

tech guide

Urinalysis and Toxicology

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Beckman Coulter

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Carolina Liquid Chemistries Corp.

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1. What is the brand name of your company's urinalysis system?	ImmTox 270	DxU Iris 840 Workcell; DxU Iris 850 Workcell	Diazyme DZ-Lite c270 clinical chemistry analyzer
2. What is the latest version of your named urinalysis system; what year was this version first released to market?	2019	2021 (US); 2022 (OUS)	Diazyme DZ-Lite c270 clinical chemistry analyzer; urine drug screens added in 2023
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510 (k), 2019	FDA 510(k); CE IVDD; Health Canada	FDA 510(k), CLIA categorization for urine drug screens in 2023
4. What are the dimensions of the named product?	21" x 32" x 27"	23" x 21" x 60"	22" x 32" x 26"
5. What is the intended use or primary function of the product?	Urine toxicology screening immunoassay analyzer	Used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis.	Urine toxicology screening and clinical chemistry analyzer
6. What types of specimen/sample does the product employ?	Urine	Unspun urine	Urine for drug screens. A variety of specimen types for other tests.
7. What types of diseases, conditions, or analytes does the system detect?	Detection of prescription drugs and drugs of abuse in urine.	Kidney function and disease, urinary tract infections, urine chemistry analysis parameters, urine microscopic parameters.	Qualitative detection of 15 prescription drugs and drugs of abuse in urine; quantitative results for a variety of other analytes, conditions, and diseases.
8. Where is the product used?	<ul style="list-style-type: none"> ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting 	<ul style="list-style-type: none"> ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting 	<ul style="list-style-type: none"> ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting
9. 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, or printed.	3 minutes for a complete urine chemistry with microscopy/sediment analysis.	Time to first result depends on assay; results are interfaceable to web-based LIS.
10. 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	Urine chemistry sample throughput 225 per hour. Sample throughput for microscopy/sediment up to 70 or 101 per hour, depending on model.	30 samples per sample wheel plus Virtual Sample Wheel allows pre-programming samples. Throughput up to 270 tests/hr.
11. 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 reporting available with a LIS for simplified ordering, patient management, result reporting and quality control records.	Optional load/unload stations, body fluids module, iWare middleware solution, edit-free automatic release results technology and continuous strip load capability.	On-the-fly sample scheduling. Can calibrate and run samples at the same time. Onboard tracking for lot numbers, reagent onboard expiration, calibration expiration, QC/Levy-Jennings monitoring, tracking and trending.
12. What is the typical training time for the product?	2 days of on-site training	1 day at customer site, 3 days of e-learning	2 days on-site
13. What types of technical support are available?	Phone support M-F 8 am-8 pm ET. 24-hour electronic support, and application support. On site field service available.	24/7 phone support and remote ProService support	Hotline available 8 am-8 pm ET; validation assistance; affordable after-sales service and support contracts.
14. 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.	Streamlines urinalysis workflow to achieve manual review rates of 4%; auto-classifies 12 urine particles and sub-classifies 27 urine particles based on size, shape, contrast, and texture to provide digital images for all samples. FDA-cleared body fluids module with linearity down to zero.	Over 60 moderate complexity tests including 15 toxicology urine drug screens, e.g., fentanyl, and opioids, e.g., oxycodone. Photometric sodium, potassium, chloride, and lithium avoid extra ISE maintenance. Alderant tests are also available.

Take the Interruptions Out
of Your Urinalysis Workflow



DxU Iris Workcell

Automated Urinalysis Solution

Industry-leading technology designed exclusively for you. Leveraging proprietary Digital Flow Morphology technology using Auto-particle Recognition (APR) software, the DxU Iris Microscopy Series isolates, identifies, and characterizes urine casts, crystals, and other particles on-screen to reduce the need for manual microscopy. All this in a scalable and fully automated solution that aligns with your laboratory needs.



Discover the future of urinalysis with DxU Iris



DxU Iris Workcell consists of DxU 840m/850m Iris urine microscopy and the Arkray AUTION MAX™ AX-4030 urine chemistry systems.

