tech guide

Urinalysis and Toxicology

	Abbott	Arkray USA	Beckman Coulter
	Clearwater, FL 855-425-9428 www.immunalysis.com	Minneapolis 877-538-8872 www.arkrayusa.com	Brea, CA 800-526-3821 www.beckmancoulter.com
1. What is the brand name of your company's urinalysis system?	ImmTox 270	Aution Eleven AE-4022 semi-automated urine analyzer	DxU Iris 840 Workcell; DxU Iris 850 Workcell
2. What year was this version first released to market?	2019	2017 (US)	2021 U.S.
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations	FDA 510 (k), 2019	FDA 510(k), 2016	
4. What are the dimensions of the named product?	21"x 32"x 27"	6.5 inches x 8.3 inches x 12.9 inches	22" × 48 "× 26"/200 lbs.
5. What is the intended use or primary function of the product?	Urine toxicology screening immunoassay analyzer	Urine chemistry.	In-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis.
6. What types of specimen/sample does the product employ ?	Urine	Well-mixed, unspun urine	Unspun Urine
7. What types of diseases, conditions, or analytes does the system detect?	Detection of prescription drugs and drugs of abuse in urine.	Urine chemistry analysis parameters: bilirubin, blood, color, glucose, ketones, leukocytes, nitrites, pH, protein, specific gravity, and urobilinogen.	Kidney function and disease, urinary tract infections, urine chemistry analysis parameters, urine microscopic parameteres, FDA cleared for eight body fluid analytes.
8. Where is the product used?	■ 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 hospital or inpatient setting ■ In a physician's office or outpatient setting	■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting
9. If you answered "elsewhere," explain briefly.	N/A	N/A	N/A
10. Under ideal conditions, what is the time to first result; how are the test results made available?	12 minutes; results are available on touchscreen interface, reported via LIS to EMR, or printed.	60 seconds	3 minutes for a complete urine chemistry with microscopy/sediment analysis.
11. What are the product's maximum specimen capacity and throughput under ideal conditions?	270 tests per hour, holds up to 30 barcoded patient samples on board	514 samples per hour	Urine chemistry sample throughput 225 per hour. Sample throughput for microscopy/sediment up to 70 or 101 per hour, depending on model.
12. Briefly describe any automation or connectivity features or options () that pertain to the product.	Continuous access to samples and reagents without interruption of testing process. Bidirectional LIS communication with HL7 interface and EMR integration options.	Semiautomated urine chemistry analysis	Optional load/unload stations, body fluids module, iWare middleware solution, edit free auto-release results technology and continuous strip load capability.
13. What is the typical training time for the product?	2 days of on-site training	N/A	1 day at customer site, 3 days with vendor
14. What types of technical support are available?	Phone support M-F 8AM-8PM ET. 24 hour electronic support, and application support. field service available.	24/7/365	24/7 phone support and remote ProService support
15. What capabilities, features, or accessories distinguish this product from others on the market?	14 assays for CLIA categorized moderate complexity testing and 25 for high complexity testing. Reusable cuvettes, and walkaway time of 3 hours.	Smallest semiautomated footprint on the market; test strips are easy to load with no calibration required; quality control and operator ID lockout functionality.	Streamlines urinalysis workflow to achieve manual review rates of 4%; Auto-classify 12 urine particles based on size, shape, contrast and texture to provide digital images for all samples.

