:

   The DUS R-50S (Urine Chemistry System) consist of the DUS R-50S Analyzer and the DUS Series Urine reagent strips (DUS 10 reagent strips and the DUS 2AC reagent strips). The DUS R-50S Analyzer is a semi-automated urine chemistry analyzer. The analyzer uses the principle of light-reflection. The strip is illuminated by white light and the reflected light from the strip is detected by the sensor. The RGB signals are digitized and this digitized image is interpreted by the processor. The parameter values are determined based on the changes in the pad color. The DUS R-50S Urine Chemistry system reports qualitative and semi-quantitative results including the date and time of the measurement, sequence number and ID stored in the analyzer.

   DUS Urine reagent strips are plastic strips with different reagent pads affixed for the determination of leukocyte, nitrite, urobilinogen, protein, pH, blood, specific gravity, ketone, bilirubin, glucose, microalbumin and creatinine in urine. The DUS Series Urine reagent strips contain the following multi-parameter strip:

   - 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Siemens Clinitek Status + Urine Chemistry Analyzer (Multistix 10SG)

2. Predicate 510(k) number(s):

   k091216

3. Comparison with predicate:

Similarities and Differences		
Item	Subject Device k171521	Predicate Device k091216 Clinitek Status
Intended Use	Qualitative and semi-quantitative measurement of glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocyte esterase, creatinine and microalbumin	Same
Measurands	Glucose, bilirubin, ketone, specific gravity, ketones, blood, pH, protein, urobilinogen, nitrite, leukocyte, creatinine and microalbumin	Albumin, bilirubin, blood (occult), creatinine, glucose, ketone, leukocytes, nitrite, pH, protein, protein-to-creatinine ratio, albumin-to-creatinine ratio, specific gravity, urobilinogen and human chorionic gonadotropin (hCG)
Sample type	Human urine	Same
Data type	Qualitative and semi-quantitative	Same
Instrument Optical System	Reflectance photometer	Same
Display	Touch screen	Same
Test strip	DUS 10 and DUS 2AC	Multistix 10 SG
Assay reaction time	60 seconds	Same

K. Standard/Guidance Document Referenced (if applicable):

CLSI-Evaluation of Precision Performance of Clinical Chemistry Devices-EP05-A3
CLSI-Evaluation of Linearity of Quantitative Analytical Methods-EP06-A
CLSI-Interference Testing in Clinical Chemistry-EP07-A2
CLSI-Method Comparison and Bias Estimation Using Patients Samples-EP09-A2

L. Test Principle:

Urobilinogen: The test is based on the Ehrlich's reaction. Color changes from light orange-pink to dark pink.

Glucose: Glucose oxidase catalyzes the oxidation of glucose to form hydrogen peroxide. The hydrogen peroxide thus formed then oxidizes a chromogen on the reaction pad by the action of peroxidase.

Bilirubin: Azo-coupling reaction of bilirubin with a diazonium salt in an acid medium to form an azo dye. Color changes from light tan to beige or light pink.

Ketones: The test is based on the Legal's test-nitroprusside reaction. Acetoacetic acid in an alkaline medium reacts with nitroferricyanide to produce a color change from beige to purple.

pH: The test is based on the double indicator system. Indicator's methyl red and bromothymol blue are used to give distinct color changes from orange to green to blue.

Blood: The test is based on the pseudo-peroxidase activity of the heme moiety of hemoglobin and myoglobin. The chromogen is oxidized by a hydroperoxide in the presence of heme and changes color from yellow to blue.

Specific Gravity (SG): Ionic solutes present in the urine cause protons to be released from a polyelectrolyte. As the protons are released the pH decreases and produces a color change of bromothymol blue from blue-green to yellow-green.

Protein: The test is based on the protein-error of-indicators reaction. When pH is held constant by a buffer, indicator dyes release H+ ions because of the protein present and change color from yellow to blue green.

Nitrite: The test is based on the diazotization reaction of nitrite with an aromatic amine to produce a diazonium salt. It is followed by an azo-coupling reaction of this diazonium salt with an aromatic compound on the reaction pad. The azo dye produced causes a color change from white to pink.

Leukocyte: This test pad contains an indoxyl ester and diazonium salt. It is followed by an azo-coupling reaction of the aromatic amine formed by leukocytes esterase with a diazonium salt on the reaction pad. The azo dye produced causes a color change from beige to violet.

