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

I Background Information:

A 510(k) Number

K193514

B Applicant

Arkray Inc.

C Proprietary and Established Names

AUTION MAX AX-4060 Urinalysis System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JIL	Class II	21 CFR 862.1340 - Urinary Glucose (Nonquantitative) Test System	CH - Clinical Chemistry
JIO	Class II	21 CFR 864.6550 - Occult blood test	HE - Hematology
CDM	Class I	21 CFR 862.1785 - Urinary urobilinogen (nonquantitative) test system	CH - Clinical Chemistry
JIR	Class I	21 CFR 862.1645 - Urinary protein or albumin (nonquantitative) test system	CH - Clinical Chemistry
JMT	Class I	21 CFR 862.1510 - Nitrite (nonquantitative) test system	CH - Clinical Chemistry

LJX	Class I	21 CFR 864.7675 - Leukocyte peroxidase test	HE - Hematology
JJB	Class I	21 CFR 862.1115 - Urinary bilirubin and its conjugates (nonquantitative) test system	CH - Clinical Chemistry
CEN	Class I	21 CFR 862.1550 - Urinary pH (nonquantitative) test system	CH - Clinical Chemistry
JIN	Class I	21 CFR 862.1435 - Ketones (nonquantitative) test system	CH - Clinical Chemistry
KQO	Class I	21 CFR 862.2900 - Automated urinalysis system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Measurement of the following in urine samples: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, turbidity, and color.

C Type of Test:

Qualitative and semi-quantitative urinalysis

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The AUTION MAX AX-4060 Urinalysis System (AUTION MAX) is comprised of the AUTION MAX AX-4060 automated urine analyzer and AUTION Sticks 9EB multi-parameter test strips.

The AUTION MAX AX-4060 urine analyzer, when used with AUTION Sticks 9EB Test Strips is a fully automated urinalysis system intended for the in vitro qualitative or semi-quantitative measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrites, leukocytes, turbidity, and color. The test results of these parameters can be used in the evaluation of kidney, urinary, liver and other metabolic disorders. This system is intended to be used by trained operators in clinical laboratories.

AUTION Sticks 9EB Test strips are test strips for the in vitro qualitative or semi-quantitative measurement of the following analytes: glucose, protein, bilirubin, urobiliogen, pH, blood, ketones, nitrite, and leukocytes with the AUTION MAX AX-4060 urine analyzer. The test results of these parameters can be used in the evaluation of kidney, urinary, liver and other metabolic disorders.

Special conditions for use statements:
Prescription use only.
AUTION Sticks 9EB test strips are not to be read visually.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

AUTION Sticks 9EB test strips are not to be read visually.

D Special Instrument Requirements:

AUTION MAX AX-4060 urine analyzer

IV Device/System Characteristics:

A Device Description:

The AUTION MAX AX-4060 Urinalysis System consists of the AUTION MAX AX-4060 urine analyzer and the AUTION Sticks 9EB test strips. The test system is fully automated and provides a semi-quantitative or qualitative measurement for glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrites and leukocytes.

The AUTION sticks 9EB test strips consist of a plastic strip containing 9 dry chemistry reagent pads impregnated with chemical substances for the determination of the above analytes in urine. These substances if present in urine lead to a chemical reaction that results in a color change, which is measured by the AUTION MAX AX-4060 urine analyzer based on spectrophotometry. In addition, three additional parameters, specific gravity, turbidity, and color tone are directly measured based on reflectance refractometry, transmitted, and scattered light measurements.

B Principle of Operation:

AUTION Sticks 9EB test strips

Glucose: Based on a double sequential enzyme reaction. Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the oxidative coupling of 4-amino-antipyrine and 1-Naphthol3-6-disulfonic acid by hydrogen peroxide to form a quinone imine purple color.

Protein: Based on the protein-error-of-indicators reaction. At a constant pH, the presence of protein causes a change in the color of the indicator to a cyan color.

Bilirubin: The test is based on azo-coupling reaction of bilirubin with diazotized 2-methyl5-nitroaniline in acidic medium. Varying bilirubin levels will produce a reddish-brown color.