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Cardinal Health	EKF Diagnostics	HORIBA Instruments Incorporated	Quidel
Dublin, OH www.cardinalhealth.com	1261 North Main Street Boerne, TX 78006 ekfusa.com	Irvine, CA 888-903-5001 (option 5) www.horiba.com	San Diego, Calif 800-874-1517 quidel.comm
Cardinal Health Urinalysis Analyzer	Uri-Trak 120	Pentra C400	Quidel Triage TOX Drug Screen, 94600
2020, US	2010	Pentra C400 (Toxicology) (2014)	2019 (US); 2020 (OUS)
TUV CE Mark, 2018; FDA 510(k) and CLIA-waiver, 2018	FDA 510(k) - 2007, CLIA - 2009, CE mark - 2010	FDA 510(k), 2005; CE Mark, 2005	FDA 510(k), 2019; IVDD self-certified CE mark, 2019; Health Canada Class 2, 2020
3"x 7.5" x 9"	5.7" x 10.6" x 10.7"	25" x 40" x 28"	2.75 inches x 6.25 inches x 8.5 inches
Reads Cardinal Health urine test strips, including microalbuminlbumin and creatinine urine strips, and calculates the albumin-to-creatinine ratio	Allows physician offices and laboratories the accuracy and consistency of advanced technology in urine chemistry testing.	Patient monitoring	Fluorescence immunoassay for the qualitative detection of drug and/or metabolites in human urine
Urine (random, first morning, midstream all acceptable)	Urine	Random specimen	Human urine, no special treatment required
Albuminuria, diabetes monitoring, kidney disease, urinary tract infection, and other renal, urinary, and metabolic disorders through analysis of blood, bilirubin, creatinine, glucose, ketones, leukocytes, microalbumin, nitrite, pH, protein, S.G., urobilinogen in urine.	Glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes.	Drugs of abuse, general chemistry	Detects drugs and/or metabolites in human urine for up to nine drug classes
■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting	■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting	■ 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 ■ Elsewhere	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ■ Elsewhere
N/A	N/A	Forensic use	Freestanding emergency department, urgent care
90 seconds or less; results are displayed on LCD screen and printed on internal thermal printer	Results can be obtained in 30 seconds in continous mode	Time to first result ~12 minutes; Results can be sent directly to LIS, an EMR through LiteDM Data Management Software, or as a printed report	Approximately 15 minutes; results can be printed and transmitted to the laboratory information system (LIS)
600 tests/hr under Quick Test Mode 36 tests/hr under Routine Test Mode"	120 strips per hour in continous mode or 60 strips per hour in single test mode	60 Sample Positions (continuous load), throughput 420 test/hour with ISEs	Up to 20 samples per hour. Test devices can be preloaded to incubate while first device is being run.
VGA connectivity to host computer and to transmit results to LIS. USB connection for barcode scanning. USB connection to connect an additional external printer.	User and QC lockouts, programmable to once every eight hours, weekly or monthly. 2,000 results stored in memory. Automatic calibration. Built-in thermal printer. Optional RS232C barcode reader and data transfer cable.	Ethernet for remote diagnostics; RS232 for LIS/middleware; optional LiteDM data management system; touchscreen interface; shock, level, and clot detection on probes; auto rerun, autocalibration, autoQC	Runs on automated meter, does a self check, needs minimal maintenance, and includes LIS connectivity, test select, QC, and operator lockouts.
Can be easily operated without additional training.	1 hour	3 Days (on site)	Approximately 1 hour for training and 6 hours for validation
Lifetime customer service and tech support by phone/email; quick reference guide; videos on the website.	Mon-Fri, 8am-4pm	Remote diagnostics, phone support, field service engineering support	Available 24/7
Ultra-compact size with CLIA-waived certification; Cardinal UA10ACR strip provides maximum reimbursement for one single urine strip: 3 CPT codes (81003, 82044, 82570) "	Ideal for testing patient samples quickly and easily. Small enough to fit into doctor's offices or small labs. Use low cost Uri-Trak strips to test for common analytes including glucose, ketones and bilirubin.	Broad menu of >70 moderately complex drugs of abuse and general chemistry assays, 52 on board reagent positions, barcoded reagents, optimized test packaging for low-medium volume labs.	Detects benzodiazepine metabolites, hydrocodone, and hydromorphone. Methamphetamine and amphetamine assays can detect prescribed stimulants. The EDDP assay ensures compliance with opioid cessation therapy.

Introducing the new DxU Iris automated urinalysis solution

Industry-leading technology that streamlines workflow by reducing manual microscopic review rates to 4%*.

- Minimize operator intervention and interruptions with load-and-go walkaway capabilities and Edit-Free Release technology
- Sleek, intuitive software user interface allows the operator to comfortably navigate, access key reference information and simplify training across multiple Beckman Coulter instruments
- Improve efficiency of urinalysis testing and reduce manpower with iWARE autoverification software that ensures the reliability of test results—a standard feature across DxU Iris instruments

Additionally, labs have the option to connect DxU Iris with Beckman Coulter's advanced software solutions including PRO*Service* remote service tool, DxONE Command Central remote monitoring and REMISOL Advance middleware, as well as a new load and unload station to increase productivity.

Learn more at beckmancoulter.com/DxUIris

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*Broadlawns Medical Center. (2019). Manual microscopy divided by on-screen microscopic verification report generated December 20, 2019.Case study published by Beckman Coulter. https://media.beckmancoulter.com/-/media/diagnostics/products/urinalysis/docs/ua-broadlawns-case-study.pdf

For Beckman Coulter's worldwide office locations and phone numbers, please visit www.beckmancoulter.com/contact AD-350858 | 2021-9294