Microalbumin: This test is based on dye binding using sulfonephthalein dye. At a constant pH, albumin binds with sulfonephthalein dye to develop a blue color. The resulting color ranges from pale green to aqua blue.

Creatinine: This test is based on the reaction of creatinine with a dye-metal complex. At an alkaline condition, creatinine reacts with a dye-metal complex to form a purplish brown color complex.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision testing was done in accordance with CLSI EP5-A3. The within-run and within-day precisions were performed by trained laboratory professionals at three clinical sites, using two levels of commercially available urine based quality control material. The studies utilized three DUS R-50S analyzers and three different lot numbers of DUS 10 and DUS 2AC reagent strips.

The within-run precision study was conducted by three laboratory professionals testing 2 levels of commercially available urine based quality control material. Ten test strips from three different lots at 3 sites were used in this study (30 tests at each site = 90 replicates per level). The within-day precision study was conducted by three laboratory professionals each testing one test strip a day from three different lots at 3 sites for ten days (30 tests at each site = 90 replicates per level).

The within-run and within-day precision studies for all 3 sites are summarized below:

Level 1 control					
		Within-run (90)		Within-day (90)	
Item	Expected test results	Exact agreement (%)	Agreement within +/-one block (%)	Exact agreement (%)	Agreement within +/-one block (%)
Urobilinogen	Normal	90/90 (100%)	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	Expected test results	Exact agreement (%)	Agreement within +/-one block (%)	Exact agreement (%)	Agreement within +/-one block (%)
Urobilinogen	4 mg/dL	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Glucose	1000 mg/dL	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 RBC/µL	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 WBC/µL	90/90 (100%)	90/90 (100%)	90/90 (100%)	90/90 (100%)
Creatinine	200mg/dL	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:

The linearity study was conducted following the recommendations in CLSI EP6-A. Samples were created by spiking known concentrations of each standard material into a negative urine pool or by serial dilution of a high concentration urine sample with negative urine.

Testing was performed on three instruments using three different lot numbers of test strips (DUS 2AC and DUS 10) by three laboratory professionals. Each sample was tested in 10 replicates with each lot of reagent strips.

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)
	30 mg/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/L	10 mg/L	100% (90/90)
	30 mg/L	30 mg/L	98.8% (89/90)
	80 mg/L	80 mg/L	97.7% (88/90)
	150 mg/L	150 mg/L	98.8% (89/90)
Creatinine	10 mg/L	10 mg/L	100% (90/90)
	50 mg/L	50 mg/L	100% (90/90)
	100 mg/L	100 mg/L	98.8% (89/90)
	200 mg/L	200 mg/L	96.6% (87/90)
	300 mg/L	300 mg/L	97.7% (88/90)

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability: No traceability is claimed

Calibration: The DUS R-50S Analyzer performs a "self-test" and calibration each time it is turned on. Each time a test is run, the analyzer re-calibrates using a white plastic calibration bar located at the upper end of the loading plate. Reflectance measurements from the bar must match the factory set calibration.

Self-life stability: The stability studies was performed to assess the shelf life (closed bottle) stability for the DUS Series Urine reagent strips on the DUS R-50S Analyzer. The protocol and acceptance criteria were reviewed and founds sufficient. The stability studies support the sponsors claim that the DUS Series Urine reagent strips, unopened, are stable for 26 months at 2-30 C° at <50% humidity.

Open vial stability: Open bottle stability studies were performed on the DUS Series Urine reagent strips used on the DUS R-50S Analyzer. The protocol and acceptance criteria were reviewed and found sufficient. Based on the studies, once opened the test strips are stable for 6 months when stored from 2-30 °C at <50% humidity.

Quality Control: No urine controls are provided with this device. In the labeling, the sponsor recommends the use of commercially available quality control material.

d. Detection limit:

A detection limit study was performed to determine the analytical sensitivity or the lowest concentration of each analyte that can be distinguished from negative. Urine samples were prepared by spiking a negative human urine pool with standard materials to create 3 levels across the measuring range for each analyte concentration.