Urobilinogen: The test is based on azo-coupling reaction of urobilinogen with diazotized 3,3'-dimethyloxy-4,4'-biphenyl bis-diazonium tetrafluoroborate in acidic medium. Varying urobilinogen levels will produce a reddish-brown color.

pH: Based on a mixed indicator principle that gives a broad range of colors (yellow to cyan) covering the entire urinary pH range.

Ketones: Legal reaction. Based on the reaction of sodium nitroprusside with acetoacetic acid to form a purple complex.

Nitrites: Griess reaction. Nitrite reacts with sulfanilamide, followed by a diazo-coupling reaction to from a pink colored product.

Leukocytes: Granulocytic leukocytes contain esterases that catalyze the hydrolysis of 3-(NToluenesulfonyl-L-alanyloxy) indole (TAI) to from indoxyl, which further reacts with 2-Methoxy-4-(N-morpholino) benzenediazonium (MMB) to form a purple product.

Blood: Based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of Cumene hydroperoxide and 3,3,5,5'- tetramethylbenzidine to form a cyan color.

AUTION MAX AX-4060 urine analyzer

Color: Urine color tone measurement, red (635 nm), green (525 nm) and blue (470 nm) lights are transmitted to the sample in the cylindrical tube, and the hue and contrast of the sample are obtained from the amount of transmitted light. Urine color is reported as colorless, yellow, orange, brown, red, violet, blue, and green. Light, normal, or dark are also reported for each color (for a total of 22 contrast and hue indications). The urine color measurement is also used in this urinalysis system for a color correction algorithm to compensate for intrinsically colored urine samples when testing for bilirubin, urobilinogen, and ketone analyte pads. The measurements glucose, protein, pH, nitrites, leukocytes, and blood are not compensated for urine color.

Two wavelengths are used for the reflectance determination of each analyte, except blood which uses a single wavelength. The percent reflectance received by the optical sensor for each analyte on the test strip is then used to calculate a semiquantitative value and a qualitative value. An internal turbidity/color tone measurement unit measures sample turbidity based on the calculation of scattered and transmitted light. Specific gravity is calculated based on the light refraction of the urine sample (reflection-refractometry).

C Instrument Description Information:

1. Instrument Name:
   AUTION MAX AX-4060 urine analyzer

2. Specimen Identification:
   Urine identification can be performed manually or with the analyzer barcode scanner.

3. Specimen Sampling and Handling:
   Samples tubes are manually placed into a rack, which is loaded into the analyzer. Alternatively, samples can be placed individually into the STAT port. Samples can be labeled with a barcode, which is read with a barcode reader. Test strip picking, sample transport, sample aspiration, sample dispensing onto the test strip, and measurement are automated by the instrument.

4. Calibration:
   The AUTION MAX AX-4060 urine analyzer requires optical unit calibration. For optical unit calibration, the instrument only needs to be calibrated if the reflectivity for each wavelength falls outside of the defined range in the measurement check and/or trouble with the instrument is suspected.

5. Quality Control:
   The sponsor states the following in their labeling: "Performance of the AUTION MAX AX-4060 and the AUTION Sticks 9EB should be confirmed regularly utilizing both known negative and known positive urine specimens or control materials."

V Substantial Equivalence Information:

A Predicate Device Name(s):
AUTION MAX AX-4030 Urinalysis System

B Predicate 510(k) Number(s):
K093098

C Comparison with Predicate(s):

Device & Predicate Device(s):	K193514	K093098
Device Trade Name	AUTION MAX AX-4060 Urinalysis System	AUTION MAX AX-4030 Urinalysis System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the in vitro measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes.	same
Specimen Type	Urine	same
General Device Characteristic Differences		
LED Wavelength	5 LED wavelengths (450, 525, 562, 635 and 760 nm)	5 LED wavelengths (430, 500, 565, 635, 760 nm)

VI Standards/Guidance Documents Referenced:

Clinical and Laboratory Standards Institute (CLSI) EP05-A3: *Evaluation of Precision Performance of Clinical Devices; Approved Guideline—Third Edition*

CLSI EP12-A2: *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition*

International Electrotechnical Commission (IEC) 60601-1-2:2014: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 61010-1 (Edition 3.1): Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)]

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Precision study was conducted in accordance with the general guidelines established in CLSI EP05-A3 and CLSI EP12-A2.

