tech guide

Urinalysis and Toxicology

	Abbott Clearwater, Fla 855-425-9428 www.gadevelop.com	Arkray USA Minneapolis 877-538-8872 www.arkrayusa.com	Beckman Coulter Brea, Calif 800-526-3821 www.beckmancoulter.com
1. What is the brand name of your company's system?	ImmTox 270	Aution Eleven AE-4022 semi-automated urine analyzer	iQ3000 Automated Urinalysis Workcell; iQ2000 Automated Urinalysis Workcell
2. What is the latest version of your named system; what year was this version first released to market?	2019 (US)	2017 (US)	2018 (US)
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 2019	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?	21.9 inches x 31.5 inches x 26.4 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?	Urine toxicology screening immunoassay analyzer	Urine chemistry.	Urine chemistry, urine microscopy, urine culture indicator, and streamline body fluids analysis in the same workcell
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?	Includes heroin metabolite, amphetamine, barbiturates, benzodiazepines, benzoylecgonine, buprenorphine, cannabinoids, carisoprodol, ethyl alcohol, ethyl glucuronide, fentanyl, ketamine, meperidine, methamphetamine, opiates, oxycodone.	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 parameters; FDA cleared for eight body fluid analytes.
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 ❑ In 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 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 patient's home or other self-testing ❑ Elsewhere
9. If you answered "elsewhere," explain briefly.			
10. Under ideal conditions, what is the time to first result; how are the test results made available?	15 minutes; results are available on touchscreen interface, reported via LIS to EMR, or printed.	60 seconds	Less than 2 minutes
11. What are the product's maximum specimen capacity and throughput under ideal conditions?	270 tests per hour; holds up to 40 barcoded patient samples onboard.	514 samples per hour	Up to 101 samples per hour, depending on the 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	Edit-free auto-release results technology, auto-validation data management software, DxOne Command Central remote lab instrument monitoring system, middleware solution, and continuous strip load capability.
13. What is the typical training time for the product?	2 days of on-site training provided at installation.	N/A	2½-day classroom training
14. What types of technical support are available?	Phone support Mon-Fri 8AM -8PM ET. 24-hour electronic support, application support, on-site field service available.	24/7/365	24/7 phone support, onsite service, online education
15. What capabilities, features, or accessories distinguish this product from others on the market?	Self-contained benchtop system holds up to 24 dual reagent tests and has walkaway capability of up to 2.5 hours. Menu of 14 moderately complex drug tests. Other features: reusable/washable cuvettes; touchscreen interface with real-time viewing of results; voice announcement of status updates.	Smallest semiautomated footprint on the market; test strips are easy to load with no calibration required; quality control and operator ID lockout functionality.	Auto-classification of 12 particle types, with 27 subcategories done by the operator, on-screen digital imaging, personalized for scalable solutions, auto-release results technology to limit the need of user intervention, UTI candidate indicator, and streamlined body fluid module; FDA-cleared for eight body fluids analytes.

FIND CLARITY AND REDUCE SUBJECTIVITY WITH IRIS

The award-winning Iris iQ 200 Automated Urinalysis System delivers standardised urine and morphology results in less than 60 seconds. Combining Digital Flow Microscopy and Artificial Intelligence, the iQ Vision Cell Recognition Software ensures consistency and precision for optimised workflow solutions that reduce user-to-user subjectivity and deliver clear results for laboratory and point-of-care.

- Walk-Away Release technology automatically releases results based on user-defined parameters creating a true walk-away solution
- Urine Culture Indicator Checklist and alerts highlighting samples that may require urine culture
- Body Fluids Module delivers accurate results for cerebrospinal fluid samples with increased throughput

