

tech. guide

Urinalysis and Toxicology

1. What is the brand name of your company's urinalysis system?
2. What is the latest version of your named urinalysis system; what year was this version first released to market?
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.
4. What are the dimensions of the named product?
5. What is the intended use or primary function of the product?
6. What types of specimen/sample does the product employ?
7. What types of diseases, conditions, or analytes does the system detect?
8. Where is the product used (check all that apply)?
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?
11. What are the product's maximum specimen capacity and throughput under ideal conditions?
12. Briefly describe any automation or connectivity features or options that pertain to the product.
13. What is the typical training time for the product?
14. What types of technical support are available?
15. What capabilities, features, or accessories distinguish this product from others on the market?

Abbott

Clearwater, FL
855-425-9428
www.immunalysis.com

Beckman Coulter

Brea, CA
800-526-3821
www.beckmancoulter.com

QuidelOrtho

San Diego, CA
800-874-1517
quidelortho.com

ImmTox 270	DxU Iris 840 Workcell; DxU Iris 850 Workcell	QuidelOrtho Triage TOX Drug Screen, 94600
2019	2021 U.S.	2019 (US); 2020 (OUS)
FDA 510 (k), 2019		FDA 510(k), 2019; IVDD self-certified CE mark, 2019; Health Canada Class 2, 2020
21" x 32" x 27"	22" x 48" x 26"/200 lbs.	2.75 inches x 6.25 inches x 8.5 inches
Urine toxicology screening immunoassay analyzer	In-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis.	Fluorescence immunoassay for the qualitative detection of drug and/or metabolites in human urine
Urine	Unspun Urine	Human urine, no special treatment required
Detection of prescription drugs and drugs of abuse in urine.	Kidney function and disease, urinary tract infections, urine chemistry analysis parameters, urine microscopic parameters.	Detects drugs and/or metabolites in human urine for up to nine drug classes
<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 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 ■ Elsewhere
	N/A	Freestanding emergency department, urgent care
12 minutes; results are available on touchscreen interface, reported via LIS to EMR, or printed.	3 minutes for a complete urine chemistry with microscopy/sediment analysis.	Approximately 15 minutes; results can be printed and transmitted to the laboratory information system (LIS)
270 tests per hour, holds up to 30 bar-coded 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.	Up to 20 samples per hour. Test devices can be preloaded to incubate while first device is being run.
Continuous access to samples and reagents without interruption of testing process. Bidirectional LIS communication with HL7 interface and EMR integration options.	Optional load/unload stations, body fluids module, iWare middleware solution, edit free auto-release results technology and continuous strip load capability.	Runs on automated meter, does a self check, needs minimal maintenance, and includes LIS connectivity, test select, QC, and operator lockouts.
2 days of on-site training	1 day at customer site, 3 days with vendor	Approximately 1 hour for training and 6 hours for validation
Phone support M-F 8AM-8PM ET. 24 hour electronic and application support.	24/7 phone support and remote ProService support	Available 24/7
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-classify 12 urine particles based on size, shape, contrast and texture to provide digital images for all samples.	Detects benzodiazepine metabolites, hydrocodone, and hydromorphone. Methamphetamine and amphetamine assays can detect prescribed stimulants. The EDDP assay ensures compliance with opioid cessation therapy.

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General Session Speaker Lineup



James Crawford, MD, PhD
 Northwell Health
 Laboratories



Victor R. De Jesús, PhD
 Centers for Disease
 Control and Prevention



Brad Nieder, MD
 Keynote Speaker
 The Healthy Humorist®



Tariq Adwan, PhD
 Helix Lab Partners



Gregg Brandush, RN, JD
 Director of the Division of Clinical
 Laboratory Improvement & Quality (DCLIQ)
 Centers for Medicare & Medicaid Services



Captain Daniel Hesselgesser, MLS(ASCP)cm
 Manager, Southern Operations Branch
 (Atlanta, Dallas)
 Centers for Medicare & Medicaid Services

General Session: Workforce Shortage Panel Lineup



Edna Garcia, MPH
 Senior Director, Scientific
 Engagement and Research
 ASCP



Marisa James
 Chief Executive Officer, National
 Accrediting Agency for Clinical
 Laboratory Sciences



Shawn Wierzbowski
 Chief Executive Officer
 Intro



Cary Montalvo
 Executive Director,
 Laboratory Services
 Texas Oncology

Breakout Session Speaker Lineup



George Fritsma, MS, MLS
 The Fritsma Factor



Emily Garnett, PhD, DABCC
 Associate Director, Clinical Chemistry
 Texas Children's Hospital



Patrick Mathias, MD, PhD
 Vice Chair of Clinical Operations
 UW Medicine



Lori Nelson, MT(ASCP)
 Area Laboratory Manager
 Texas Oncology



James Payne AHI (AMT), CPT (NHA)
 Monroe 2 Orleans BOCES



Cindy Peterson, AMT
 North/NE Texas Area
 Laboratory Manager
 Texas Oncology



Dana Powell Baker, MBA, MS, MLS(ASCP)
 Manager, Academic Partnerships
 Association of Public Health Laboratories



Andrea Prinizi, PhD, MPH, SM(ASCP)
 Medical Science Liason
 BioMerieux



Tracy Pryor, MBA
 ACOO
 HCA

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Randox Toxicology

Kearneysville, WV
304-728-2890
www.randoxtoxicology.com

Sysmex America

Lincolnshire, IL
1-800-379-7639

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Lincolnshire, IL
1-800-379-7639

