510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K171883

B. Purpose for Submission:

Clearance of a new device

C. Manufacturer and Instrument Name:

Sysmex America, Inc., Sysmex® UF-5000 Fully Automated Urine Particle Analyzer

D. Type of Test or Tests Performed:

Microscopic analysis of formed elements in urine. The analyzer quantitates the following parameters: RBC, WBC, Epithelial Cells, Casts, Bacteria, and flags the presence of Pathologic Casts, Crystals, Sperm, Yeast like cells, and Mucus.

E. System Descriptions:

1. Device Description:

The Sysmex UF-5000 Automated Urine Particle Analyzer is a fully automated urine particle analyzer that is used in the clinical laboratory to analyze formed elements in urine samples quantitatively and flag for the presence of particles in the sample. It provides screening of abnormal samples. The Sysmex UF-5000 reports analysis results for five quantitative parameters in urine: RBC (Red Blood Cells), WBC (White Blood Cells), EC (Epithelial Cells), CAST and BACT (Bacteria). It also flags the following urine elements: Pathologic Cast, Crystal, Sperm, Yeast like cell and Mucus. This flagging information alerts the operator of the need for further testing and/or review.

The Sysmex UF-5000 is a dedicated system for the analysis of microscopic formed elements in urine and uses a Microsoft® Windows Operating System. The analyzer consists of the following units:

- **Main Unit** which aspirates, dilutes, mixes and analyzes urine samples and processes data from the main unit and provides the operator interface with the system
- **Sampler Unit** which supplies samples to the main unit automatically
- **Pneumatic Unit** which supplies pressure and vacuum to the main unit

The analyzer uses five reagents—UF-CELLSHEATH (sheath reagent), UF-CELLPACK CR and UF-CELLPACK SF (diluents) and UF-Fluorocell CR and UF-Fluorocell SF (stains). The quality control material is UF-CONTROL.

2. Principles of Operation:

The Sysmex UF-5000 uses the flow cytometry method to analyze particles in urine. Fluorescent stain is applied to specific characteristics within the cells that are placed in a suspension surrounded by sheath fluid and then ejected through a nozzle sequentially. Particles and cells pass through in single file through a sheath-like laminar flow. A blue semiconductor laser beam is irradiated on the particles and cells stained with a UF Fluorocell stain and the particle is classified based on the following four types of signals:

1) **Forward scattered light**: reflects information about the size and permeability of particles
2) **Side scattered light**: reflects the thickness and internal structure of particles
3) **Fluorescence intensity**: reflects the stainability of particles
4) **Depolarized side scattered light**: reflects the intensity of birefringence of particles

Cells and particles are detected by forward light scattering, which occurs with objects that are the same size or bigger than the size of the wavelength of the laser. The Sysmex UF-5000 laser has a wavelength of 488 nm, which can detect particles as small as 0.488 μm. Based on the principle of flow cytometry, the Sysmex UF-5000 fractionates particles and expresses the following parameters quantitatively: RBC (Red Blood Cells); WBC (White Blood Cells); EC (Epithelial Cells); CAST; and BACT (Bacteria).

3. Modes of Operation:

Manual Sampling Mode and Automated Sampling Mode

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 _____ or No ___X_____

4. Specimen Identification:

Automated specimen identification by barcode reader or by hand-held barcode reader

5. Specimen Sampling and Handling:

   Samples can be introduced onto the Sysmex UF-5000 using sampler analysis or STAT analysis. Sampler analysis allows the operator to load the sample tubes into a rack (up to 10 samples per rack), which is automatically transported into the UF-5000 for processing. The analyzer automatically mixes, aspirates, and analyzes samples. STAT analysis is performed when the operator analyzes samples by interrupting the sampler analysis, or when the sample volume is low. In STAT analysis, the operator manually mixes samples and manually loads the sample tubes individually.

6. Calibration:

   Calibration and calibration verification of the Sysmex UF-5000 is performed by trained field service personnel upon installation, when quality control or system errors indicate changes in sensitivity parameters, and when major components are replaced. User calibration is not required.

7. Quality Control:

   The control material used for quality control (QC) of the Sysmex UF-5000 is UF-CONTROL. There are two levels of controls used for routine monitoring of instrument performance for the following parameters: RBC, WBC, EC, CAST, BACT and Cond. (Conductivity is not a reportable parameter). UF-CONTROL contains latex control particles for use in quality control measurement procedure of the Sysmex UF-5000.

