

## Alere Inc

Waltham, Mass  
(877) 262-4669  
www.alere.com

## Alere Toxicology Inc

Portsmouth, Va  
(800) 340-4029  
www.aleretoxicology.com

## Arkray USA Inc

Minneapolis, Minn  
(877) 538-8872  
www.arkrayusa.com

1. What is the brand name of your company's urinalysis system?	Alere BinaxNow Streptococcus pneumoniae antigen card	Alere iCup Dx 14 SVT drug screen	Aution Eleven AE-4022 semiautomated urine analyzer
2. What is the intended use or primary function of the product?	An in vitro rapid immunochromatographic assay for the detection of <i>Streptococcus pneumoniae</i> antigen in the urine of patients with pneumonia.	Point-of-care diagnosis and monitoring of therapeutic and illicit drugs.	Urine chemistry.
3. What types of specimen or sample does the product employ?	Urine specimens in standard containers; store at room temperature (59–86°F, 15–30°C) if assayed within 24 hours of collection; clean catch urine is not necessary.	Urine.	Well-mixed, unspun urine.
4. What types of diseases, conditions, or analytes does the system detect?	In conjunction with culture and other methods, aids in the diagnosis of pneumococcal pneumonia.	Screens for 14 prescription and illicit drugs, including amphetamines, barbiturates, benzodiazepines, buprenorphine glucuronide, cocaine, ecstasy, marijuana, methadone, methamphetamine 500 mg, morphine, oxycodone, phencyclidine, propoxyphene, and tricyclic antidepressants.	Urine chemistry analysis parameters: bilirubin, blood, color, glucose, ketones, leukocytes, nitrites, pH, protein, specific gravity, and urobilinogen.
5. Where is the product used (check all that apply)?	<input type="checkbox"/> At a community screening event <input checked="" type="checkbox"/> In a reference lab or other independent lab setting <input checked="" type="checkbox"/> In a hospital or inpatient setting <input type="checkbox"/> In a physician's office or outpatient setting <input type="checkbox"/> In a patient's home or other self-testing <input type="checkbox"/> Elsewhere	<input type="checkbox"/> At a community screening event <input type="checkbox"/> In a reference lab or other independent lab setting <input checked="" type="checkbox"/> In a hospital or inpatient setting <input checked="" type="checkbox"/> In a physician's office or outpatient setting <input type="checkbox"/> In a patient's home or other self-testing <input checked="" type="checkbox"/> Elsewhere	<input type="checkbox"/> At a community screening event <input checked="" type="checkbox"/> In a reference lab or other independent lab setting <input checked="" type="checkbox"/> In a hospital or inpatient setting <input checked="" type="checkbox"/> In a physician's office or outpatient setting <input type="checkbox"/> In a patient's home or other self-testing <input type="checkbox"/> Elsewhere
6. If you answered "elsewhere," explain briefly.		Workplaces, as part of drug screening programs.	
7. Under ideal conditions, what is the time to first result; how are the test results made available?	15 minutes; a negative specimen produces one control line; a positive specimen produces two lines, indicating that the antigen was detected.	5 minutes; test results are made available via visual read.	60 seconds.
8. What are the product's maximum specimen capacity and throughput under ideal conditions?	No limits.	Single use.	514 samples per hour.
9. Briefly describe any automation or connectivity features or options.	n/a	n/a	Performs semiautomated urine chemistry analysis.
10. What types of technical support are available?	Technical support available online through the Alere website.	Technical support available through Alere Toxicology at (800) 340-4029; training available online.	Technical support is available 24/7/365.
11. What capabilities, features, or accessories distinguish this product from others on the market?	Can also aid in the diagnosis of pneumococcal meningitis by testing cerebral spinal fluid; it enables use of targeted narrow-spectrum antibiotics and is advocated by worldwide community-acquired pneumonia guidelines.	The CLIA-waived system minimizes urine exposure and tests for 14 drugs and five forms of specimen validity; performance comparable to laboratory screening methods; in less than 5 minutes the patented self-contained cup delivers reliable results that can be photocopied for result recording.	Smallest semiautomated footprint on the market; test strips are easy to load with no calibration required; quality control and operator ID lockout functionality.