Three (3) independent AX-4060 Analyzers and Test Strip lot sets were tested according to a 20 day, two (2) runs per day, and two (2) replicates (duplicates). The study was performed by four (4) operators. For each analyte, three sample levels (Negative/Normal, Mid, and High) were tested. Within run (repeatability) and total imprecision (reproducibility) were calculated. The results are displayed below:

Precision – Negative

Analyte	Expected Result	Repeatability (N=240)		Reproducibility (N=240)	
		Exact match	Within ± 1 CB	Exact match	Within ± 1 CB
Glucose	Normal	100%	100%	100%	100%
Protein	Negative	100%	100%	100%	100%
Bilirubin	Normal	100%	100%	100%	100%
Urobilinogen	Negative	100%	100%	100%	100%
pH	5	99%	100%	100%	100%
Blood	Negative	100%	100%	100%	100%
Ketones	Negative	100%	100%	100%	100%
Nitrite	Negative	100%	100%	100%	100%
Leukocytes	Negative	100%	100%	100%	100%
Turbidity	Negative	100%	100%	100%	100%
Color	Colorless	100%	100%	100%	100%

Precision – Positive test

Analyte	Expected Result	Repeatability (N=240)		Reproducibility (N=240)	
		Exact match	Within ± 1 CB	Exact match	Within ± 1 CB
Glucose	1+	100%	100%	100%	100%
Protein	1+	91%	100%	95%	100%
Bilirubin	2+	100%	100%	100%	100%
Urobilinogen	2+	100%	100%	96%	100%
pH	6.5	99%	100%	100%	100%
Blood	1+	100%	100%	100%	100%
Ketones	1+	98%	100%	99%	100%
Nitrite	1+	100%	100%	100%	100%
Leukocytes	250 (Leu/µL)	100%	100%	100%	100%
Turbidity	1+	100%	100%	100%	100%
Color	Yellow	100%	100%	100%	100%

Precision – High Positive

Analyte	Expected Result	Repeatability (N=240)		Reproducibility (N=240)	
		Exact match	Within ± 1 CB	Exact match	Within ± 1 CB
Glucose	3+	100%	100%	100%	100%
Protein	3+	91%	100%	95%	100%
Bilirubin	3+	100%	100%	100%	100%
Urobilinogen	4+	100%	100%	96%	100%
pH	5	99%	100%	100%	100%
Blood	2+	100%	100%	100%	100%
Ketones	3+	98%	100%	99%	100%
Nitrite	2+	100%	100%	100%	100%
Leukocytes	>500 (Leu/µL)	100%	100%	100%	100%
Turbidity	2+	100%	100%	100%	100%
Color	Dark Yellow	100%	100%	100%	100%

2. Linearity:

The sponsor performed other studies to establish sensitivity/cutoffs. Refer to the Detection Limit and Sensitivity studies in section 6 below, for more information.

3. Analytical Specificity/Interference:

Analytical specificity studies were conducted to assess for interfering effects of endogenous substances (including pH and specific gravity) and therapeutic drugs on the AUTION MAX AX-4060 Urinalysis System. Testing was performed on one (1) analyzer using one (1) lot of test strips and conducted with urine samples prepared at two concentrations for each analyte, with six (6) replicates per sample. A high positive sample was prepared by spiking each analyte into pooled negative urine. A negative sample pool was also used. The sample pools were spiked with potential interfering substances. Interference was defined when the color block changed by more than ±1. The results of testing depicting the highest concentration of the interferent tested with no effect, are provided below:

Substances with no interference at the highest levels tested

Interfering Substances	Highest Concentration Tested with No Interference
Therapeutic drugs	
Acetaminophen	40 mg/dL
Acetoacetic Acid Lithium	150 mg/dL
Ammonium Chloride	400 mg/dL
Amoxicillin	360 mg/dL
Calcium Chloride	300 mg/dL
Citric Acid Monohydrate	75 mg/dL
Methyl-dopa	40 mg/dL
Oxalic Acid Dihydrate	70 mg/dL

Interfering Substances	Highest Concentration Tested with No Interference
Therapeutic drugs	
Potassium Chloride	1000 mg/dL
Sodium Chloride	2000 mg/dL
Sodium Dihydrogen Phosphate	1000 mg/dL
Sodium Nitrate	10 mg/dL
Sodium Nitrite	2 mg/dL
Endogenous substances	
Albumin	1000 mg/dL
Creatinine	600 mg/dL
Fructose	100 mg/dL
Galactose	100 mg/dL
Glucose	2000 mg/dL
Glycine	450 mg/dL
Lactose	108 mg/dL
Low Urine pH	pH 5
Riboflavin	10 mg/dL
Urea	3000 mg/dL

