

REVIEW MEMORANDUM
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

- A. 510(k) Number:**
k063390
- B. Purpose for Submission:**
New submission for the Urine Chemistry Analyzer UR-50 for use with IND Diagnostic's previously cleared Urinalysis Reagent Strips (k993850). A name change to "IND Urinalysis Reagent Strips" and an updated indication for use for IND Urinalysis Reagent Strips (k993850), to include "may be read visually or instrumentally by the IND UR-50 reader".
- C. Measurand:**
Glucose, Blood, Leukocytes, Specific Gravity, pH, Nitrite, Protein, Ketones, Urobilinogen and Bilirubin in urine
- D. Type of Test:**
Qualitative/Semi-Quantitative
- E. Applicant:**
IND Diagnostic Inc.
- F. Proprietary and Established Names:**
Urine Chemistry Analyzer UR-50, Model 900-UR50; reagent strips are known as IND Urinalysis Reagent Strips.
- G. Regulatory Information:**
1. Regulation section:
 - 21 CFR § 862.1340 – Urinary Glucose (nonquantitative) test system
 - 21 CFR § 864.6550 – Occult Blood Test
 - 21 CFR § 864.7675 – Leukocyte peroxidase test
 - 21 CFR § 862.2800 – Refractometer for clinical use
 - 21 CFR § 862.1550 – Urinary pH (nonquantitative) test system
 - 21 CFR § 862.1510 – Nitrite (nonquantitative) test system
 - 21 CFR § 862.1643 – Urinary protein or albumin (nonquantitative) test system
 - 21 CFR § 862.1435 – Ketones (nonquantitative) test system
 - 21 CFR § 862.1785 – Urinary urobilinogen (nonquantitative) test system
 - 21 CFR § 862.1115 – Urinary bilirubin and its conjugates (nonquantitative) test system
 - 21 CFR § 862.2900 – Automated urinalysis system

2. Classification:
Class II
3. Product Code:
 - JIL Enzymatic Method, Glucose (Urinary, Non-quantitative)
 - JIO Blood, Occult, Colorimetric, in urine
 - LJX Test, Urine Leukocyte
 - JRE Refractometer for Clinical Use
 - CEN Dye-Indicator, pH (urinary, non-quantitative)
 - JMT Diazo (colorimetric), Nitrite (urinary, non-quantitative)
 - JIR Indicator method, Protein or Albumin (urinary, non-quantitative)
 - JIN Nitroprusside, Ketones (urinary, non-quantitative)
 - CDM Diazonium colorimetry, Urobilinogen (urinary, non-quantitative)
 - JJB Azo-Dyes, colorimetric, Bilirubin & its conjugates (urinary non-quantitative)
 - KQO Automated Urinalysis System
4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
See indications for use below.
2. Indication(s) for use:
Urine Chemistry Analyzer UR-50 (UR-50) is for use with IND Urinalysis Reagent Strips for the determination of glucose, bilirubin, ketone, blood, protein, urobilinogen, nitrite, leukocytes, pH, and specific gravity in urine. It can be used for testing in the clinical laboratory setting. For professional use only. These measurements are useful in the evaluation of renal, urinary, and metabolic disorders.
3. Special Conditions for use statement(s):
For professional use only
4. Special instrument requirements:
IND Urine Chemistry Analyzer UR-50

I. Device Description:

The Urine Chemistry Analyzer UR-50 (UR-50) is a benchtop instrument, intended for use with the sponsor's cleared test strips (k993850). The UR-50 reports results semi-quantitatively on up to 10 analytes. The UR-50 contains the electronics, sample transport mechanism, display screen and printer.