8. Software:

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

   Yes___X_____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5200, Automated cell counter

2. Classification:

   Class II

3 Product code:

   LKM – Counter, Urine Particle

4. Panel:

Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer is an automated urine particle analyzer for in vitro diagnostic use in screening patient populations found in clinical laboratories. The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer analyzes the following parameters in urine samples: RBC, WBC, Epithelial cells, Cast, Bacteria and flags the presence of the following: Pathologic Cast, Crystals, Sperm, Yeast like cell and Mucus.

2. Special Conditions for Use Statement(s):

For prescription use only

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

Sysmex® UF-1000i Automated Urine Particle Analyzer – K070910

2. Comparison with Predicate Device:

Similarities		
Item	Device Sysmex® UF-5000, Fully Automated Urine Particle Analyzer K171883	Predicate Sysmex® UF-1000i, Automated Urine Particle Analyzer K070910
Intended Use/Indications for Use	The Sysmex® UF-5000 Fully Automated Urine Particle Analyzer is an automated urine particle analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The Sysmex® UF- 5000 Fully Automated Urine Particle Analyzer analyzes the following parameters in urine samples: RBC, WBC,	The Sysmex® UF-1000i is an automated urine particle analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The UF-1000i analyzes the following parameters in urine samples: RBC, WBC, Epithelial cells, Cast and Bacteria and flags the presence of the following: Pathologic Cast, Crystal,

Similarities		
Item	Device Sysmex® UF-5000, Fully Automated Urine Particle Analyzer K171883	Predicate Sysmex® UF-1000i, Automated Urine Particle Analyzer K070910
	Epithelial cells, Cast, Bacteria and flags the presence of the following: Pathologic Cast, Crystals, Sperm, Yeast like cell and Mucus	Sperm, Small Round Cell, Yeast like cell and Mucus
Parameters	Quantitative parameters: RBC, WBC, Epithelial cells, Cast, Bacteria in urine Flags: Pathologic Cast, Crystal, Sperm, Yeast like cell and Mucus	Quantitative parameters: RBC, WBC, Epithelial cells, Cast, Bacteria in urine Flags: Pathologic Cast, Crystal, Sperm, Small Round Cell, Yeast like cell, Mucus
Test Methodology	The instrument utilizes Sysmex® flow cytometry using a blue semiconductor laser (wavelength 488 nm) for analyzing organized elements of urine. Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis. There are two channels- CR channel for WBC, EC, Bacteria and SF channel for RBC, Cast	The instrument utilizes Sysmex® flow cytometry using a red semiconductor laser (wavelength 635 nm) for analyzing organized elements of urine. Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis. There is also a bacteria channel and side scattered light signal
Specimen Type	Random Urine Specimen	Same
Sample Aspiration/Fluidic Pathway	Single Pathway	Same

Differences		
Item	Device Sysmex® UF-5000, Fully Automated Urine Particle Analyzer K171883	Predicate Sysmex® UF-1000i, Automated Urine Particle Analyzer K070910
Parameters	No flag for Small Round Cell	Flag for Small Round Cell
Reagents	UF-CELLSHEATH (sheath) UF-CELLPACK CR (diluent) UF-Fluorocell CR (stain) UF-CELLPACK SF (diluent) UF-Fluorocell SF (stain)	UFII SHEATH (sheath) UFII PACK –SED (diluent) UFII SEARCH –SED (stain) UFII PACK –BAC (diluent) UFII SEARCH –BAC (stain)
Quality Control	UF-CONTROL–2 levels with 5 parameters	UFII CONTROL–2 levels with 5 parameters
Measuring Channels	CR channel: WBC, EC, Bacteria SF channel: RBC, Cast	SED channel: WBC, RBC, EC, CAST BAC channel: Bacteria
Throughput	105 samples/ hour	100 samples/ hour
Minimum Particle Size Detected	0.488 µm	0.633 µm
Aspiration Volume	0.45 mL	0.8 mL

I. Special Control/Guidance Document Referenced (if applicable):

CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition

CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline – Third Edition

CLSI EP07-A2, Interference Testing In Clinical Chemistry; Approved Guideline – Second Edition

CLSI EP09-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition

CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition

CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition

CLSI EP25-A, Evaluations of Stability of In Vitro Diagnostic Reagents; Approved Guideline

CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition

CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard – Second Edition

IEC 60825-1: 2007, Safety of laser products – Part 1: Equipment classification and requirements

IEC 61010-1: 2010, Safety equirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

IEC 61010-2-081: 2001, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

IEC 61010-2-101: 2002, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

IEC 61326-2-6:2005, Electrical equipment for measurement, control, and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

Method Comparison

A method comparison study was conducted to demonstrate performance equivalency between the Sysmex UF-5000 and the Sysmex UF-1000i (predicate device). The method comparison study included a total of 551 residual urine samples collected without preservatives across three clinical sites in the U.S. All samples were run in automated sampling mode in singlet on the UF-1000i analyzer and within 1 hour on the UF-5000. Samples used in the study covered the full reportable measuring ranges to the extent possible. When native samples were not available to adequately span the full analytical measuring range, concentrated, diluted and/or spiked samples were used.

Patient demographics included both males and females ranging in age from 1 day old to 97 years of age. A total of 101 normal (no flags) and 450 abnormal (flagged) urine samples were tested. Weighted Deming and Deming Linear Regression analysis, including 95% confidence intervals (CI) and estimates of the bias/difference were calculated for each parameter. In addition, Bland-Altman plots were generated to show the differences between the two devices for all reportable parameters. The results of the regression analyses including 95% CI are included in the following tables:

Weighted Deming Regression (Sysmex® UF−1000i vs. Sysmex® UF−5000: All Sites)

Parameter Unit	Result Range	Correlation Coefficient	Intercept (95% CI)	Slope (95% CI)
RBC (/µL)	0.0–10139.6	0.9606	-0.071 (-0.310, 0.169)	0.903 (0.838, 0.967)
WBC (/µL)	0.1–9013.4	0.8784	-0.091 (-0.125, -0.058)	0.944 (0.900, 0.988)
EC (/µL)	0.0–186.2	0.8358	0.0001 (0.000002, 0.0003)	0.900 (0.848, 0.952)

Deming Regression (Sysmex® UF−1000i vs. Sysmex® UF−5000: All Sites)

Parameter Unit	Result Range	Correlation Coefficient	Intercept (95% CI)	Slope (95% CI)
CAST (/µL)	0.00–20.12	0.4133	0.222 (-0.134, 0.578)	0.436 (0.192, 0.680)
BACT (/µL)	0.0–8920.4	0.7474	301.884 (191.069, 412.698)	1.727 (1.340, 2.113)

There are noted technological differences between the UF-5000 and the UF-1000i (i.e. wavelength used for analyzing urine elements, minimum particle size detected, measuring channels). In addition, clinical data demonstrate agreement between the UF-5000 and manual microscopy. For these reasons, the method comparison data for CAST and BACT were found to be acceptable.

Flagging Comparison

A flagging comparison study was incorporated into the method comparison study to demonstrate that the flagging capabilities of the UF-5000 are equivalent to those of the UF-1000i for the following findings: Pathologic Cast, Crystal, Sperm, Yeast like cell, and Mucus. The agreement of the flagging capabilities was established using the flagging results obtained from the samples used in the method comparison study. Samples were divided into two categories: (1) Normal, healthy subjects – No flags and (2) Abnormal, subjects with positive morphologies/concentrations – Flags present.

Agreement between the flagging of the UF-1000i (predicate device) and the UF-5000 analyzers was determined using the following calculations:

- Positive Percent Agreement (PPA) = TP/(TP + FN) x 100
- Negative Percent Agreement (NPA) = TN/(TN + FP) x 100
- Overall Agreement = (TP+TN/ TP+FP+TN+FN) x100

Results of the flagging comparison between the UF-1000i and the UF-5000 analyzers are listed in the tables below:

Overall Flagging Analysis (All Sites Combined)

All Sites (N=550)		UF-1000i		
		Positive (Abnormal)	**Negative (Normal)**	**Total**
UF-5000	**Positive (Abnormal)**	413	17	430
	Negative (Normal)	36	84	120
	Total	449	101	550

All Sites (N=550)	95% Confidence Intervals
Positive Percent Agreement	91.9 (89.0–94.3)
Negative Percent Agreement	83.1 (74.4–89.8)
% Overall Agreement	90.3 (87.5–92.7)

The bacteria flagging agreement between the UF-5000 and UF-1000i is presented in the table below to demonstrate that the analyzers are substantially equivalent in regards to the BACT parameter.

