

AUTO UA® Liquid Urinalysis Reagents

The Power of AUTO UA® Automated Urinalysis Reagent Systems



Sciteck and the companies it evolved from (Chimera Research) began providing liquid reagents to laboratories for urinalysis on automated chemistry analyzers in 1989. Some of the advantages of using the liquid reagents to obtain quantitative results include such things as:

1. Utilization of equipment already on hand. For instance, many laboratories have one of more clinical chemistry analyzers with open channel capability that are underutilized (e.g. Hitachi, Beckman, Olympus and Mira instruments) which are compatible with these reagents. Thus, it may not be necessary to purchase new equipment.
2. Results for each analyte may be reported in true, quantitative units instead of current vague subjective terms (i.e. trace, moderate and large).
3. Because these assays utilize automated chemistry analyzers to produce quantitative results, a traditional and effective quality control program can be used from the software that is on-board the analyzers.
4. Use of a single automated chemistry analyzer for quantitative urinalysis and standard, quantitative serum chemistries can provide new, improved data for the attending physician. This is achieved by combining the quantitative data for urine and serum obtained using formulas and indices to produce valuable clinically significant information.

AUTO UA® Technology

The **AUTO UA®** System by Sciteck is a user-friendly, automated analyzing system for the quantitative and semi-quantitative analysis of fifteen (15) analytes in human urine. The system includes liquid reagent assays for pH, specific gravity, ketone bodies, beta-hydroxybutyric acid, bile acids¹, blood (Hgb), leukocyte esterase (WBC), nitrite, micro-protein (total), glucose, bilirubin, urobilinogen, creatinine and electrolytes (Na, K and Cl).

Historically, the first urinalysis was actually the beginning of laboratory medicine. References to the study of urine can be found in the pre-civilized drawings of cavemen and also in the Egyptian hieroglyphics such as the Edwin Smith Surgical Papyrus. The early physicians depicted in these ancient drawings often never saw the patient, only the patient's urine. Although these physicians lacked the sophisticated testing mechanisms now available, they were able to obtain basic diagnostic information². The evolution of urinalysis continues from ancient times to the dry chemistry methods (dipsticks) of yesterday to the automated liquid urinalysis system of today that is capable of providing clinically significant values while saving time and money.

AUTO UA® Compatibility

The **AUTO UA®** system of reagents is compatible with the Hitachi 717, 911, 747, the Olympus series, Beckman, and other auto-analyzers. Currently, the Sciteck system of reagents is used by large reference laboratories as well as small hospital laboratories providing an alternative to the use of dipstick or dipstick technology. The use of our system allows a laboratory to perform urinalysis on a truly "walk-away" basis. For example, a single Hitachi 747-200 operated by one technician can run approximately 4800 tests per hour. The fastest strip readers for example can run no more than about 60 urine tests per hour and a high speed analyzer for example can run as many as 5,000 assays per hour. The cost of running thousands of specimens per hour on 8 or 10 automated strip readers requiring 6 to 8 technicians cannot be compared to the more efficient use of one Hitachi 747-200 and one technician. Not only does the **AUTO UA®** system provide a savings between the reagents costs compared to the cost of dipsticks, but also a much larger savings in time and personnel.

AUTO UA® Liquid Urinalysis Reagents (continued)

Business Analysis

Current cost for a lab conducting 100,000 UA's per annum via UA dipsticks

$$\frac{\text{Dipsticks + Labor}}{\text{Annual Volume}} = \text{Cost / UA}$$

$$\frac{(100,000 \times \$0.62) + (100,000 \times \$1.89)^*}{100,000} = \$2.00 / \text{UA}$$

AUTO UA decreases costs 144% for labs conducting 100,000 urines per annum.

Proposed costs for utilizing AUTO UA (11) automated urinalysis system

$$\frac{\text{Annual reagent cost + Labor}}{\text{Annual Volume}} = \text{Cost / UA}$$

$$\frac{(\$ 65,000.00) + (100,000 \times \$0.375)}{100,000} = \$0.97 / \text{UA}$$

Formula assumes a 5 fold decrease in labor costs for use of Auto-analyzer

**This figure is conservative based on analysis sited in article 3 which indicates actual costs per dipstick UA to be between \$2.51 and \$3.24.*

References:

1. This assay is still currently in development.
2. S.K. Strasinger, *Urinalysis and Body Fluids*. F.A. Davis Co., Phil 1994.
3. Kaplan, R.E., Springate, J.E., and Feld, L.G. *Screening Dipstick Urinalysis: A Time to Change*. Pediatrics. 1997; 100:919-921.