Each samples concentration was analyzed 30 times using three reagent strip lots, on three DUS R-50S Analyzer. Sensitivity was defined as the cutoff which 95% of the contrived pool measurements were trace or positive. The detection limit study and the linearity study support the following reportable ranges for the DUS 10 reagent strips and the DUS 2AC reagent strips:

DUS 10 reagent strips:

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

DUS 2AC reagent strips

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

e. Analytical specificity:

Potential interferents and drugs were evaluated to assess the interfering effect on the performance of the DUS R-50S (Urine Chemistry System). A urine sample pools was prepared at 3 concentrations (negative, low positive and high positive) for each urine chemistry analyte. A negative urine pool was spiked with potential interfering substances at various interference concentrations and analyzed in three replicates using three lots of DUS strips (DUS10, DUS2AC) on three DUS R-50S analyzer. Interference was defined as change in output of ±1 color block between the spiked and unspiked control sample. The results of the interference studies are summarized 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 (sulfamethoxazole)	140 mg/dL
Bilirubin	3 mg/dL
Captopril	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
Formaldehyde	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 which did interfere with one or more of the

DUS Series Urine Reagent Strip analytes. Results are expressed as the lowest concentration of interfering substances that exhibited 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	≥4 mg/dL	+1
	Formaldehyde	≥150 mg/dL	-1
	Nitrofurantion	≥40 mg/dL	+1
	p-Amino salicylic acid	≥750 mg/dL	+1
	Phenazopridine	≥37 mg/dL	+1
	Riboflavin	≥25 mg/dL	+1
	Selenium	≥220 mg/dL	+1
Glucose	Sodium hypochlorite	≥1%	+1
	Formaldehyde	≥150 mg/dL	+1
	Lithium acetoacetate	≥40mg/L	-1
	Ascorbic acid	≥40 mg/dL	-1
	Bilirubin	≥6 mg/dL	+1
	Specific gravity	≥1.040	+1
Bilirubin	Selenium	≥220 mg/L	+1
	p-amino salicylic acid	≥12500 mg/L	+1
	Phenazoptridine	≥37 mg/L	+1
	Ascorbic acid	≥40 mg/dL	-1
Ketones	Bilirubin	≥4 mg/dL	+1
	Captopril	≥100 mg/L	+1
	Specific gravity	≥1.040	+1
Specific gravity	pH	≥ 9	+1
Protein	Acetaminophen	≥ 50 mg/dL	+1
	Bilirubin	≥ 6 mg/dL	+1
	Hemoglobin	≥ 5 mg/dL	+1
	Nitrofurantoin	≥ 20 mg/dL	+1
	Riboflavin	≥20 mg/dL	-1

Analyte	Potential interfering substance	Concentration at which interference was observed	Change in color block output
	Urobilinogen	>20 mg/dL	-1
	pH	≥ 9	+1
Blood (hemolyzed and non-hemolyzed)	Albumin	≥ 1000 mg/L	-1
	Ascorbic acid	≥ 30 mg/dL	-1
	Bilirubin	≥ 6 mg/dL	+1
	Captopril	≥ 150 mg/dL	-1
	Sodium hypochlorite	≥ 0.5 %	+1
	Formaldehyde	≥ 150 mg/dL	+1
	Specific gravity	≥ 1.040	-1
	Nitrofurantoin	≥ 30 mg/dL	+1
	Riboflavin	≥ 50 mg/dL	+1
	Urobilinogen	≥ 20 mg/dL	-1
Nitrite	Ascorbic acid	≥ 40 mg/dL	-1
	Bilirubin	≥4 mg/dL	+1
	Nitrofurantoin	≥ 20 mg/dL	+1
	Phenazopyridine	≥ 37 mg/dL	+1
	Riboflavin	≥ 50 mg/dL	+1
	Selenium	≥ 300 mg/dL	+1
	Urobilinogen	≥ 15 mg/dL	+1
Leukocytes	Albumin	≥ 1000 mg/dL	-1
	Bilirubin	≥ 4 mg/dL	+1
	Captopril	≥ 150 mg/dL	-1
	Sodium hypochlorite	≥ 0.5 %	+1
	Formaldehyde	≥ 150 mg/dL	+1
	Specific gravity	≥ 1.040	-1
	Nitrofurantoin	≥ 30 mg/dL	+1
	Oxalic acid	≥ 45 mg/dL	-1
	Glucose	≥ 1500 mg/dL	-1
	Phenazopyridine	≥ 50 mg/dL	+1
	Riboflavin	≥ 37 mg/dL	+1
	Selenium	≥ 300 mg/dL	+1
	Tetracycline	≥ 40 mg/dL	-1

