[tech] guide

Urinalysis

	Alere Inc Waltham, Mass (877) 262-4669; www.alere.com	Alere Toxicology Inc Portsmouth, Va (800) 340-4029; www.aleretoxicology.com	Arkray Minneapolis (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
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 1999.	FDA 510(k), 2013.	FDA 510(k), 2013.
3. What is the intended use or primary function of the product?	An in vitro rapid immunochromatographic assay for the detection of *Streptococcus pneumoniae* antigen in the urine of patients with pneumonia.	Point-of-care diagnosis and monitoring of therapeutic and illicit drugs.	Urine chemistry and urine sediment analysis.
4. What types of specimen/sample does the product employ?	Collect 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.
5. 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.	The integrated test cup screens for 14 prescription and illicit drugs, including amphetamine, barbiturates, benzodi-azepines, buprenorphine glucuronide, cocaine, ecstacy, 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, turbidity, and urobilinogen; urine sediment analysis enumerated parameters: bacteria, epithelial cells, hyaline casts, red blood cells, and white blood cells; flagged parameters: crystals, mucus, pathological casts, small round cells, sperm, and yeast.
6. Where is the product used?	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ❑ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ■ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's homeor other self-testing ❑ Elsewhere
7. If you answered "elsewhere," explain briefly.		Workplaces, as part of drug screening programs.	
8. 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.	2 minutes and 15 seconds; one consolidated report for both chemistry and microscopic results.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	No limits.	Single use.	100 to 200 results per hour, depending on test mix.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	n/a	n/a	Performs automated urine chemistry and sediment analysis; on-demand barcoded consumables management; onboard troubleshooting; short sample detection; reflex testing capability; bidirectional laboratory information system interface.
11. What is the typical training time for the product?	Less than 30 minutes.	Less than 30 minutes.	Primary operator training: one operator, 2 days at vendor office; secondary operator training: up to five operators on site.
12. What types of technical support are available?	Technical support available online through the Alere Web site at www.alere.com/en/home/product-details/binaxnow-streptococcus-pneumoniae.html.	Technical support available through Alere Toxicology at (800) 340-4029; training available online at aleretoxicology.com/training.	Technical support is available 24/7/365.
13. What capabilities, features, or accessories distinguish this product from others on the market?	In addition to testing for pneumonia, the card can also aid in the diagnosis of pneumococcal meningitis by testing cerebral spinal fluid; it enables 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. With performance comparable to laboratory screening methods, the patented self-contained cup delivers reliable results in less than 5 minutes that can be photocopied for result recording.	The compact size is 30% to 50% smaller than competitive products; test strips are easy to load with no calibration required; accurately enumerates bacteria with nucleic acid stain; anticarry-over function and amorphous crystal removal; minimal maintenance, less than 5 minutes daily hands-on time.