Bacteria Flagging Comparison to UF-1000i (All Sites Combined)

All Sites (N=550)		UF-1000i		
		Positive (Abnormal)	**Negative (Normal)**	**Total**
UF-5000	**Positive (Abnormal)**	171	90	261
	Negative (Normal)	12	277	289
	Total	183	367	550

All Sites (N=550)	95% Confidence Intervals
Positive Percent Agreement	93.4 (88.8–96.5)
Negative Percent Agreement	75.4 (70.7–79.7)
% Overall Agreement	81.4 (77.9–84.6)

The overall flagging results of all sites combined met the predefined acceptance criteria.

Sensitivity and Specificity

Analytical sensitivity and specificity were determined by evaluating the flagging capabilities of the UF-5000 analyzer against the reference method (manual microscopy). The study was conducted using the flagging results obtained from the samples used in the method comparison study. Samples were divided into two categories: (1) Normal, healthy subjects – No flags, and (2) Abnormal, subjects with positive morphologies/concentrations – Flags are present. The established reference ranges for the UF-1000i (predicate device) were used to discriminate between normal and abnormal results for the UF-5000 and manual microscopy.

The results of the flagging comparison between the manual microscopy and UF-5000 analyzer are presented in the tables below. The following calculations were used:

- Sensitivity = 100 x [TP/(TP + FN)]
- Specificity = 100 x [TN/(FP + TN)]
- Prevalence = 100 x (TP + FN)/TP
- Positive Predictive Value (PPV) = 100 x [TP/(TP + FP)]
- Negative Predictive Value (NPV) = 100 x [TN/(FN + TN)]
- Efficiency = 100 x (TP + TN)/N

Overall Flagging Comparisons to Manual Microscopy (Clinical Sensitivity and Specificity: All Sites Combined)

All Sites (N=549)		**Manual Microscopy**		
		Positive (Abnormal)	**Negative (Normal)**	**Total**
UF-5000	**Positive (Abnormal)**	388	41	429
	Negative (Normal)	45	75	120
	Total	433	116	549

All Sites (N=549)	**95% Confidence Intervals**
% Sensitivity	89.6 (86.3–92.3)
% Specificity	64.6 (55.2–73.3)
Positive Predictive Value	90.4 (87.6–93.2)
Negative Predictive Value	62.5 (53.8–71.1)
Prevalence	111.6
Efficiency	84.3 (81.0 - 87.2)

The results obtained from the flagging comparison of the UF-5000 to manual microscopic method met predefined acceptance criteria.

b. Precision/Reproducibility:

Repeatability

Repeatability was evaluated using residual natural urine specimens without preservatives around the low and high end of the analytical measuring range. Ten replicates of each sample were tested for each parameter (RBC, WBC, EC, BACT and CAST) using the Manual Analysis Mode of the UF-5000. Testing was conducted across three sites using three analyzers and two different reagent lots. The precision (repeatability) performance data met predefined limits for all samples at concentrations greater than or equal to the predefined limit concentrations. Samples below the predefined limit concentrations were determined to be acceptable.

Reproducibility

Reproducibility studies were performed to evaluate within-run, between-run, between-day, between-site, and total imprecision of the UF-5000 analyzer. Testing was performed across three clinical sites (one operator per site), using two levels of UF-CONTROL material (Low and High). Each level was run in the Automated Sampling Mode in duplicate twice each day for 20 days using one reagent lot. The results of the precision (reproducibility) study met the predefined acceptance criteria. Results from all sites combined are presented in the table below.

Reproducibility for Combined Sites

Parameter (Unit)	Control Level	N	Mean	Within Run		Between Run		Between Day		Between Site		Total Imprecision	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
RBC (/µL)	High	240	199.90	7.019	3.51	0.000	0.00	1.546	0.77	2.026	1.01	7.468	3.74
	Low	240	39.46	2.334	5.91	0.693	1.76	0.000	0.00	0.715	1.81	2.537	6.43
WBC (/µL)	High	240	781.01	15.401	1.97	5.644	0.72	12.413	1.59	5.202	0.67	21.218	2.72
	Low	240	39.91	2.709	6.79	1.121	2.81	0.704	1.76	0.000	0.00	3.015	7.55
EC (/µL)	High	240	91.11	7.779	8.54	0.000	0.00	3.811	4.18	8.015	8.80	11.802	12.95
	Low	240	11.84	1.916	16.18	0.000	0.00	0.650	5.49	1.572	13.28	2.562	21.63
CAST (/µL)	High	240	20.62	2.658	12.89	0.000	0.00	0.898	4.36	1.423	6.90	3.146	15.26
	Low	240	4.95	1.087	21.98	0.000	0.00	0.212	4.29	0.293	5.92	1.146	23.16
BACT (/µL)	High	240	816.20	32.893	4.03	5.187	0.64	9.114	1.12	31.080	3.81	46.453	5.69
	Low	240	222.56	17.307	7.78	4.380	1.97	0.000	0.00	7.966	3.58	19.549	8.78