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Quidel Triage Meterpro	Acusera Urinalysis Control	cobas pro integrated solutions	UN-2000 Automated Urinalysis Solution
Quidel Triage MeterPro, 2006		2020	UN2000-011 Automated Urinalysis Solution; released 2020 (US)
TUV CE mark, FDA 510(k), 2006, CLIA waived BNP for use with whole blood.	CE Mark, 2009; FDA 510(k) clearance, 2011; Health Canada Licence, 2010; TGA Certificate (Australia), 2014	FDA 510(k), 2019; CE mark, 2018	UF-5000 FDA 510(k), 2018; Siemens Clinitek Novus, FDA 510(k), 2014
3" x 6" x 8"		56" x 188" x 48"	35" x 51" x 36"
Drug of abuse and cardiac testing at point of care applications as well as laboratory use.	Intended as a control for urinalysis.	For diagnostic testing, patient monitoring, therapeutic drug monitoring, and viral load monitoring.	Integrated urine chemistry and urine particle screening device
Plasma, whole blood, urine	100% human urine	Plasma, serum, urine, whole blood, cerebrospinal fluid	Urine
BNP - aid in diagnosis and risk stratification of ACS and HF; D-Dimer aid in assessing and evaluating patients with DIC, PE/DVT; Cardiac Panel - Aid in diagnosis of MI; TOX Drug Screen in human urine.	Albumin, bilirubin, blood, creatinine, glucose, hCG, ketones, leukocytes, nitrate, pH, protein (total), specific gravity, urobilinogen	A broad menu of more than 186 tests for clinical chemistry, immunoassay and ISE, including many unique high medical value assays in areas such as toxicology, cardiac, infectious disease, oncology, women's health, diabetes, and neurology.	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.
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15 minutes. Results are available on the screen, can be printed out and transmitted to LIS.	Same as patient sample.	Immunoassay reaction times in 9 minutes/18 minutes/27 minutes all clinical chemistry) assay reaction times in 10 minutes or less	Time to first result varies by configuration.
Can store up to 750 patient results. 20 tests per hour per meter after initial test.		Holds up to 800 samples at one time; maximum throughput of 1,800 tests per hour for ISE tests; 2,000 tests per hour for CC; 600 tests per hour for IA.	80 to 250 samples onboard; urine chemistry up to 240/hr throughput; urine microscopy/sediment up to 105/hr throughput.
Automated - QC and operator lockouts, meter determines device endpoint; Calibrated - lot specific multi-point calibration, no calibration needed, QC 1/month or new lot; Connected - Test Select for customized panels, LIS-compatible, no manual entry.	Connects to Acusera 24.7 - our interlaboratory data management software. With the unique ability to generate real-time peer group data while also automatically calculating measurement uncertainty.	Integrates CC, IA and ISE testing. To simplify daily operation, provides features that minimize hands-on work. Connects to Roche and select third-party automation systems.	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
A field application specialist will install system and train users usually in less than 1 day.		Key operator training typically 4.5 days at customer training center; additional operators conducted at customer site. User assistance videos onboard the analyzer.	The UN-Series training curriculum includes 9 hours of live Virtual Instructor Led Training (VILT) as well as on-demand access to e-learning material.
A field application Specialist will install system and train users. Technical support is available by phone 24/7.	24/7 phone and email support, online educational material and references, onsite support (available in certain circumstances)	24/7/365 telephone support; onsite technical and service support; remote support and troubleshooting; onboard user assistance.	24-hour phone support via a technical assistance center; onsite service varies by service contract.
Large POC menu that includes cardiology and toxicology; Triage TOX DS, 94600 detects the metabolites of the most prescribed benzodiazepines on the market.	For use in the quality control of urine test strips, this liquid ready-to-use control will dramatically reduce preparation time while a stability of 30 days minimizes waste. Values are provided for 13 analytes; the control is manufactured using 100% human urine, mimicking the patient sample.	Integrates CC, IA and ISE testing, giving access to a menu of >186 assays. Simplifies daily operations, minimizing hands-on work. Ensures simple/effective work for network organizations with standardized results and operation to cobas pure integrated solutions.	Integrated UA 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.

REGISTER TODAY!



MAY 7-9, 2024

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Rochelle Walensky, MD, MPH
19th Director of the Centers for Disease Control and Prevention



Lee A. Fleisher, MD
Former Chief Medical Officer and Director of the CMS Center for Clinical

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