Analyte	Potential interfering substance	Concentration at which interference was observed	Change in color block output
	Urobilinogen	≥ 15 mg/dL	+1
Microalbumin	Acetaminophen	≥ 50 mg/dL	+1
	Bilirubin	≥ 4 mg/dL	+1
	Hemoglobin	≥ 5 mg/dL	+1
	Nitrofurantoin	≥ 20 mg/dL	+1
	Phenazopyridine	≥50 mg/dL	+1
	Riboflavin	≥ 25 mg/dL	-1
	Urobilinogen	≥ 15 mg/dL	-1
	pH	≥ 9	+1
Creatinine	Sodium hypochlorite	≥ 1%	+1
	Hemoglobin	≥ 5 mg/dL	+1
	Nitrofurantoin	≥ 30 mg/dL	+1
	Riboflavin	≥37 mg/dL	+1
	Urobilinogen	≥ 20 mg/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 can't be determined. The test area will react with interfering substances known to react with Ehrlich's reagent, such as p- amino salicylic acid. Drugs containing azo gantrisin (sulfamethoxazole) 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 result in 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 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 affect the pH pas, then pH results may be erroneously decreased. This phenomenon is called “carry-over effect.”

Blood: Elevated specific gravity or protein in urine may reduce the reactivity of the blood test pad. 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 blood concentrations. Substances that cause abnormal urine color, such as drug containing azo dyes, nitrofurantoin and riboflavin may cause false positive results. 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 positive results.

Nitrite: Ascorbic acid (>40mg/dL) may cause false negative result with urine containing low levels of nitrite (<0.03mg). The negative result does not always mean that the patient is free from bacteriuria. Medication such as phenazopyridine or other azo-containing compounds or other dyes 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. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison study was conducted at three clinical sites with a total of 867 samples (Site A 255 samples, Site B 280 samples and Site C 332). Three trained laboratory professionals performed the testing at each site. Fresh urine samples were obtained at each medical facility. The samples were processed within 4 hours. 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). No altered samples were used in this study. The results of the method comparison study for the combined sites are shown in the table below. The data for the combined sites is representative of the data collected at each site.

Urobilinogen

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

Glucose

New device (mg/dL)	Predicate device (mg/dL)					
	Neg	**100**	**250**	**500**	**1000**	**2000**
2000						24
1000				1	41	
500			2	59		
250		1	71	3		
100		71				
Neg	594					
Total	594	72	73	63	41	24
Exact agreement	100%	99%	97%	94%	100%	100%
Within 1 block	100%	100%	100%	100%	100%	100%

Bilirubin

New device (mg/dL)	Predicate device (mg/dL)			
	Neg	**1**	**2**	**4**
4				46
2		4	87	1
1		82	3	
Neg	644			
Total	644	86	90	47
Exact agreement	100%	95%	97%	98%
Within 1 block	100%	100%	100%	100%

Ketones

New device (mg/dL)	Predicate device (mg/dL)					
	Neg	**5**	**15**	**40**	**80**	**160**
160						9
80				3	39	
40				60		
15			86	1		
5		60	7			
Neg	602					
Total	602	60	93	64	39	9
Exact agreement	100%	100%	92%	94%	100%	100%
Within 1 block	100%	100%	100%	100%	100%	100%

Blood

New device (RBC/µL)	Predicate device (RBC/µL)				
	Neg	**10**	**25**	**80**	**200**
200				4	159
80			8	150	1
25		7	145	5	
10		159	1		
Neg	228				
Total	228	166	154	159	160
Exact agreement	100%	96%	94%	94%	99%
Within 1 block	100%	100%	100%	100%	100%

Protein

New device (mg/dL)	Predicate device (mg/dL)					
	Neg	**15**	**30**	**100**	**300**	**1000**
1000					1	17
300				4	51	
100			5	104		
30		4	126	1		
15		133	2			
Neg	419					
Total	419	137	133	109	52	17
Exact agreement	100%	97%	95%	95%	98%	100%
Within 1 block	100%	100%	100%	100%	100%	100%