c. *Linearity*:

Linearity for RBC, WBC, EC, CAST and BACT was evaluated at one site using three UF-5000 analyzers. Urine specimen pools were created by concentrating, diluting, and spiking natural urine samples, including a wide range of cell type concentrations (high and low), to cover the full measuring range for each enumerated parameter. Eleven evenly spaced concentration levels were tested for RBC, WBC, and BACT. Five evenly spaced concentration levels were tested for EC and CAST. Each parameter was tested in three replicates. Regression analysis was used to assess linearity for first order model (e.g. linear), and polynomial regression was used to assess linearity for second and third order models (e.g, quadratic and cubic). BACT, EC, and CAST achieved linearity with a first order model while RBC and WBC linearity was achieved through polynomial regression.

Parameter (Unit)	Linear Range
RBC (/μL)	0.2–10558.9
WBC (/μL)	0.2–12323.0
EC (/μL)	0.2–252.1
CAST (/μL)	0.1–29.2
BACT(/μL)	2.6–11938.2

The UF-5000 demonstrated linearity for RBC, WBC, EC, CAST and BACT parameters from lower limit to upper limit, and met acceptance criteria for measurement error.

d. *Carryover*:

Carryover was evaluated by testing residual urine samples without preservatives with high RBC, WBC, EC, Cast and Bacteria counts three consecutive times (H1, H2, H3) followed immediately by testing samples with low counts three consecutive times (L1, L2, L3). Testing was performed in the Automated Sampling Mode across three clinical sites. Carryover effect was calculated for each parameter using the formula (L1-L3)/ (H3-L3) x 100% , where L1 is the first low sample analyzed; L3 is the last low sample analyzed; and H3 is the last high sample analyzed. The carryover results for the UF-5000 analyzer met the predefined limits for all parameters across sites.

e. *Interfering Substances*:

The potential interference effects of hematuria, turbidity (intralipid), and preservative tubes were evaluated for the UF-5000 by adding different levels of interfering substances to urine specimens and system diluent. Control baseline pools (absence/normal concentration of substance) and stock pools with potential

interfering substance were prepared for each test run. Baseline control samples were included with each interfering substance test run and prepared the same as the test pool, except the test interferent was replaced with the same volume of solvent used to prepare the stock test pool. Samples were measured three consecutive times using the Manual Sampling Mode.

Serial dilutions of intralipid were used to evaluate the potential interference of turbidity on the UF-5000 for WBC, RBC, EC, CAST and BACT results. Results demonstrated that there was no significant turbidity (intralipid) interference up to a concentration of 0.100 g/dL for RBC, WBC and CAST parameters, and up to a concentration of 0.040 g/dL for EC and BACT parameters. Intralipid concentrations ≥0.200 g/dL caused measurement error due to the high density of the specimen.

Serial dilutions of known high RBC concentrations were used to evaluate the potential interference of hematuria on the UF-5000 for WBC, EC, CAST and BACT results. Results demonstrated that there was no significant hematuria interference up to 98,444.8/µL for EC and CAST parameters, up to 78,117.7/µL for WBC and up to a concentration of 56,020.7/µL for BACT.

Several different types of preservative tubes, including Iwaki,Greiner Vacuette Urine Culture, Greiner Vacuette Urine CCM and Sarsteds V-Monovette tubes were used to evaluate their potential interference effects. System diluent (4 mLs) was delivered to the control tube and 10 mLs of diluent was added to each preservative tube prior to analysis on the UF-5000. Results demonstrated that there was no significant interference seen with the use of Iwaki, Greiner Vacuette Urine Culture, Greiner Vacuette Urine CCM or Sarsteds V-Monovette tubes for WBC, EC and CAST parameters.