For interfering substances whose effects on various analytes were observed in the initial screening, an additional dose-dependency evaluation was performed to establish the concentration limit below which no significant interference is expected. The results are provided in the table (below):

Substances interfering with test analytes

Analyte	Substance	Concentration limit with no significant interference	Effect when above the concentration limit
Glucose	Ascorbic Acid	20 mg/dL	At 50 mg/dL decreased from +2 to +1
	Urobilinogen	4 mg/dL	At 8 mg/dL decreased from +2 to +1
	MESNA	100 mg/dL	At 150 mg/dL increased from NORMAL to +/-
Protein	Sodium Bicarbonate	200 mg/dL	At 250 mg/dL increased from +3 to +4
	Specific Gravity	1.02	At 1.025 decreased from +3 to +2
	Hemoglobin	10 mg/dL	At 12 mg/dL increased from - to +/-
Urobilinogen	Bilirubin	3.5 mg/dL	At 7 mg/dL increased from NORMAL to +1
Blood	Ascorbic Acid	50 mg/dL	At 100 mg/dL decreased from +2 to +1
	MESNA	50 mg/dL	At 100 mg/dL decreased from +2 to +1

Analyte	Substance	Concentration limit with no significant interference	Effect when above the concentration limit
	Urine pH	pH 8.5	At pH 9 decreased from +2 to +/-
	Methyl-dopa	50 mg/dL	At 67 mg/dL increased from - to +/-
Ketones	MESNA	1.5 mg/dL	At 3 mg/dL increased from - to +/-
Nitrite	Ascorbic Acid	50 mg/dL	At 100 mg/dL decreased from +2 to +1
	MESNA	150 mg/dL	At 200 mg/dL decreased from +2 to +1
	Urobilinogen	5 mg/dL	At 8 mg/dL decreased from +2 to +1
Leukocytes	Bilirubin	7 mg/dL	At 10.5 mg/dL increased from negative to 25
	Hemoglobin	3 mg/dL	At 6.25 mg/dL decreased from 250 to 75
	MESNA	370 mg/dL	At 660 mg/dL decreased from 250 to 75

Interference effect of intrinsic urine color: Studies were conducted to verify that the test strip analytes of protein, leukocytes, nitrite, ketones, glucose, urobilinogen and blood were insensitive to interference from red, brown, orange, green and various yellow-intensity colored urine samples. The results demonstrated that red, brown, orange, green and various yellow-intensity urine colors do not significantly impact the results for those analytes tested since all results were within +/- 1 color block.

Color Correction: The candidate device includes a feature that corrects for intrinsic urine color for bilirubin, urobilinogen, and ketones. The sponsor also provided information to support this feature.

Limitations: The following limitations are included in the labeling:

1. Elevated hematuria (6.25 mg/dL Hb, approximately 2,156 RBC/µL) has been shown to cause falsely lowered Leukocyte readings and should be considered when interpreting Leukocyte results.
2. Samples from patients taking methyl dopa may be falsely elevated for blood, negative to trace at 67 mg/dL and negative to +1 at 225 mg/dL. Patients taking the maximum daily dose of methyl dopa may have approximately 210 mg/dL methyl dopa excreted in the urine.
3. Patients taking SGLT2 or similar inhibitors may have extremely high urinary glucose values. Due to a hook effect on the glucose pad, if a patient's urine glucose level is greater than 20,000 mg/dL, then falsely decreased glucose results may be obtained with the test.

4. When acidic or alkaline compounds, such as ascorbic acid and sodium bicarbonate are taken internally for treatment or as supplements, they may affect urine pH.