Nitrite

New device	Predicate device		
	Neg	**Trace**	**Pos**
Pos			311
Trace		125	4
Neg	427		
Total	427	125	315
Exact agreement	100%	100%	99%
Within 1 block	100%	100%	100%

Leukocytes

New device (mg/dL)	Predicate device (mg/dL)				
	Neg	**15**	**70**	**125**	**500**
500				2	108
125			3	136	6
70			122	4	
15		105	2		
Neg	379				
Total	379	105	127	142	114
Exact agreement	100%	100%	96%	96%	95%
Within 1 block	100%	100%	100%	100%	100%

pH

New device	Predicate device						
	5	**6**	**6.5**	**7**	**7.5**	**8**	**8.5**
8.5						5	72
8					5	103	
7.5				7	106	3	
7			3	151	5		
6.5		5	182	2			
6	1	143	7				
5	91	6					
Total	92	154	192	160	116	111	42
Exact agreement	99%	93%	95%	94%	91%	93%	100%
Within 1 block	100%	100%	100%	100%	100%	100%	100%

Specific gravity

New device	Predicate device						
	1.000	**1.005**	**1.010**	**1.015**	**1.020**	**1.025**	**1.030**
1.030						5	82
1.025					5	107	
1.020				6	167	2	
1.015			5	166	7		
1.010		5	147	5			
1.005		104	4				
1.000	50						
Total	50	109	156	177	179	114	82
Exact agreement	100%	95%	94%	94%	93%	94%	100%
Within 1 block	100%	100%	100%	100%	100%	100%	100%

Creatinine

New device (mg/dL)	Predicate device (mg/dL)				
	10	**50**	**100**	**200**	**300**
300				7	188
200			7	191	11
100		9	198	9	
50		151	6		
10	90				
Total	90	160	211	207	199
Exact agreement	100%	94%	94%	92%	94%
Within 1 block	100%	100%	100%	100%	100%

Microalbumin

New device (mg/dL)	Predicate device (mg/dL)			
	1	**3**	**8**	**15**
15				445
8		3	98	3
3		72	8	
1	238			
Total	238	75	106	448
Exact agreement	100%	96%	92%	99%
Within 1 block	100%	100%	100%	100%

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

*b. Clinical specificity**:***

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   Literature references were provided to support the stated reference ranges:

   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 to 8.

   Blood: Normally, no hemoglobin is detectable in urine (0.010mg/dl; 3 RBC/μl). When hemoglobin appears in urine it indicates 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 levels in urine are under 2mg/dl. Microalbuminuria is indicated with results of 3~30mg/dl.

   Creatinine: The urine of healthy individuals contains 10~300mg/dl of creatinine. 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 at a ratio result of 30-300 mg/g (abnormal) and clinical albuminuria at a ratio result of >300mg/g (high abnormal).

Kaplan LA and Pesce AJ. Clinical Chemistry Theory Analysis and Correlation. CV Mosby Co., St. Louis, pp. 1004-1007 (1984)

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

N. Instrument Name:

DUS R-50S Analyzer

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X_____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ____X____ or No _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

3. Specimen Identification:

   The DUS R-50S user manual instructs the user to input the patient and sample ID number into the DUS R-50S analyzer by pressing the number keypad of the display (Maximum 10 digits).

4. Specimen Sampling and Handling:

   The urine sample should be collected in a clean, dry container with no added preservatives. The specimen should be tested by the user by dipping a DUS test strip into a patient's urine specimen for no more than two seconds. The user removes the strip and excess urine and places the test strip onto the instrument. The DUS R-50S will perform the reading and evaluation of the urine strip.

5. Calibration:

   The DUS R-50S analyzer calibrates using a white plastic calibration pad located on the edge of the strip tray. Calibration is performed automatically before each reagent strip is read. Reflectance measurements from the pad must match the factory set calibration. When strong variations are detected by contamination of the calibration pad or low light intensity an error message (system check failed) will be displayed.

6. Quality Control:

   The sponsors states the following in their labeling: For best results, performance of reagent strips should be confirmed by commercially available quality control or assayed urine controls whenever a new bottle of DUS reagent strips are first opened. Water should NOT be used as a negative control. Controls should be tested after performing maintenance or service on the reader. Quality Control materials should be used in accordance with local, state, and/or federal requirements for QC testing.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.