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	Siemens Healthineers 511 Benedict Avenue Tarrytown, NY 10591-5005 USA	Sysmex America Lincolnshire, Ill 800-379-7639 www.sysmex.com	Sysmex America Lincolnshire, Ill 800-379-7639 www.sysmex.com
1. What is the brand name of your company's urinalysis system?	Viva-ProE System	UN-2000-011 Automated Urinalysis Solution	UN3000-111 Automated Urinalysis Solution
2. What year was this version first released to market?	2014 (US/OUS)	2020 (US)	2015 (OUS); 2019 (US)
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations	UL certification: 2012, FDA 510(k) clearance: 2012, CE-marking (notification): 2014"	UF-5000 FDA 510(k), 2018; Siemens CliniTek Novus, FDA 510(k), 2014	FDA 510(k), 2018
4. What are the dimensions of the named product?	Height excluding monitor 23.2", Width 49.2", Depth 24.4"	35" x 52" x 36"	35" x 26" x 36"
5. What is the intended use or primary function of the product?	Automated chemistry analyzer used in combination with reagents for in vitro diagnostic measurement of analytes in samples of serum, plasma, urine, and aqueous standard solutions.	Urine chemistry analyzer and urine particle analyzer	Urine particle analyzer
6. What types of specimen/ sample does the product employ ?	The analyzer can support the following specimen types: Serum, plasma, urine and aqueous standard solutions. Random specimen.	Urine	Urine
7. What types of diseases, conditions, or analytes does the system detect?	Urine drug testing (drugs of abuse), therapeutic drugs, immunosuppressive drugs, serum toxicology and specimen validity	Semiquantitative measurement of parameters in urine to assist diagnosis of carbohydrate metabolism, kidney and liver function, metabolic disorders, urinary tract infection. Quantitative results for bacteria, casts, epithelial cells, erythrocytes, leukocytes. Flags information for crystals, pathological casts, sperm, yeast-like cells.	Quantitative results for bacteria, casts, epithelial cells, erythrocytes, leukocytes. Flags information for crystals, pathological casts, sperm, yeast-like cells.
8. 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 ■ Elsewhere	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting
9. If you answered "elsewhere," explain briefly.	Designed for criminal justice, drug courts, treatment centers, toxicology & clinical laboratories, industrial facilities, pre-employment testing centers, workplace testing, and transplant management centers	N/A	N/A
10. Under ideal conditions, what is the time to first result; how are the test results made available?	Average time to first result: 10 minutes for a 2-reagent assay. Results displayed on-screen, printout and on LIS	Time to first result varies by configuration	Time to first result varies by configuration
11. What are the product's maximum specimen capacity and throughput under ideal conditions?	133 tests/hour with two reagents. Sample continuous-load: • 50 positions, bar-coded • 12 positions without bar codes"	80 to 250 samples onboard; throughput varies	Up to 80 samples onboard; maximum throughput 105 per hour
12. Briefly describe any automation or connectivity features or options that pertain to the product.	• Host-Query interface • RS232 or Ethernet (TCP/IP) through LIS-2A protocol • Internal bar-code reader for sample tubes • Heated Reagent probe • Liquid level detection, integrated stirrer • Operator's guide linked to software	Liquid level sensing cap detection, autovalidation, auto-reflex rules, evidence-based maintenance, real-time quality control monitoring, remote system diagnostics, optional automated tube decapper, optional remote review workstation	Liquid level sensing cap detection, autovalidation, auto-reflex rules, evidence-based maintenance, real-time quality control monitoring, remote system diagnostics, optional automated tube decapper, optional remote review workstation
13. What is the typical training time for the product?	Viva-ProE System Operator Course is three days	5 hours	3 hours
14. What types of technical support are available?	Remote Services Center (RSC) M-F 8:00am 5:00pm EST 1-800-227-8994 (USA) Technical Application Specialist and Field Service Engineer assigned per account Online Education: Personalized Education Plan (PEP connect) https://pep.siemens-info.com/en-us/laboratory-diagnostics	24-hour phone support via a technical assistance center; onsite service varies by service contract.	24-hour phone support via a technical assistance center; onsite service varies by service contract.
15. What capabilities, features, or accessories distinguish this product from others on the market?	• Since 1972, Syva EMIT has been the trusted brand in drug testing. The EMIT method has been acknowledged by the U.S. Supreme Court as part of a highly accurate drug-testing program. • Onboard waste and water storage • Proven reliability, with robust, long-life components that reduce user maintenance • Periodic maintenance visits to one per year	Integrated system combining chemistry and microscopy analysis. Two separate reaction chambers and reagents for enhanced classification, specific fluorescent dyes for identifying particles based on nucleic acid components, and reagents that minimize interferences.	Two separate reaction chambers and reagents for enhanced classification, specific fluorescent dyes for identifying particles based on nucleic acid components, and reagents that minimize interferences.