4. Assay Reportable Range:
Measurement results are represented as qualitative and semi-quantitative values as listed below:

Analyte Measurement ranges Qualitative/Semi-Quantitative

Analyte	Reportable range	
Glucose	Qualitative:	normal, ±, 1+, 2+, 3+, 4+
	Semi-quantitative:	normal, 30-50, 70-100, 150-200, 300-500, ≥1000 mg/dL
Protein	Qualitative:	negative, ±, 1+, 2+, 3+, 4+
	Semi-quantitative:	negative, 10-20, 30-70, 100-200, 300-600, >600 mg/dL
Bilirubin	Qualitative:	negative, 1+, 2+, 3+, 4+
	Semi-quantitative:	negative, 0.5-1.0, 2.0-4.0, 6.0-10.0, >10.0 mg/dL
Urobilinogen	Qualitative:	normal, 1+, 2+, 3+, 4+
	Semi-quantitative:	normal, 2.0-3.0, 4.0-6.0, 8.0-12.0, >12.0 mg/dL
Blood	Qualitative:	negative, ±, 1+, 2+, 3
	Semi-quantitative:	negative, 0.03, 0.06-0.10,0.20-0.50, ≥1.0 mg/dL
Ketones	Qualitative:	negative, ±, 1+, 2+, 3+, 4+
	Semi-quantitative:	Negative, 10-20, 40-60, 80-100, ≥150 mg/dL
Nitrite	Qualitative:	negative, 1+, 2+
pH	Measured value:	5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
Leukocytes	Semi-quantitative:	negative, 25, 75, 250, 500 Leu/µL

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
The system is traceable to internal standards.

6. Detection Limit:

Limits of Detection and Minimum Detection Sensitivity were determined using three instruments and three reagent lots. In the table (below), are the quantitative values indicating the lower limit of the block in which 50% or more of the results fall into the specific block:

Detection Sensitivity for each Analyte per block

Analyte	Qualitative Block Output	Semi-Quantitative rank	Evaluation concentration (mg/dL)	% Positive
Bilirubin	+1	0.5-1.0	0.5	53
	+2	2.0-4.0	1.5	93
	+3	8.0-12.0	5	93
	+4	Over 12.0	12	93
Blood	+/-	0.03	0.023	100
	+1	0.06-0.10	0.045	100
	+2	0.20-0.50	0.15	97

Analyte	Qualitative Block Output	Semi-Quantitative rank	Evaluation concentration (mg/dL)	% Positive
	+3	1.00-over	0.75	73
Glucose	+/-	30-50	30	100
	+1	70-100	60	93
	+2	150-200	125	97
	+3	300-500	250	100
	+4	1000-over	750	100
Ketones	+/-	Below 9	4	97
	+1	10-20	7.5	100
	+2	40-60	30	100
	+3	80-100	70	63
	+4	150-over	150	100
Leukocytes	25	25	14 cells/µL	100
	75	75	48 cells/µL	70
	250	250	172 cells/µL	60
	500	500	396 cells/µL	90
Nitrites	+1		0.075	57
	+2		0.3	100
Protein	+/-	10-20	10	67
	+1	30-70	30	77
	+2	100-200	85	53
	+3	300-600	250	73
	+4	Over 600	800	93
pH	5.5	5.5	5.3	100
	6	6	5.8	100
	6.5	6.5	6.2	100
	7	7	6.8	93
	7.5	7.5	7.3	80
	8	8	8	100
	8.5	8.5	8.5	100
	9	9	8.8	87
Urobilinogen	+1	2.0-3.0	2	60
	+2	4.0-6.0	4	80
	+3	8.0-12.0	7	100
	+4	Over 12.0	14	100

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Refer to the Method Comparison studies below for more information about the device's accuracy.

9. Carry-Over:

A study was performed to evaluate carry-over contamination potential caused by the AX-4060 nozzle and pump tubing from one sample to the next. Two sample pools were created at two different analyte concentration levels (low target value [LTV] sample and high target value [HTV] sample) created by spiking the pools with the appropriate analytes and tested to ensure high/low testing rank. Testing found all the measurement results of the LTV sample after HTV measurement agreed with the target block for each measurement item.

B Comparison Studies:

1. Method Comparison with Predicate Device:
A method comparison study was conducted at two (2) clinical laboratories to evaluate the agreement of results from the AUTION MAX AX-4060 Urinalysis System to the predicate device, the AUTION MAX AX-4030 Urinalysis System.