AUTO UA® Liquid Urinalysis Reagents (continued)

Comparison Between Automated and Manual Urinalysis

Analyte	AUTO UA	UA Dipstick
Creatinine (quant.)	✓	
Micro-protein (total)	✓	
Sodium (Na)	✓	
Potassium (K)	✓	
Chloride (Cl)	✓	
Protein/Creatinine Ratio	✓	
Beta-Hydroxybutyric	✓	
Total Ketones Beta/Aceto	✓	
Urobilinogen	✓	✓
Bilirubin	✓	✓
Nitrite	✓	✓
Blood (Hgb)	✓	✓
Leukocyte Esterase	✓	✓
Ketone Bodies	✓	✓
Glucose	✓	✓
pH	✓	✓
Specific Gravity	✓	✓

Additional Benefits

Formulas and Indices for use with Automated Urinalysis Data

- Selectivity: Profile and panels for urinalysis can be selected and run in accordance with client preference thereby providing a cost savings to the laboratory and customer.
- Low volume requirements of less than 1.0 mL.
- Sciteck will provide an analyzer that will meet the needs of your laboratory. Instruments are provided to you based on reagent purchase volumes and length of contract. The reagent system utilizes 11 to 13 slots on the auto-analyzer leaving approximately 17 empty reagent slots available for expansion of esoteric testing, chemistry, drug screening, etc. . In addition, at the end of the contract the instrument belongs to you.
- Clinically significant indices can be calculated from the data:
 - RFI** (renal failure index), this is an expression of the urinary sodium concentration as a function of urine creatinine to serum.
 - FE** (Fractional excretion of Sodium), this is an expression of the fraction of filtered sodium that escapes reabsorption and is excreted into the urine. Early warning of volume depletion for hospitalized patients on I.V. is often difficult to detect at bedside. Detection could easily prevent acute renal failure and subsequent transfer to ICU.
 - NI** (Nutritional Index) is determined by serum BUN indexed to urine creatinine.
 - P/C ratio** (Protein / Creatinine ratio) is an expression of protein concentration relative to creatinine in untimed specimens is another way to avoid the necessity of collection of a 24-hour urine. Urinary protein/creatinine concentration ratios in excess of 3.5 usually indicate nephrotic range protein urea.
 - Total Ketone Bodies** Using both acetoacetic acid (e.g. Ketone assay) and Beta-hydroxybutyrate acid concentration providing valuable information for Diabetics.

AUTO UA® Liquid Urinalysis Reagents (continued)

U.S. and Foreign Patents and Patents Pending: 5,955,374; 5,801,059; 5,801,060; 5,759,860; 5,776,780; 5,780,239; 5,516,700; 5,733,785; 5,736,408; 6,468,805; 5,753,451; 6,617,123; 6,537,823

Usage: The **AUTO UA®** Assay System is a user friendly, automated open channel analyzer reagent system for the quantitative analysis of eleven (12) analytes in human urine. The system includes tests for pH, specific gravity, ketone bodies, blood (Hb), leukocyte esterase (LE), nitrite, protein, glucose, bilirubin, urobilinogen, beta-hydroxybutyrate and creatinine.

Principle:

pH: This test is based on an indicator principle which gives a broad range of color intensity covering the entire urinary pH range.

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urine of increasing ionic concentration. The assay is designed to detect ions in solution and is not based on refractive index. Results are procedure dependent. Every lab should establish its own in-house ranges.

Glucose: Glucose detection is based on an enzymatic reaction. This method was first described by Ba-nauch in 1975 for the determination of glucose in urine. The glucose test of this system is a further development of that test principle. The reaction utilizes an enzyme to catalyze the formation of gluconic acid and a hydrogen ion from the oxidation of glucose in the presence of a coenzyme. In turn, the coenzyme is reduced by the hydrogen ion and then measured by spectrophotometry.

Protein: The test for the detection of protein in urine employs an indicator dissolved in an acid medium which reacts with protein to form a colored protein dye complex. The amount of color produced is proportional to the protein concentration. This method was first described by Bradford in 1976. This protein test is a further development of the Bradford test principle.

Nitrite: This test depends on the conversion of nitrate (derived from the diet) to nitrite in the urine by the action of Gram negative bacteria. Nitrite, if present, reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a color complex.

Ketones: This test is based on the development of color due to the reaction of acetoacetic acid with nitroprusside. The assay detects acetoacetic acid in urine and is procedure dependent. Every lab should establish its own in-house test ranges. For Research and Laboratory use only.

Beta-Hydroxybutyrate: Beta-Hydroxybutyrate in the presence of NAD⁺ is converted to acetoacetate, producing NADH which can be monitored at 340 nm.