Test strips are manually dipped into the urine sample and placed on the strip platform. The strip is transported into the instrument where readings of each analyte are taken at timed intervals. Readings are converted to concentrations

which are displayed to the operator and printed by the on-board printer. There are options to print results or to transmit them to a computer system. The sponsor does not supply the necessary cables or software to accomplish this transfer and does not plan to promote this feature.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Bayer Clinitek 50 Urine Chemistry Analyzer; Bayer Multistix and Urinalysis Reagent Strips
2. Predicate 510(k) number(s):
Clinitek Analyzer k960546; Bayer Multistix k905396 and Urinalysis Reagent Strips k993850
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Used in the determination of glucose, blood, leukocytes, specific gravity, pH, nitrite, protein, ketones, urobilinogen, and bilirubin in urine.	Same
Basic Operating Principle	Reflectance Photometry	Same
Testing Options	Single sample	Same
Test Steps	Dip and place urine strip onto test table/platform	Same
Printer	Internal or External	Same

Differences		
Item	Device	Predicate
Output Results	Normal System (combination of words and number values)	+/- System
Environmental Requirements	5 – 40° C. Relative Humidity ≤ 80%	18 - 30° C. Relative Humidity 20 - 85%
Dimension	230 x 180 x 110 mm	200 x 130 x 130 mm
Weight	2.5 lbs.	3.0 lbs.

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

None were referenced in the submission.

L. Test Principle:

The Urine Chemistry Analyzer UR-50 is a portable reflectance spectrophotometer that combines color sampling technology with an advanced photo sensor chip that translates detected color spectrums into frequencies. The frequencies are converted into clinically useful results.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

IND In-house reproducibility studies used three different UR-50 analyzers and three different lot numbers of IND Urinalysis Reagent strips. BioRad urine control materials levels 1 and 2 were used as samples. Two trained technicians each tested 15 test strips of each lot number of strips on each analyzer (90 tests/analyte). Results were pooled. Note the sponsor considered pH changes of ± 0.5 and Specific Gravity ± 1 level (0.005) in agreement due to the variance in the parameters.

Level 1

Analyte	In Agreement	Not In Agreement	% Agreement
Glucose	90	0	100%
Bilirubin	90	0	100%
Ketone	90	0	100%
Specific Gravity	90 within range of ± 0.005		100%
Blood	90	0	100%
pH	90 within range of ± 0.5		100%
Protein	90	0	100%
Urobilinogen	90	0	100%
Nitrite	90	0	100%
Leukocytes	90	0	100%

Level 2

Analyte	In Agreement	Not In Agreement	% Agreement
Glucose (500 mg/dL)	90	0	100%
Bilirubin (Large)	90	0	100%
Ketone (40 mg/dL)	77	13	86%
Specific Gravity	90 within range of ± 0.005		100%
Blood	83	7	92%

pH	90 within range of ± 0.5		100%
Protein (≥ 300 mg/dL)	90	0	100%
Urobilinogen (8.0 EU/dL)	90	0	100%
Nitrite	90	0	100%
Leukocytes (Large)	90	0	100%

Note: All results not in 100% agreement (ketones and blood) are within \pm color block difference.

In addition to IND in-house reproducibility studies, testing was performed by a trained medical technician at a medical site using BioRad urine control materials, one UR-50 analyzer and one lot of IND Urinalysis Reagent test strips.

Level 1

Analyte	In Agreement	Not In Agreement	% Agreement
Glucose	20	0	100%
Bilirubin	20	0	100%
Ketone	20	0	100%
Specific Gravity	18 of 20 samples in range of ± 0.005		90%
Blood	20	0	100%
pH	20 within range of ± 0.5		100%
Protein	20	0	100%
Urobilinogen	20	0	100%
Nitrite	20	0	100%
Leukocytes	20	0	100%

Level 2

Analyte	In Agreement	Not In Agreement	% Agreement
Glucose (500 mg/dL)	19	1	95%
Bilirubin (Large)	20	0	100%
Ketone (15- 40 mg/dL)	20 within range +/- 1 color block		100%
Specific Gravity (1.020 –	20 within range of \pm 0.005		100%

1.025)			
Blood (Mod – Large)	20 within range +/- 1 color block		100%
pH (7.0 +/- 0.5)	20 within range of ± 0.005		100%
Protein (≥300 mg/dL)	20 within range +/- 1 color block		100%
Urobilinogen (8.0 EU/dL)	20	0	100%
Nitrite	20	0	100%
Leukocytes (Large)	20	0	100%

- b. *Linearity/assay reportable range:*
IND in-house linearity studies were performed by spiking commercially acquired artificial urine to achieve various concentrations of the various analytes. Testing was done on two instruments using two different lot numbers of test strips, four tests per strip lot on each instrument at each level.