Evidence MultiSTAT Analyzer	UN-2000 Automated Urinalysis Solution	UN-3000 Automated Urinalysis Solution
	UN2000-011 Automated Urinalysis Solution; released 2020 (US)	UN3000-111 Automated Urinalysis Solution; Released 2020 (US)
FDA pending	UF-5000 FDA 510(k), 2018; Siemens Clinitek Novus, FDA 510(k), 2014	UD-10 FDA 510(k), 2018; UF-5000 FDA 510(k), 2018; Siemens Clinitek Novus, FDA 510(k), 2014
23" x 21" x 22.5" / 106lb	35" x 51" x 36" (H x W x D) benchtop configuration	35" x 77" x 36" (H x W x D) benchtop configuration
"Urine toxicology screening immunoassay analyzer"	Integrated urine chemistry and urine particle screening device	Integrated urine chemistry and urine particle screening device
Urine	Urine	Urine
Simultaneous detection of 16 classical, prescription and synthetic drugs from a single urine sample	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; Optional Digital Imaging capture to confirm flagged and/or suspected presence of urine particles.
<ul style="list-style-type: none"> ■ 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 	<ul style="list-style-type: none"> ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting 	<ul style="list-style-type: none"> ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting
N/A	N/A	N/A
Results within 19 minutes. Results are available on a digital touchscreen interface, which can be printed or exported to LIMS.	Time to first result varies by configuration. Time to first result varies by configuration	Time to first result varies by configuration. Time to first result varies by configuration
3 samples / 48 results per hour	80 to 250 samples onboard; Urine Chemistry up to 240/hr throughput; Urine microscopy/sediment up to 105/hr throughput.	80 to 250 samples onboard; Urine Chemistry up to 240/hr throughput; Urine microscopy/sediment up to 105/hr throughput; Digital imaging confirmation up to 50/hr.
Fully automated process from sample input to results output; automated reagent and sample dispensing, incubation, washing and imaging. LIMS integrated.	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
2 days of on-site training	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.	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.
24/7 global customer support	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.
The MultiSTAT DOA Urine 16-Plex contains multiple diagnostic test assays for the qualitative determination of the parent molecule and metabolites of drugs in urine, including widely prescribed Fentanyl, along with the Creatinine assay as an adulteration check. This FDA-pending array is a reliable option for highly accurate drug screening.	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. Optional automated decapping; TLA connectivity	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. Optional automated decapping; TLA connectivity

Thermo Fisher Scientific

Waltham, MA
1-800-232-3342
www.thermofisher.com/doascreen

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Waltham, MA
1-800-232-3342
www.thermofisher.com/doascreen

USA Arkray

Minneapolis
877-538-8872
www.arkrayusa.com

Mindray BS-480	Thermo Scientific Indiko Plus	Aution Eleven AE-4022 semi-automated urine analyzer
2014 (US)	2012 (USA, OUS)	2017 (US)
FDA 510K, 2014	2011; cleared with number k110035 (Indiko Plus 98640000)	FDA 510(k), 2016
45" X 46" X 28"	24.4" / 51.2" (height/with open cover) x 37" (width) x 27.6" (depth).	6.5" x 8.3" x 12.9"
Urine Drugs of Abuse	Urine Drugs of Abuse	Urine chemistry.
Urine	Urine	Well-mixed, unspun urine
Urine Drugs of Abuse	Urine Drugs of Abuse	Urine chemistry analysis parameters: bilirubin, blood, color, glucose, ketones, leukocytes, nitrites, pH, protein, specific gravity, and urobilinogen.
<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 ■ Courts of law 	<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 ■ Courts of law 	<ul style="list-style-type: none"> ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting
		N/A
approximately 8 to 9 minutes; test results made available under the Results Tab of the software (example amphetamine ng/mL)	approximately 8 to 9 minutes; test results made available under the Results Tab of the software (example Amphetamine ng/mL)	60 seconds
90 samples Throughput 400/hr	Up to 200 samples per hour; 54 specimens per run	514 samples per hour
Probe level sense, collision with auto-recovery, bubble and clot detection. Refrigerated Reagent Disk 80 positions, (2 - 8 degrees) 90 glass cuvettes, automatic sample probe, reagent probe and cuvette washing. Auto repeat, Auto-dilution. On-Board Troubleshooting.	Probe level sense, Cooled reagent compartment with 44 reagent positions (approximately 8 degrees below room temperature). Disposable plastic cuvettes (reduces carryover between samples). Automatic sample and reagent probes.	Semiautomated urine chemistry analysis
Usually 1-2 days for operation and maintenance, depending on experience and prior knowledge of tech being trained	Usually 1-2 days for operation and maintenance, depending on experience and prior knowledge of tech being trained	N/A
Customer Service 1-800-232-3342, or emailing Techservice.mgc@thermofisher.com	Customer Service 1-800-232-3342, or emailing Techservice.mgc@thermofisher.com	24/7/365
Reliable MTBF - 2500 Operating hours, Minimum Hands on Maintenance, Most software commands, Intuitive Software. Operators Manual built into software, Touch screen monitor, Open System, Solid Dry Heat Incubation	Fast and accurate, minimal hands-on time, continuous access, self-contained, auto-dilution and reruns, bidirectional LIS connection, intuitive software interface and comprehensive testing menu	Smallest semiautomated footprint on the market; test strips are easy to load with no calibration required; quality control and operator ID lockout functionality.