BD Franklin Lakes, NJ (201) 847-6800; www.bd.com/vacutainer	Beckman Coulter Brea, Calif. (800) 526-3821; www.beckmancoulter.com	Beckman Coulter Brea, Calif. (800) 526-3821; www.beckmancoulter.com	Bio-Rad Laboratories Hercules, Calif (800) 224-6723; www.bio-rad.com
BD Vacutainer urine collection family of products	Iris iRicell	Iris iChemVelocity.	Liquichek Urinalysis
TUV CE mark, 2011.	n/a	FDA 510(k), 2011.	CE mark, 2007; FDA 510(k), 2007.
Patient diagnosis.	Performs chemistry and microscopic analysis of urine specimens to aid in the diagnosis of acute tubular necrosis, genitourinary or transitional cell (bladder) carcinoma, kidney function anomalies, liver function, metabolic disorders, and urinary tract infections.	Performs urine chemistry screening to aid in the diagnosis of kidney function anomalies, liver function, metabolic disorders, and urinary tract infections.	Quality controls and connectivity software are intended to monitor the precision of test systems and methods.
Can be used to collect all types of urinalysis specimens.	First morning or random urine should be midstream collections that are uncentrifuged. Other body fluids employed include cerebrospinal, pericardial, peritoneal, peritoneal dialysate, peritoneal lavage, pleural, general serous fluids, and synovial fluids.	First morning or random urine specimens; all urine specimens should be midstream collections that are uncentrifuged.	Liquid, human urine.
The tube is designed to preserve a sample for up to 72 hours without refrigeration. It helps maintain sample integrity.	Ascorbic acid, bacteria, bilirubin, blood, casts, clarity, color, crystals, epithelial cells, glucose, ketones, leukocyte esterase, mucus, nitrites, pH, protein, proteinuria, specific gravity, sperm, urobilinogen, yeast; can detect presence of diabetes and diabetic ketoacidosis, hematuria, hemolytic anemic diseases, hepatic and/or hepatobiliary disease, nonspecific genitourinary cancers, non-specific kidney disease causing proteinuria, urinary tract infection.	Ascorbic acid, bilirubin, blood, clarity, color, glucose, ketones, leukocyte esterase, nitrites, pH, protein, specific gravity, and urobilinogen; can aid in the diagnosis of diabetes and diabetic ketoacidosis, hematuria, hemolytic anemic diseases, hepatic disease, hepatobiliary disease, non-specific genitourinary cancers, non-specific kidney disease causing proteinuria, and urinary tract infection.	Bilirubin, blood, clarity, color, creatinine, glucose, human chorionic gonadotropin, keytones, leukocytes, microalbumin, microscopics, nitrite, osmolality, pH, protein (total), specific gravity, and urobilinogen.
■ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's homeor other self-testing ■ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's homeor other self-testing ■ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
	Universities, research centers.	Universities, research centers.	
Preserved tube ensures that the sample is ready for automated or manual processing immediately after collection of the urine specimen.	Approximately 4 minutes; results are available on the computer screen and sent to the laboratory information system (LIS).	Approximately 2 minutes; results are available on the computer screen and sent to the laboratory information system (LIS).	n/a
Preserves samples for up to 72 hours without refrigeration.	Processes 210 chemistry and 101 microscopic samples per hour.	Processes 210 chemistry samples per hour.	n/a
Tube is compatible with fully and semi-automated systems and is ready to load on a urinalysis instrument after the specimen has been collected.	Fully automated walkaway solution; automatically detects specimens, classifies 12 urine particles, and releases results to the LIS; the system's IQ200 work cell is used to automate the complete routine urinalysis profile.	Fully automated walkaway solution; automatically detects specimens and releases results to the LIS.	Quality control (QC) data management and peer group comparison with Unity real-time connectivity software; includes automatic QC data importing, support for runtime decision making, troubleshooting, and QC design.
2 to 5 minutes with all clinical staff who collect or process urine samples.	3.5 days at Beckman training center and 1 day onsite.	1 day onsite.	n/a
Clinical studies, white papers, posters, and a technical service department and sales team provide support for any questions or training needs.	Toll-free hotline available 24/7; clinical applications team and field service engineers for onsite support.	Toll-free hotline available 24/7; clinical applications team and field service engineers for onsite support.	Full-service technical support department.
Helps to maintain sample integrity and minimize preanalytical errors and unnecessary cultures due to bacterial contamination or overgrowth; allows for easier mixing; mercury free; helps to enhance instrument compatibility.	Digital flow morphology uses automated particle recognition software for standardization; increased productivity, reduced urine cultures, lower review rates, and review by exception; advanced technology allows for testing of body fluids and urine samples in a preservative tube.	Test pad identifies possible ascorbic acid interference with key chemistry assays; offers high capacity and ease of use to maximize lab performance and productivity; evaluates nonstandard urine chemistry and ascorbic acid, as well as clarity, color, and specific gravity.	Consolidated, multianalyte control; liquid-based QC; 30-day open-vial stability at 2–25°C; 2.5 year shelf life at 2–8°C.