Glucose

	Applied Concentration, mg/dL						
		0	50	100	250	500	1000
Concentration Reported by Analyzer with Strip, mg/dL	1000					1	16
	500					14	
	250				13	1	
	100			14	3		
	Negative	16	16	2			
	Total # of Samples at Concentration	16	16	16	16	16	16

Bilirubin

	Applied Concentration, mg/dL					
		0	0.25	0.50	1	2
Concentration Reported by Analyzer with Strip, mg/dL	Large				2	16
	Moderate			13	14	
	Small		12	3	1	
	Negative	16	4			
	Total # of Samples at Concentration	16	16	16	16	16

Ketones

	Applied Concentration, mg/dL						
Concentration Reported by Analyzer with Strip, mg/dL		0	2	5	15	40	80
	≥ 80						14
	40					15	2
	15				14	1	
	Trace		1	12	2		
	Negative	16	15	4			
	Total # of Samples at Concentration	16	16	16	16	16	16

Specific Gravity

	Applied Concentration,							
Concentration Reported by Analyzer with Strip		1.000	1.005	1.010	1.015	1.020	1.025	1.030
	1.030							16
	1.025					1	14	
	1.020				2	12	2	
	1.015			2	13	3		
	1.010			13	1			
	≤1.005	16	16	1				
	Total # of Samples at Concentration	16	16	16	16	16	16	16

Occult Blood

	Applied Concentration, mg/dL					
Concentration Reported by Analyzer with Strip, mg/dL		0	0.03	0.06	0.15	0.75
	Large					16
	Moderate				13	
	Small			13	3	
	Trace		6	3		
	Negative	16	10			
	Total # of Samples at Concentration	16	16	16	16	16

pH

	Applied Concentration								
		5.0	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Concentration Reported by Analyzer with Strip	≥8.5						2	14	16
	8.0					1	14	2	
	7.5				2	14			
	7.0			4	13	1			
	6.5		4	10	1				
	6.0		12	2					
	5.5								
	5.0	16							
Total # of Samples at Concentration		16	16	16	16	16	16	16	16

Protein

	Applied Concentration, mg/dL						
		0	7	15	30	100	300
Concentration Reported by Analyzer with Strip, mg/dL	300					1	16
	100					15	
	30			1	13		
	Trace		1	14	3		
	Negative	16	15	1			
	Total # of Samples at Concentration		16	16	16	16	16

Nitrite

	Applied Concentration, mg/dL				
		0	0.02	0.05	0.3
Concentration Reported by Analyzer with Strip, mg/dL	Positive		2	12	16
	Negative	16	14	4	
	Total # of Samples at Concentration		16	16	16

Leukocytes

	Applied Concentration, mg/dL						
	0	2	5	15	75	200	
Concentration Reported by Analyzer with Strip, mg/dL	Large						16
	Moderate					13	
	Small				13	3	
	Trace		2	9	3		
	Negative	16	14	6			
Total # of Samples at Concentration	16	16	16	16	16	16	

Urobilinogen

	Applied Concentration, mg/dL					
	0.2	1.0	2.0	4.0	8.0	
Concentration Reported by Analyzer with Strip, mg/dL	≥ 8.0				2	15
	4.0				13	1
	2.0			15	1	
	1.0		16	1		
	0.2	16				
Total # of Samples at Concentration	16	16	16	16	16	

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Same as k993850
 - d. *Detection limit:*
See assay reportable range above.
 - e. *Analytical specificity:*
Same as k993850
 - f. *Assay cut-off:*
Not applicable
2. Comparison studies:
- a. *Method comparison with predicate device:*

Patient and spiked samples were tested in hospital settings on both the UR-50 analyzer and Bayer Clinitek-50 using the respective reagent strips for each system. For this testing, pH changes of 0.5 and Specific Gravity ± 1 level (0.005) are considered in agreement due to the variance in the parameters.

Note that the IND UR-50 analyzer would measure and result any pH over 8.5 as ≥ 8.5 , no samples were found or contrived for these pH levels.