A significant increase in results was seen with the use of Greiner Vacuette Urine Culture and Greiner Vacuette Urine CCM tubes for RBC and BACT parameters.

2. Other Supportive Instrument Performance Data Not Covered Above:

a. Reference Intervals

A reference interval study was performed to establish a combined male and female reference range for the UF-5000 analyzer. A total of 237 prospectively collected random urine samples were collected across three U.S. sites from generally healthy consenting individuals. Ninety-six samples were excluded due to positive results on the UF-1000i and/or manual microscopy. The remaining 141 eligible enrolled subjects, 68 males and 73 females between the ages of 17 and 68 years of age representative of the United States population (i.e. race demographics), were included in the final analysis. The mean, standard deviation, and 95% confidence intervals (non-parametric method) were calculated for the established reference range for the UF-5000 analyzer. The results of the established combined male and female reference intervals for the UF-5000 are supported by published literature.

Parameter (Unit)	Male	Female	Combined (Male and Female) Reference Range
RBC (/μL)	0.0–16.5	0.1–20.8	0.0–20.8
WBC (/μL)	0.0–18.4	0.0–23.2	0.0–23.2
EC (/μL)	0.0–4.9	0.2–38.8	0.0–38.8
CAST (/μL)	0.00–0.41	0.00–0.69	0.00–0.69
BACT (/μL)	0.0–1247.5	1.0–1933.2	0–1933.2

b. Detection Limits (LoB, LoD, and LoQ)

The Limit of Blank (LoB), the Limit of Detection (LoD), and the Limit of Quantitation (LoQ) were determined for the WBC, RBC, Epithelial Cell, Cast and Bacteria parameters on the UF-5000 analyzer.

Limit of Blank (LoB)

The determination of the LoB was conducted using the system diluent (UF CELLPACK) as blank samples. Four blank samples were prepared with five repeat measurements performed per day for each of the four samples over a period of three days in the Manual Sampling Mode, resulting in a total of 60 blank measurements for each parameter (4 samples x 5 reps x 3 days). The mean and SD and LoB were calculated for each parameter. The LoB was calculated as follows:

LoB = Mean + (1.645 x SD)

Limit of Detection (LoD)

Four low level urine samples without preservative and concentrations in the approximate range of one to five times the calculated LoB of each parameter were used to establish the LoD. Each sample was analyzed five consecutive times in the Manual Sampling Mode, over a period of three days using two reagent lots for a total of 120 measurements for each parameter (4 samples x 5 reps x 3 days x 2 staining reagent lots). The mean and SD were calculated for each parameter per reagent lot. The reagent lot with the maximum estimated value for each parameter was carried forward to calculate the limit of detection of each parameter. The LoD was calculated as follows:

LoD = LoB + (1.645 x SD)

Limit of Quantitation (LoQ)

To determine the LoQ, four low level urine samples without preservatives at concentrations around the calculated LoD of each parameter were used. Each sample

was analyzed three consecutive times over a period of three days, for a total of 36 measurements for each parameter (4 samples x 3 reps x 3 days). The LoQ was calculated as follows:

Westgard model: $TE = \left| Bias \right| + 2s$

The LoB, LoD, and LoQ for all parameters met the predefined acceptance criteria. Detection limits for each measured parameter are presented in the table below:

Parameter (Unit)	LoB	LoD	LoQ
RBC (/µL)	0.2	0.8	2.0
WBC (/µL)	0.0	0.8	1.8
EC (/µL)	0.1	0.9	1.4
CAST (/µL)	0.00	0.75	1.41
BACT (/µL)	0.5	4.2	4.5

c. Sample Stability

Stability testing was conducted to demonstrate the stability of urine samples at room temperature (18–26°C) and refrigerated temperature (2–8°C) on the UF-5000 analyzer. Ten normal urine samples (results with no flags) and 10 abnormal urine samples (results containing flags) were tested at one site using one analyzer. Normal and abnormal samples were processed at each of the following time points: baseline (time zero (0)) and after 6, 23, 24, and 25 hours at refrigerated storage conditions; baseline and after 1, 2, 3, 4, and 5 hours at room temperature. For each time point, results were compared to the respective baseline results. Acceptance criteria were met for each storage condition. Results demonstrated stability of 4 hours for urine samples stored at room temperature (18–26°C) and 24 hours for urine samples stored at refrigerated temperature (2–8°C).

K. Proposed Labeling:

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

L. Conclusion:

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