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	EKF Diagnostics Cardiff, UK (800) 531-5535; www.ekfdiagnostics.com	Randox Laboratories Crumlin, UK (866) 472-6369; www.randox.com	Roche Diagnostics Indianapolis (800) 428-5074; usdiagnostics.roche.com/en/point_of_care_testing.html
1. What is the brand name of your company's urinalysis system?	Stanbio Uri-Trak 120	TxBCardio	Urisys 1100
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE mark, 2008; FDA 510(k), 2008.	ANVISA, 2015; CE mark, 2013; Health Canada, 2014; SFDA, 2015; TGA, 2014.	n/a
3. What is the intended use or primary function of the product?	Initial diagnosis and monitoring.	Quantitative immunoturbidimetric immunoassay for urinary evaluation of response to aspirin therapy.	A semiautomated analyzer intended for in vitro semiquantitative determination of urine analytes.
4. What types of specimen/sample does the product employ?	Urine (random).	Human urine is the recommended sample matrix. Freshly collected samples should be refrigerated and analyzed within 48 hours. Samples not analyzed within 48 hours should be frozen at –20°C or lower until use.	First-morning, freshly voided, or post-prandial urine specimen.
5. What types of diseases, conditions, or analytes does the system detect?	Bilirubin, blood, glucose, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen.	Determines levels of 11-dehydro thromboxane B2 (11dhTxB2) in human urine, which aids in the determination of platelet response to acetylsalicylic acid ingestion.	Bilirubin, erythrocytes, glucose, ketones, leukocytes, nitrite, protein, pH, specific gravity, and urobilinogen.
6. Where is the product used?	❑ At a community screening event ❑ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ❑ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ■ Elsewhere	❑ At a community screening event ❑ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
7. If you answered "elsewhere," explain briefly.		Any laboratory with an automated clinical chemistry analyzer.	
8. Under ideal conditions, what is the time to first result; how are the test results made available?	60 seconds for first result; test results can be viewed on screen and printed out using the built-in thermal printer.	Dependent on the clinical chemistry analyzer in use.	70 seconds; the analyzer will automatically print results to be evaluated and placed in the patient's profile.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	120 strips per hour.	Kits can contain up to 120 tests, but this will vary depending on the analyzer.	Designed for optimal performance with test volumes between 10 and 50 tests per day; maximum throughput is 50 tests per hour.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Self-test diagnostic at start-up; quality control (QC) program with lockout; user lockout; laboratory information system connectivity; operator ID and patient ID.	Can be performed on most automated clinical chemistry analyzers, without need for dedicated equipment.	Automated results printout; connectivity for results downloading; error messaging to assist with troubleshooting.
11. What is the typical training time for the product?	30 minutes.	None.	n/a
12. What types of technical support are available?	Telephone and e-mail support.	Full technical support is available at technical.services@randox.com.	24/7 technical assistance.
13. What capabilities, features, or accessories distinguish this product from others on the market?	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.	Allows response to aspirin therapy to be tested on an automated clinical chemistry analyzer, without need for dedicated equipment; assay time as little as 10 minutes; can be implemented for high-throughput screening.	Eliminates vitamin C interference; reads all Chemstrip reagent pads at once 1 to 2 minutes after dipping; promotes safe and hygienic testing by holding strips facing downward; ensures uniform liquid penetration and prevents runover on adjacent pads; test pad placement grouped by disease states; detects both acetoacetic acid and acetone.

Roche Diagnostics **Indianapolis** **(800) 428-5074;** **usdiagnostics.roche.com/en/point_of_care_testing.html**	Siemens Point of Care Diagnostics **Norwood, Mass** **(781) 269-3000;** **www.siemens.com/poc**	Siemens Point of Care Diagnostics **Norwood, Mass** **(781) 269-3000;** **www.siemens.com/poc**
Cobas u 411	Clinitek AUWi Pro automated urine workstation	Clinitek Novus automated urine chemistry analyzer
n/a	TUV CE mark, 2013; FDA 510(k), 2014.	TUV CE mark, 2012; FDA 510(k), 2014.
A semiautomated urine test strip analyzer intended to determine urine analytes.	Provides walkaway urine chemistry testing and sediment analysis.	A fully automated urinalysis instrument for clinical laboratory use; reads Clinitek Novus cassettes and determines specific gravity and clarity of urine specimens.
First-morning, freshly voided, or post-prandial urine specimen.	Random specimen; should be tested within 2 hours of collection or refrigeration of sample required.	Random specimen; should be tested within 2 hours of collection or refrigeration of sample required.
Bilirubin, blood (erythrocytes/hemoglobin), color, glucose, ketones, leukocytes, nitrite, protein, pH, specific gravity, and urobilinogen.	Routine chemistry and microscopic analysis of urine specimens for detecting various diseases and conditions ranging from kidney disease to urinary tract infections.	Semiquantitative measurement of albumin, bilirubin, blood (occult), creatinine, glucose, ketone (acetoacetic acid), leukocytes, nitrite (qualitative), pH, protein, color, urobilinogen, albumin-to-creatinine ratio, and protein-to-creatinine ratio; for in vitro diagnostic use to assist in diagnosis of disorders of carbohydrate metabolism (such as diabetes mellitus), kidney and liver function, and urinary tract infection.
❑ At a community screening event ❑ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
Every 6 seconds with continuous strip loading.	n/a; integrates urine chemistry and sediment results into a user-defined, consolidated patient report that can be reviewed onscreen or printed.	n/a
Throughput of 600 test strips per hour.	Accepts up to 100 sample tubes simultaneously; completes up to 80 tests per hour.	One-time loading of 200 sample tubes; processes up to 240 samples per hour.
Automatic strip detection by two sensors.	Seamless integration of the Clinitek Novus urine chemistry analyzer and the Sysmex UF-1000i urine cell analyzer delivers load-and-go productivity for automated urinalysis; workstations are linked by a common sample track and integrated with workflow management software.	Load-and-go cassette supports 450 tests; automated entry of lot number and expiration via radiofrequency identification tag.
n/a	1 to 3 days of onsite training.	1 to 3 days of onsite training.
24/7 technical assistance; loaner/repair program.	Siemens technical support and education available 24/7.	Siemens technical support and education available 24/7; remote system diagnostics available to assist in troubleshooting.
Eliminates vitamin C interference; reads all Chemstrip reagent pads at once 1 to 2 minutes after dipping; promotes safe and hygienic testing by holding strips facing downward; ensures uniform liquid penetration and prevents runover on adjacent pads; test pad placement grouped by disease states; detects both acetoacetic acid and acetone.	Accurate results: separate bacteria channel that dissolves amorphous cells in the sample and improves accuracy; streamlined workflow: automatically transports samples, reflexes samples, and verifies results; and maximum productivity: one-time loading of 100 samples, load-and-go capability.	System identifies tube type and senses if cap has been removed, improving pipette reliability; customer-driven design: color touchscreen, tiltable display, customizable menu options; unique cassettes offer two test menus based on customer need.