# EKF Diagnostics USA (Stanbio Laboratory)

Boerne, Tex  
(800) 531-5535  
www.ekfusa.com

# Quantimetrix

Redondo Beach, Calif  
(310) 536-0006  
quantimetrix.com

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Redondo Beach, Calif  
(310) 536-0006  
quantimetrix.com

# Siemens Healthineers

Norwood, Mass  
(877) 229-3711; usa.healthcare.  
siemens.com/urinalysis

Stanbio Uri-Trak 120	Quantimetrix Dipper urinalysis dipstick control	Quantimetrix Dip&Spin urinalysis dipstick/microscopics control	Clinitek Novus automated urine chemistry analyzer
Initial diagnosis and monitoring.	Intended as a control for urinalysis reagent strips, microalbumin, and creatinine by the listed test methods, and as a control for confirmatory tests such as K-Check and Ictotest reagent tablets, and for hCG methods.	Intended as a control for urinalysis reagent strips, microalbumin, and creatinine by the listed test methods, and as a control for confirmatory tests, and for hCG methods; intended as a means of validating the processing and centrifugation of patient urine samples prior to the microscopic evaluation of urine sediment.	Urine chemistry.
Urine (random).	General urine specimen.	General urine specimen and chemistry analytes.	Random urine.
Bilirubin, blood, glucose, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen.	Provides values for all dipstick analytes plus microalbumin and creatinine, and qualitative results for hCG early pregnancy detection.	Engineered calcium oxalate dihydrate (COD) crystals that are formulated with real human RBCs and WBCs and are easily recognized by both standard and automated microscopy.	Bilirubin, clarity, color, glucose, ketone, leukocytes, nitrite, occult blood, pH, protein, specific gravity, and urobilinogen.
<input type="checkbox"/> At a community screening event <input type="checkbox"/> In a reference lab or other independent lab setting <input checked="" type="checkbox"/> In a hospital or inpatient setting <input checked="" type="checkbox"/> In a physician's office or outpatient setting <input type="checkbox"/> In a patient's home or other self-testing <input type="checkbox"/> Elsewhere	<input type="checkbox"/> At a community screening event <input checked="" type="checkbox"/> In a reference lab or other independent lab setting <input checked="" type="checkbox"/> In a hospital or inpatient setting <input checked="" type="checkbox"/> In a physician's office or outpatient setting <input type="checkbox"/> In a patient's home or other self-testing <input type="checkbox"/> Elsewhere	<input type="checkbox"/> At a community screening event <input checked="" type="checkbox"/> In a reference lab or other independent lab setting <input checked="" type="checkbox"/> In a hospital or inpatient setting <input checked="" type="checkbox"/> In a physician's office or outpatient setting <input type="checkbox"/> In a patient's home or other self-testing <input type="checkbox"/> Elsewhere	<input checked="" type="checkbox"/> At a community screening event <input checked="" type="checkbox"/> In a reference lab or other independent lab setting <input checked="" type="checkbox"/> In a hospital or inpatient setting <input checked="" type="checkbox"/> In a physician's office or outpatient setting <input checked="" type="checkbox"/> In a patient's home or other self-testing <input type="checkbox"/> Elsewhere
60 seconds for the first result; test results can be viewed on screen and printed out using the built-in thermal printer.	Same as patient sample.	Same as patient sample.	First result in 15 seconds, subsequent results every 15 seconds; results sent to laboratory information system or printed.
120 strips per hour.	n/a	n/a	Maximum capacity: 200 tubes (single load); throughput is 240 specimens per hour.
Self-test diagnostics at startup; quality control (QC) program with lockout; user lockout; laboratory information system connectivity; operator ID and patient ID.	n/a	n/a	Connects to CentraLink data management system; 2D bar-code reader captures tube type, cap detector, and crash protection on analyzer; can connect to Sysmex UF-1000i system for complete automation.
Telephone, webinar, and e-mail support.	Phone and e-mail.	Phone and e-mail.	Onsite support, 24/7 phone support, online education, and references.
User lockout prevents unapproved users from testing; up to 10 lab operators can perform testing but only the lab administrator can change analyzer settings; QC lockout prevents testing without passing QC; QC tests can be programmed to run once every 8 hours, daily, weekly, or monthly; analyzer will alert when to run QC test; barcode reader optional.	Users can monitor the performance of visual and instrument readings of urinalysis dipsticks by immersing the dipstick into the control; designed for use with most urinalysis reagent strips; can also be used for confirmatory tests and refractometry.	Supplied liquid, ready-to-use in two levels; do not require reconstitution or dilution; prepared from human urine to which stabilized human red and white blood cells, calcium oxalate crystals, and other compounds have been added to produce the desired reactions.	Reagent cassette with reagent cards and radiofrequency identification chip; digital technology detects intact red blood cells and enables advanced algorithms; well for quantified specific gravity measurement; same dry pad reagents as other Siemens Healthineers urinalysis products.

