taab	Abbott	Arkray USA	Beckman Coulter
tech guide _{Urinalysis}	Chicago www.abbott.com	Minneapolis (877) 538-8872 www.arkrayusa.com	Brea, Calif (800) 526-3821 www.beckmancoulter.com
1. What is the brand name of your company's urinalysis system?	Afinion ACR	Aution Eleven AE-4022 semiautomated urine analyzer	iQ3000 Workcell; iQ2000 Workcell
 What is the latest version of your named urinalysis system; what year was this version first released to market (US, OUS)? 	2007 (OUS); 2008 (US).	2017 (US).	2018 (US).
 Specify the authorizing agency, type, and year of the product's regulatory authorizations (eg, TUV CE mark, 2013; FDA 510(k), 2015). 	FDA 510(k), 2008; CE mark, 2007.	FDA 510(k), 2016.	iQ200 portion, FDA 510(k), 2003; AX-4030 portion, FDA 510(k), 2009.
4. What are the dimensions of the named product (H x W x D)?	7.2 inches × 7.5 inches × 13.0 inches.	6.5 inches x 8.3 inches x 12.9 inches.	22 inches x 48 inches x 26 inches.
5. What is the intended use or primary function of the product (eg, diag- nosis, patient monitoring, point-of- care applications, therapeutic drug monitoring, viral load monitoring)?	Quantitative determination of albumin, creatinine, and albumin/creatinine ratio (ACR) in human urine.	Urine chemistry.	Urine chemistry and urine microscopy.
6. What types of specimen/sample does the product employ (eg, random specimen, first morning specimen, midstream collection, urine sediment)?	Spot urine sample.	Well-mixed, unspun urine.	Random.
7. What types of diseases, condi- tions, or analytes does the system detect?	Albuminuria; nephropathy, chronic kidney disease.	Bilirubin, blood, color, glucose, ketones, leukocytes, nitrites, pH, protein, specific gravity, and urobilinogen.	Kidney function and disease, urinary tract infections, urine chemistry anal- ysis parameters, urine microscopic parameters, FDA cleared for eight body fluid analytes.
8. Where is the product used (check all that apply)?	 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 	 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 	 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
9. Under ideal conditions, what is the time to first result?	5 minutes.	60 seconds.	Less than 2 minutes.
10. What are the product's maximum specimen capacity and throughput under ideal conditions?	One at a time; approximately 10 samples per hour.	514 samples per hour.	Depending on the model, up to 101 samples per hour.
11. Briefly describe any automation or connectivity features or options (eg, autocalibration, autodetection of specimens, onboard real-time quality control, troubleshooting) that pertain to the product.	All-in-one hygienic test cartridge; automatic processing; comprehensive fail-safe systems prevent possibility of erroneous results; QC and operator lockout possibilities. Built-in connec- tivity using POCT1-A, HL7, and ASTM protocols.	Performs semiautomated urine chemistry analysis.	Edit-free release, Iware, command central, Remisol, continuous strip load capability.
12. What is the typical training time for the product?	Approximately 45 minutes.	N/A	2 ¹ / ₂ -day classroom training.
13. What types of technical support are available?	Toll-free line for technical support; training provided; step-by-step quick reference guide; videos on the website.	Technical support is available 24/7/365.	24/7 phone support, onsite service, online education.
14. What capabilities, features, or accessories distinguish this prod-uct from others on the market?	Compact size and panel of tests; suited for point-of-care testing in physician offices, clinics, community health centers, and hospital outpatient clinics. From small urine or fingerstick whole blood sample, highly accurate results for HbA1c and ACR are made available during the consultation.	Smallest semiautomated footprint on the market; test strips are easy to load, with no calibration required; quality control and operator ID lockout functionality.	Pairs the Iris Iricell series of urine microscopy instruments and the Arkray Aution Max AX-4030 fully automated urine chemistry analyzer. Digital flow morphology technol- ogy uses auto particle recognition software.



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BeAMedTech.