Find our solutions today at beckmancoulter.com/irisanalysis

	Cardinal Health Dublin, Ohio www.cardinalhealth.com	Medtox Diagnostics Burlington, NC 800-334-1116 www.medtoxdiagnostics.com	Quidel San Diego, Calif 800-874-1517 quidel.com
1. What is the brand name of your company's system?	Cardinal Health Urinalysis Analyzer and Test Strips	Profile-V MedtoxScan Drugs of Abuse Test System	Quidel Triage TOX Drug Screen, 94600
2. What is the latest version of your named system; what year was this version first released to market?	2020 (US)	2009	2019 (US); 2020 (OUS)
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	TUV CE Mark, 2018; FDA 510(k) and CLIA-waiver, 2018	FDA 510(k), 2009; Health Canada, 2009	FDA 510(k), 2019; IVDD self-certified CE mark, 2019; Health Canada Class 2, 2020
4. What are the dimensions of the named product?	3 inches x 7.5 inches x 9 inches	3.5 inches x 5.5 inches x 8 inches	2.75 inches x 6.25 inches x 8.5 inches
5. What is the intended use or primary function of the product?	Reads Cardinal Health urine test strips and calculates albumin-to-creatinine ratio	Qualitative test for drugs of abuse in hospital laboratory setting	Fluorescence immunoassay for the qualitative detection of drug and/or metabolites in human urine
6. What types of specimen/sample does the product employ?	Urine (random, first morning, midstream all acceptable)	Urine	Human urine, no special treatment required
7. What types of diseases, conditions, or analytes does the system detect?	Albuminuria, diabetes monitoring, kidney disease, urinary tract infection, and other renal, urinary, and metabolic disorders through analysis of blood, bilirubin, creatinine, glucose, ketones, leukocytes, and other components in urine.	Drug use	Detects drugs and/or metabolites in human urine for up to nine drug classes
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 ❑ In 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 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 patient's home or other self-testing ■ Elsewhere
9. If you answered "elsewhere," explain briefly.			Freestanding emergency department, urgent care
10. Under ideal conditions, what is the time to first result; how are the test results made available?	90 seconds or less (5 seconds on Quick Test Mode); results displayed on LCD screen and printed	10 minutes	Approximately 15 minutes; results can be printed and transmitted to the laboratory information system (LIS)
11. What are the product's maximum specimen capacity and throughput under ideal conditions?	600 tests per hour under Quick Test Mode; 36 tests per hour under Routine Test Mode	One at time	Up to 20 samples per hour. Test devices can be preloaded to incubate while first device is being run.
12. Briefly describe any automation or connectivity features or options that pertain to the product.	Bidirectional RS232 interface for data transfer to host; barcode reader for patient and operator ID.	All-in-one reader that reads MedTox drugs of abuse testing devices. Able to interface with LIS and/or middleware.	Runs on automated meter, does a self check, needs minimal maintenance, and includes LIS connectivity, test select, QC, and operator lockouts.
13. What is the typical training time for the product?	No additional training needed	30 minutes	Approximately 1 hour for training and 6 hours for validation
14. What types of technical support are available?	Phone/email; step-by-step quick reference guide; videos on the website	Toll-free line to tech support and quick reference guides	Available 24/7
15. What capabilities, features, or accessories distinguish this product from others on the market?	Ultra-compact size with CLIA-waived certification; Quick Test Mode (5 seconds to result); automatically calculates the microalbumin-to-creatinine ratio (ACR); Cardinal UA10ACR strip provides maximum reimbursement for one single urine strip: 3 CPT codes (81003, 82044, 82570).	Most comprehensive drugs of abuse testing system in the hospital laboratory market. Tests up to 13 drugs with results in 10 minutes.	Detects benzodiazepine metabolites, hydrocodone, and hydromorphone. Methamphetamine and amphetamine assays can detect prescribed stimulants, and there is a wider window to detect if someone has used methamphetamine. The EDDP assay ensures compliance with opioid cessation therapy. The meter can also run BNP, D-dimer, and cardiac assays.

Rapid, Automated Drug Screening at your Point-of-Care.

Providing adequate pain relief while monitoring compliance is critical for maximizing physician productivity and ensuring safe pain management practices and guidelines.

The Triage TOX Drug Screen, PCM provides an accurate and actionable result in about 15 minutes with the option to interface with your laboratory system.

Triage
TOX DRUG SCREEN, PCM

For more information, contact Biosite Incorporated at
[illegible]

[illegible]

	Sysmex America Lincolnshire, Ill 800-379-7639 www.sysmex.com	**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 system?	UN-3000-111 Automated Urinalysis Solution	UN-2000-011 Automated Urinalysis Solution	UF- 5000 Fully Automated Urine Particle Analyzer
2. What is the latest version of your named system; what year was this version first released to market?	2020 (US)	2020 (US)	2015 (OUS); 2019 (US)
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	UF-5000 and UD-10 portion, FDA 510(k), 2018; Siemens CliniTek Novus, FDA 510(k), 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?	35 inches x 76 inches x 36 inches	35 inches x 52 inches x 36 inches	35 inches x 26 inches x 36 inches
5. What is the intended use or primary function of the product?	Urine chemistry analyzer and urine particle analyzer with urine particle digital imaging device	Urine chemistry analyzer and urine particle analyzer	Urine particle analyzer
6. What types of specimen/sample does the product employ?	Urine	Urine	Urine
7. What types of diseases, conditions, or analytes does the system detect?	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.	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 ❑ In 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 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 patient's home or other self-testing ❑ Elsewhere
9. Under ideal conditions, what is the time to first result; how are the test results made available?	Time to first result varies by configuration	Time to first result varies by configuration	Time to first result varies by configuration
10. What are the product's maximum specimen capacity and throughput under ideal conditions?	80 to 250 samples onboard; throughput varies	80 to 250 samples onboard; throughput varies	Up to 80 samples onboard; maximum throughput 105 per hour
11. Briefly describe any automation or connectivity features or options that pertain to the product.	Liquid level sensing cap detection, autovalidaton, autoreflex rules, evidence-based maintenance, real-time quality control monitoring, remote system diagnostics.	Liquid level sensing cap detection, autovalidaton, autoreflex rules, evidence-based maintenance, real-time quality control monitoring, remote system diagnostics.	Autovalidaton, autoreflex rules, evidence-based maintenance, real-time quality control monitoring, remote system diagnostics.
12. What is the typical training time for the product?	8 hours	5 hours	3 hours
13. What types of technical support are available?	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.	24-hour phone support via a technical assistance center; onsite service varies by service contract.
14. What capabilities, features, or accessories distinguish this product from others on the market?	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. Microscopic quality images with size particle grouping to streamline reviews.	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.