Upcoming Tech Guides

Each month, *CLP* invites leading IVD manufacturers and clinical laboratory suppliers to complete a standarized topic-specific questionnaire highlighting their products.

Below is a preview of topics that will appear in future issues of *CLP:*

MAY
Clinical Chemistry and Integrated Analyzers

JUNE
Immunoassay Analyzers

JULY
Anatomic and Digital Pathology Instruments and Tools

AUGUST
Point-of-Care Assays and Analyzers

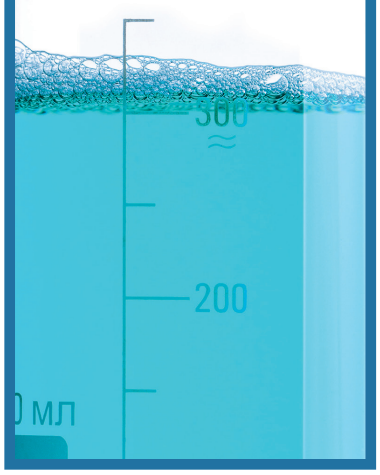
SEPTEMBER
Molecular Diagnostic Instruments

OCTOBER
Hematology Analyzers

NOVEMBER
Lab and Patient Safety Products

DECEMBER
Buyer's Guide

To be considered for inclusion, contact associate editor Elaine Wilson at ewilson@allied360.com



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Urinalysis

	Streck	Streck	Sysmex America Inc
	Omaha, Neb (800) 843-0912; www.streck.com	Omaha, Neb (800) 843-0912; www.streck.com	Lincolnshire, Ill (800) 379-7639; www.sysmex.com
1. What is the brand name of your company's urinalysis system?	UA-Cellular Complete	UA-Cellular for iQ	UF-1000i
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	Canadian license class II, 2014; CE mark, 2014; FDA 510(k), 2014.	Canadian license class II, 2009; CE mark, 2009; FDA 510(k), 2009.	CE mark, 2006; FDA 510(k), 2007.
3. What is the intended use or primary function of the product?	To verify accuracy of Siemens Clinitek Atlas and Sysmex UF-1000i combined urinalysis system.	To verify the accuracy of Iris Diagnostics iQ instruments that perform automated cellular and particle analysis on patient urine samples.	A fully automated urine particle analyzer intended for in vitro diagnostic use in urinalysis.
4. What types of specimen/sample does the product employ?	Urine sediment and chemistry analytes.	Urine sediment.	Urine only.
5. What types of diseases, conditions, or analytes does the system detect?	Controls for all chemistry analytes tested on the Atlas; controls for bacteria, casts, crystals, epithelial cells, red blood cells, and white blood cells on the UF-1000i.	Crystal values, non-squamous epithelial cells, red blood cells, and white blood cells.	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.
6. Where is the product used?	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's homeor other self-testing ❑ Elsewhere
7. If you answered "elsewhere," explain briefly.			
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Printouts from the instrument or files on the instrument.	Printouts from the instrument or files on the instrument.	Under 3 minutes; results can be viewed onscreen, printed, and sent to the laboratory information system.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?	40 tests per bottle.	40 tests per bottle.	100 samples per hour, with maximum of 50 samples onboard at one time.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	n/a	n/a	Real-time quality control monitoring.
11. What is the typical training time for the product?	n/a	n/a	4 hours.
12. What types of technical support are available?	Streck technical services at technicalservices@streck.com.	Streck technical services at technicalservices@streck.com.	24-hour phone support via a technical assistance center; onsite service varies by service contract.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Contains both chemistry analytes and cellular components to closely mimic a patient sample; technologists can use one control to test both urinalysis instruments.	Offers open-vial stability of 30 days and closed-vial stability of 105 days.	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.