Blood (Hb): The chemical detection of blood is based on the strong pseudoperoxidase action of hemoglobin in erythrocytes. Numerous methods are described in the literature, which include various substrates (peroxides) and chromogens. Hemoglobin and myoglobin, if present, catalyze the oxidation of the indicator by the organic peroxide resulting in measurable color development. The Hemoglobin assay has a Zero Calibrator (PN# 204-02) that is specifically designed for this assay to ensure proper performance.

Leukocyte Esterase (LE): Leukocytes in urine are detected by the action of esterase, present in granulocytes. The esterase catalyzes the hydrolysis of the reagent's amino acid ester liberating a chromophore which produces color. The assay detects esterase activity in urine and is procedure dependent. Every lab should establish its own test ranges.

Bilirubin: The detection of bilirubin is based on the coupling reaction of a diazonium salt with bilirubin in an acid medium containing a surfactant to yield a measurable color reaction.

Urobilinogen: The detection of urobilinogen is based on the coupling reaction of a diazonium salt with urobilinogen in an acid medium containing a surfactant to yield a measurable color reaction.

Storage and Stability: Store at 2-10°C. The reagent is stable until expiration date on the container.

Specimen Collection & Preparation: The **AUTO UA®** reagents may be used on any freshly voided urine specimen or urine collected under special conditions, such as first-morning specimens and post-prandial urine. The urine, collected in a clean container, should be tested as soon as possible (do not centrifuge or use preservatives). If testing cannot be performed within one hour after collection, the specimen should be refrigerated at 2-10° C immediately and returned to room temperature before testing.

AUTO UA® Liquid Urinalysis Reagents (continued)

Catalog #	Description	Quantity
203-30	pH Reagent R (1)	900 mL
206-30	sG Reagent R (1)	825 mL
207-30	Glucose Reagent R(1) & R(1a)	750 mL + dry
208-30	Protein (Total/Micro) Reagent R (1)	750 mL
211-30	Nitrite Reagent R (1) & R(2)	390 mL & 390 mL
205-30	Ketone Reagent R(1) & R (2)	390 mL & 390 mL
221-30	Beta-Hydroxybutyrate	390 mL & 390 mL
204-30	Hemoglobin (RBC) Rgt R (1) + R (1a) and R (2)	600 mL + dry 300 mL
209-30	Leukocyte Esterase Reagent R (1)	550 mL
212-30	Bilirubin Reagent R (1) and R (1a)	750 + dry
213-30	Urobilinogen Reagent R (1) and R (2) with R (2a)	375 mL 375 mL + dry
139	Creatinine Quant. Reagents R(1) & R(2)	750 & 150 mL

Urinalysis and Clinical Chemistry Calibrators and Controls

203-02	pH CALS 4.5 and 9.0	2 x 60 mL ea
206-01	Specific Gravity Cals 1.005 and 1.030	2 x 60 mL ea
132-01	Creatinine Calibrator 20 mg/dL	60 mL
208-02	Protein Calibrator 5 mg/dL	60 mL
209-2S	Leukocyte Esterase 20.0 EAU/L	25 mL

Glucose / Protein Combination Calibrators

207/208-02	30 / 20 mg/dL	25 mL
207/208-03	75 / 50 mg/dL	25 mL
207/208-04	1000 / 1000 mg/dL	25 mL

Nitrite / Ketone Combination Calibrators

211/205-2S	Nitrite 0.10/10 mg/dL, 0.20/20 mg/dL	2 x 25 mL ea
211/205-02	Nitrite / Ketone 0.10 / 10 mg/dL	25 mL
211/205-03	Nitrite / Ketone 0.20 / 20 mg/dL	25 mL

Hemoglobin Calibrators

204-3S	100, 500 and 1000 µg/dL	3 x 25 mL ea
204-02	Hemoglobin Zero Cal <i>Note: This calibrator is to be only used for the Hgb Assay</i>	25 mL
204-03	Hemoglobin (RBC) 100 µg/dL	25 mL
204-05	Hemoglobin (RBC) 500 µg/dL	25 mL
204-06	Hemoglobin (RBC) 1000 µg/dL	25 mL

Bilirubin / Urobilinogen Combination Calibrators

212/213-2S	Bili/Uro 1.0/1.0 and 30.0/30.0 mg/dL	2 x (3 x 3mL ea)
212-213-02	Bili / Uro Cal 1.0 / 1.0 mg/dL	3 x 3 mL ea
212-213-03	Bili / Uro Cal 30.0 / 30.0 mg/dL	3 x 3 mL ea

Zero Cal

214-01	Zero (0) Calibrator For use with Glucose, Protein, Nitrite, Ketone, Leukocyte Esterase (WBC), Bilirubin and Urobilinogen, SVT®, and EIA™ assays.	60 mL
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NOTE:

1. Zero Calibrator (Cat No. 214-01) may be used for calibrator diluting.
2. This Calibrator is not designed for use with the Hemoglobin assay (204-30).