Glucose

1000				2	6
500				9	2
250		1	14	2	
100	24	9	1		
Negative	133	2			
Predicate	Negative	Trace	1+	2+	3+

Bilirubin

Large				6
Moderate			5	2
Small	1	7	2	2
Negative	177	10		
Predicate	Negative	1+	2+	3+

Ketones

≥ 80				1	9
40			1	15	3
15			7	2	
Trace	7	22	8		
Negative	122	9	1		
Predicate	Negative	trace	1+	2+	3+

Specific Gravity

1.030				2	8	27
1.025			1	12	1	13
1.020		1	16	9	4	
1.015	2	16	13	11		
1.010	18	12	5			
1.005						
Pred	1.005	1.010	1.015	1.020	1.025	1.030

Occult Blood

Large					4	27
Moderate					10	4
Small			3	6	1	
Trace	7		21	2	1	
Negative	94	2	8		1	
Predicate	Negative	Trace lyse	Trace intact		1+	2+ 3+

pH

9.0									
8.5							1		
8.0						4	4		
7.5						2			
7.0				3	23	11	3		
6.5	4	1		4	12				
6.0		9	22	15					
5.5	35	18	21	1					
5.0	17	1							
Predicate	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	≥ 9.0

Protein

300					9
100			1	12	5
30	1	10	24	17	
Trace	14	5	6		
Negative	89	7	7		
Predicate	Negative	Trace	1+	2+	3+

Nitrite

Positive	26	22
Negative	145	0
Predicate	Negative	Positive

Leukocytes

Large				1	6
Moderate			5	5	3
Small	1	2	8	5	
Trace	24	13	9		
Negative	124	3			
Predicate	Negative	Trace	1+	2+	3+

Urobilinogen

≥ 8.0						7
4.0					7	
2.0		1		5		
1.0		5	8	2		
0.2		170	9			
Negative						
Predicate	Negative	0.2	1.0	2.0	4.0	≥ 8.0

- 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:
Same as k993850

N. Instrument Name:
Urine Chemistry Analyzer UR-50, Model 900-UR50

O. System Descriptions:

1. Modes of Operation:
Single sample application
2. Software:

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

Yes or No

The following sections are present in the submission and they appear adequate based on the level of concern and the information provided in *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* issued May 11, 2005.

Level of Concern – The sponsor has classified their device as a Moderate Level of Concern.

Software Description – An overview of the features controlled by the software and the software operating environment is present.

Hazard Analysis – A summary of the hardware and software hazards, severity assessments and mitigations are present. The cause(s) of hazards, methods of control and corrective measures taken are listed.

Software Requirements Specification (SRS) – Documents listing functional requirements for the software are provided.

Architecture Design Chart – Depictions of functional units and software modules are provided in the form of flow charts.

Software Design Specification (SDS) – Software design specification documents are provided.

Traceability Analysis – Traceability among requirements, specifications, identified hazards and mitigations are provided.

Software Development Environment – A summary of the software life cycle development plan is provided.

Verification and Validation Documentation -- Functional test plan, pass/fail criteria and results are present.

Revision Level History – The sponsor has provided the revision log.

Unresolved Anomalies – A list of unresolved software anomalies. The sponsor indicated that none were unresolved.

3. Specimen Identification:
Manual (hand written)
4. Specimen Sampling and Handling:
Manually dip and place reagent strip onto strip platform
5. Calibration:
No user calibration is required. When the system is powered on, the instrument does a self-calibration of the optics.
6. Quality Control:
The sponsor recommends the following to their users:

1. Positive and negative control solutions should be tested on a regular basis.
2. Controls should be prepared according to the product instructions and tested like other samples.
3. Testing can be done at the beginning of the day, when a new lot is used and when the user has changed.
4. The user should run controls when there is a discrepancy between the printed results and the visual results or when there is doubt about the test results.
5. Users should always follow the appropriate federal, state and local guidelines concerning the use of external quality control materials discussed above.

P. Other supportive Instrument Performance Characteristics Data Not Covered in the “Performance Characteristics” Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10. The manual includes operating instructions, test interferences, sample handling instructions and an explanation of common problems.

R. Conclusion:

The data submitted by IND Diagnostic supports a Substantial Equivalence (SE) determination to other Automated Urinalysis System regulated under 21 CFR § 862.2900 – Automated urinalysis system. The data also supports the change in indicated use for Urinalysis Reagent Strip (k993850).