1044 natural patient samples were tested at two sites, with additional spiked and archived samples used to supplement abnormal analyte levels. Testing was performed in duplicate on the comparator AX-4030. The results below compare the first replicate on the AX-4060 (candidate device) to the first replicate from the AX-4030 (comparator device). Duplicates measured on the comparator were used to identify samples near the cutoff (i.e., where sample replicates were not exact matches but were within one block). Based on duplicate testing on the comparator, some of the discordant samples in the tables below were near the cutoff with duplicate results within one color block.

Analyte Concordance Charts are depicted below:

Concordance Chart for Bilirubin

Bilirubin		Comparator: AX-4030				
		Negative (-)	1+	2+	3+	4+
AX-4060	Negative (-)	1181	4	0	0	0
	1+	4	65	1	0	0
	2+	0	1	40	0	0
	3+	0	0	0	24	0
	4+	0	0	0	0	18
Total sample #		1185	70	41	24	18
Exact Match %		99.7	92.9	97.6	100	99.3
Within ±1 Color Block %		100	100	100	100	100

Concordance Chart for Blood

Blood		Comparator: AX-4030				
		Negative (-)	±	1+	2+	3+
AX-4060	Negative (-)	648	6	0	0	0
	±	4	126	7	0	0
	1+	0	18	97	3	0
	2+	0	0	13	51	2
	3+	0	0	0	11	58
Total sample #		652	150	117	65	60
Exact Match %		99.4	84.0	82.9	78.5	96.7
Within ±1 Color Block %		100	100	100	100	100

Concordance Chart for Glucose

Glucose		Comparator: AX-4030					
		Normal	±	1+	2+	3+	4+
AX-4060	Normal	663	3	0	0	0	0
	±	2	44	2	0	0	0
	1+	0	2	40	3	0	0
	2+	0	0	0	28	6	0
	3+	0	0	0	2	62	0
	4+	0	0	0	0	7	180
Total		665	49	42	33	75	180
Exact Match %		99.7	89.8	95.2	84.8	82.7	100
Within ±1 Color Block %		100	100	100	100	100	100

Concordance Chart for Ketones

Ketones		Comparator: AX-4030					
		Negative	±	1+	2+	3+	4+
AX-4060	Negative	1123	3	0	0	0	0
	±	2	40	4	0	0	0
	1+	0	1	45	1	0	0
	2+	0	0	0	58	3	0
	3+	0	0	0	2	33	0
	4+	0	0	0	0	1	20
Total #		1125	45	48	61	37	20
Exact Match %		99.8	90.9	91.8	95.1	89.2	100.0
Within ±1 Color Block %		100	100	100	100	100	100

Concordance Chart for Leukocytes

Leukocytes		Comparator: AX-4030				
		Negative	25	75	250	500
AX-4060	Negative	692	6	0	0	0
	25	5	62	12	0	0
	75	0	5	81	6	0
	250	0	0	6	59	6
	500	0	0	0	4	100
Total		697	73	99	69	106
Exact Match %		99.3	84.9	81.8	85.5	94.3
Within ±1 Color Block %		100	100	100	100	100

Concordance Chart for Nitrite

Nitrite		Comparator: AX-4030		
		Negative	1+	2+
AX-4060	Negative	926	0	0
	1+	2	26	1
	2+	0	0	91
Total		928	26	92
Exact Match %		99.8	100	98.9
Within ± 1 Color Block %		100	100	100

Concordance Chart for Protein

Protein		Comparator: AX-4030					
		Neg	±	1+	2+	3+	4+
AX-4060	Neg	410	24	0	0	0	0
	±	8	213	32	0	0	0
	1+	0	1	185	10	0	0
	2+	0	0	1	84	1	0
	3+	0	0	0	3	51	0
	4+	0	0	0	0	12	13
Total sample #		418	238	218	97	64	13
Exact Match %		98.1	89.5	84.9	86.6	79.7	100
Within ± 1 Color Block %		100	100	100	100	100	100

Concordance Chart for Urobilinogen

Urobilinogen		Comparator: AX-4030				
		Normal	1+	2+	3+	4+
AX-4060	Normal	1192	5	0	0	0
	1+	2	55	2	0	0
	2+	0	0	44	4	0
	3+	0	0	0	21	3
	4+	0	0	0	0	13
Total sample #		1194	60	46	25	16
Exact Match %		99.8	91.7	95.7	84.0	81.3
Within ± 1 Color Block %		100	100	100	100	100