## Siemens Healthineers

Norwood, Mass  
(877) 229-3711; usa.healthcare.  
siemens.com/urinalysis

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Norwood, Mass  
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siemens.com/urinalysis

## Sysmex America Inc

Lincolnshire, Ill (800)  
379-7639  
www.sysmex.com

1. What is the brand name of your company's urinalysis system?	Clinitek Advantus urine chemistry analyzer	Clinitek Status family of analyzers	UF-1000i
2. What is the intended use or primary function of the product?	Urine chemistry.	Point-of-care applications, including urine HCG and microalbumin.	A fully automated urine particle analyzer intended for in vitro diagnostic use in urinalysis.
3. What types of specimen or sample does the product employ?	Random urine.	Random urine.	Urine only.
4. What types of diseases, conditions, or analytes does the system detect?	Routine testing; frontline assessment for albuminuria; early detection of kidney disease; monitoring and management of disease states: diabetes, kidney disease, and urinary tract infection.	Routine testing; frontline assessment for albuminuria; pregnancy testing; early detection of kidney disease; monitoring and management of disease states: diabetes, kidney disease, and urinary tract infection.	Provides quantitative results for bacteria, casts, epithelial cells, erythrocytes, and leukocytes; also provides flagging information for crystals, pathological casts, small round cells, sperm, and yeast-like cells.
5. Where is the product used (check all that apply)?	<input checked="" type="checkbox"/> At a community screening event <input checked="" type="checkbox"/> In a reference lab or other independent lab setting <input checked="" type="checkbox"/> In a hospital or inpatient setting <input checked="" type="checkbox"/> In a physician's office or outpatient setting <input checked="" type="checkbox"/> In a patient's home or other self-testing <input type="checkbox"/> Elsewhere	<input checked="" type="checkbox"/> At a community screening event <input checked="" type="checkbox"/> In a reference lab or other independent lab setting <input checked="" type="checkbox"/> In a hospital or inpatient setting <input checked="" type="checkbox"/> In a physician's office or outpatient setting <input checked="" type="checkbox"/> In a patient's home or other self-testing <input type="checkbox"/> Elsewhere	<input type="checkbox"/> At a community screening event <input checked="" type="checkbox"/> In a reference lab or other independent lab setting <input checked="" type="checkbox"/> In a hospital or inpatient setting <input type="checkbox"/> In a physician's office or outpatient setting <input type="checkbox"/> In a patient's home or other self-testing <input type="checkbox"/> Elsewhere
6. If you answered "elsewhere," explain briefly.			
7. Under ideal conditions, what is the time to first result; how are the test results made available?	7 seconds to test result.	Dependent on test specimen; HCG cassette, 2–5 minutes; urine strip, 60 seconds; results are viewed on screen, printed, or available in laboratory information system (LIS), and/or middleware.	Under 3 minutes; results can be viewed on screen, printed, and sent to the laboratory information system.
8. What are the product's maximum specimen capacity and throughput under ideal conditions?	Operator-dependent: strip analyzed every 7 seconds; semiautomated.	Individual test strip.	100 samples per hour, with maximum of 50 samples onboard at one time.
9. Briefly describe any automation or connectivity features or options.	Semiautomated; connects to Conworx middleware or laboratory information system; automatic calibration at startup; auto-checks for strip verification; quality control lockout functionality.	Semiautomated; connects to POCcelerator, RapidComm data management system, Relaymed, and other middleware or LIS; automatic calibration at startup; auto-checks for strip verification; operator and quality control lockout functionality.	Real-time quality control monitoring.
10. What types of technical support are available?	Warranty swap-out.	Warranty swap-out.	24-hour phone support via a technical assistance center; onsite service varies by service contract.
11. What capabilities, features, or accessories distinguish this product from others on the market?	Auto-check technology allows for automatic detection of humidity overexposure and test strip configuration; offers standardization of urine testing; end-to-end solution from lab to physician office.	Auto-check technology allows for automatic detection of humidity overexposure and test strip configuration; uniquely offers urine test strips and hCG rapid testing on one system; offers standardization of urine testing; end-to-end solution from lab to physician office.	Two separate reaction chambers and reagents for enhanced classification; specific fluorescent dye for bacteria detection and elimination of nonspecific staining; review-by-exception design for fewer manual slide reviews.