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Kova International	Siemens Healthineers	Sysmex America	Sysmex America
Garden Grove, Calif (855) 217-6399 www.kovaintl.com	Norwood, Mass www.siemens-healthineers.com	Lincolnshire, Ill (800) 379-7639 www.sysmex.com	Lincolnshire, Ill (800) 379-7639 www.sysmex.com
Kova Liqua-Trol	CliniTek AUWi Pro automated urinalysis system	UN-2000 automated urinalysis system	UF-5000 fully automated urine particle analyzer
Kova Liqua-Trol	N/A	2015 (OUS); 2019 (US).	2015 (OUS); 2019 (US).
FDA, 2013; CE mark, 2013.	CE mark; FDA 510(k).	FDA 510(k), 2018.	FDA 510(k), 2018.
15 mL and 120 mL	27 inches x 63 inches x 35 inches.	35 inches x 52 inches x 36 inches.	35 inches x 26 inches x 36 inches.
Quality control.	Urine chemistry analyzer and urine particle analyzer.	Urine particle analyzer and urine particle digital imaging.	Urine particle analyzer.
N/A	Random urine.	Urine.	Urine.
Ascorbic acid, bacteria, bilirubin, casts, creatine, crystals, glucose, hemoglobin, ketones, leukocyte esterase, microalbumin, nitrite, pH, protein, red cells, urobilino- gen, white cells.	Albuminuria, diabetes monitoring, kidney disease, urinary tract infection. Sediment: bacteria, casts, epithelial cells, erythrocytes, flagging for crys- tals, leukocytes; pathological casts, small round cells, sperm, yeast-like cells.	Quantitative results for bacteria, casts, epithelial cells, erythrocytes, leukocytes. Flagging information for crystals, pathological casts, sperm, yeast-like cells.	Quantitative results for bacteria, casts, epithelial cells, erythro- cytes, leukocytes. Flagging infor- mation for crystals, pathological casts, sperm, yeast-like cells.
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Results are determined by reagent strip/analyzer.	45 seconds to test result.	Under 3 minutes.	Under 3 minutes.
Capacity determined by analyzer.	100-tube onboard capacity for con- tinuous loading; throughput at least 80 tubes per hour.	From 80 to 250 samples onboard; throughput varies.	Up to 80 samples onboard; maxi- mum throughput 105 per hour.
Automation and connectivity determined by analyzer.	Connects to Centralink data manage- ment system; 2-D bar-code reader captures tube type; cap detector and crash protection on analyzer. Connects to UF1000i system using WAM software for single integrated LIS.	Autovalidation, autoreflex rules, evi- dence-based maintenance, real-time quality control monitoring, remote system diagnostics.	Autovalidation, autoreflex rules, evidence-based maintenance, real- time quality control monitoring, remote calibration, remote system diagnostics
Less than 1 hour.	Offsite training course, online train- ing by PEP Connect.	4 hours.	4 hours.
Tech support provided by phone/ email.	Onsite support, 24/7 phone support, online education, and references.	24-hour phone support via a techni- cal assistance center; onsite service varies by service contract.	24-hour phone support via a tech- nical assistance center; onsite ser- vice varies by service contract.
Ready-to-use with two levels including microscopics; 30-day room temperature stability; 27-month shelf life from date of manufacture	Integrated System with single LIS connection. Combines benefits of CliniTek Novus (reagent cassette, digital technology, same dry pad chemistry) with Sysmex UF1000i. Two separate reaction chambers and reagents for enhanced classification. Auto-heating of samples removes amorphous crystals prior to sedi- ment analysis.	Two separate reaction chambers and reagents for enhanced classification; specific fluorescent dyes for identi- fying particles based on internal and external particle characteristics, cell- pack reagents that minimize interfer- ences; review-by-exception design for fewer manual slide reviews; digi- tal imaging of particles to allow for classification by the operator	Two separate reaction chambers and reagents for enhanced classi- fication; specific fluorescent dyes for identifying particles based on internal and external particle char- acteristics, cellpack reagents that minimize interferences; review-by- exception design for fewer manual slide reviews.

INTRODUCING A NEW ADDITION TO OUR LINE OF LIQUID LINEARITY AND DAILY QC





LINEARITY FLQ SPECIAL DIABETES FOR SIEMENS CENTAUR



This product is intended to simulate human patient samples for determining linearity, calibration verification, and the verification of reportable range for the analytes C-peptide and Insulin.

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