Concordance Chart for pH

pH		Comparator: AX-4030								
		5.0	5.5	6	6.5	7.0	7.5	8.0	8.5	9
AX-4060	5.0	70	2	0	0	0	0	0	0	0
	5.5	15	266	8	0	0	0	0	0	0
	6.0	0	9	227	7	0	0	0	0	0
	6.5	0	0	8	186	2	0	0	0	0
	7.0	0	0	0	11	109	1	0	0	0
	7.5	0	0	0	0	6	43	0	0	0
	8.0	0	0	0	0	0	14	33	0	0
	8.5	0	0	0	0	0	0	6	18	0
	9	0	0	0	0	0	0	0	11	11
Total sample #		85	277	243	204	117	58	39	29	11
Exact Match %		82.4	96.0	93.4	91.2	93.2	74.1	84.6	62.1	100
Within ± 1 Color Block %		100	100	100	100	100	100	100	100	100

Concordance Chart for Turbidity

Turbidity		Comparator: AX-4030		
		-	1+	2+
AX-4060	-	827	2	0
	1+	12	149	1
	2+	0	0	30
Total		839	151	31
Exact Match %		98.6	98.7	96.8
Within ± 1 Block %		100%	100%	100%

Color Tone: This is a light-transmission-based color detection system which is integrated into the AX-4060 analyzer and is independent of the 9EB test strip. This system reports the color tone results and can detect the following urine colors: Colorless, Yellow, Orange, Brown, Red, Violet, Blue, and Green. As a result of a lack of natural clinical specimens for Brown, Green, Blue, Violet, and Red colors (due to the infrequent occurrence of urine specimens of these colors), these colors were evaluated using contrived samples (dyes added to natural urine samples).

Concordance Chart for Color Tone

Color Tone		Comparator: AX-4030							
		Colorless	Yellow	Orange	Brown	Red	Violet	Blue	Green
AX-4060	Colorless	17	0	0	0	0	0	0	0
	Yellow	127	822	0	0	0	0	0	7
	Orange	5	52	20	6	0	0	0	0
	Brown	0	0	0	108	0	0	0	0
	Red	0	0	0	0	63	0	0	0
	Violet	0	0	0	0	2	91	0	0
	Blue	0	0	0	0	0	0	66	0
	Green	0	0	0	0	0	0	0	92
Total sample #		149	874	20	114	65	91	66	99
Exact Match %		11.4	94.1	100	94.7	96.9	100	100	92.9
Within ± 1 Color Block %		100	100	100	100	100	100	100	100

Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Glucose
A small amount of glucose may be detected in normal urine. Generally, the amount of glucose is below the sensitivity level of the method; however, on occasion may produce ± (trace) results.

Consistently positive glucose results should be clinically investigated.

Protein
Although very small quantities of protein are normally excreted, the amount is generally below the sensitivity level for detection. Positive results require clinical assessment/additional testing to determine its significance.

Bilirubin
In normal urine, no bilirubin is normally detected. Positive findings should be diagnostically and clinically investigated.

Urobilinogen
Healthy individuals may excrete a small amount of Urobilinogen and may be increased especially after exercise. Concentrations are generally at their peak in the afternoon.

pH
Normal and abnormal urine pH ranges from 5.0 to 8.0 and is influenced by diet. Typical values for first morning specimens, from healthy individuals, are between pH 5.0 - 6.0.

Blood
A blue-green dotted reaction indicates the presence of erythrocytes. Up to 5 erythrocytes / µL may be found in normal urine specimens. Urine from menstruating women may contain blood. A large amount of blood should be clinically investigated.

Ketones
Ketones are not normally detected in urine specimens from healthy individuals. However, urine specimens from individuals who are fasting, pregnant, or who undergo regular strenuous exercise, may exhibit significant amounts of ketones. The presence of ketones, in urine specimens from patients with diabetes, may provide a useful marker for metabolic status.

Nitrite
A nitrite concentration of as low as 0.08 mg/dL may be detected and produce a positive test. A negative result may occur during fasting episodes since nitrates are not appearing in the urine.

Leukocytes
Normal urine specimens should not produce a positive reaction. Small amounts of leukocyte esterase, causing a positive reaction should be repeated, using a fresh urine specimen, from the same patient. Positive results require further testing for pyuria.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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