

tech. guide

Urinalysis and Toxicology

	Biochemical Diagnostics, Inc. Edgewood, NY 631-595-9200 https://www.kovaintl.com/kova-products.html#/bcdprod	Biochemical Diagnostics, Inc. Edgewood, NY 631-595-9200 https://www.kovaintl.com/kova-products.html#/bcdprod	Bio-Rad Laboratories Hercules, CA 800-224-6723 www.bio-rad.com
1. What is the brand name of your company's urinalysis system?	DETECTABUSE Series Liquid Urine Immunoassay Control	DETECTABUSE POC Controls	qUAntify Plus Control
2. What is the latest version of your named urinalysis system; what year was this version first released to market?	1991	STAT-SKREEN 23 and STAT-SKREEN 23H. 1991	2004 US and 2009 OUS
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510K, CE marked	FDA 510K	FDA Class II, 510(k) exempt; CE Mark
4. What are the dimensions of the named product?	N/A	N/A	N/A
5. What is the intended use or primary function of the product?	Drugs of abuse immunassay monitoring (quality controls)	Monitor the performance of lateral flow, rapid disposable test devices for urine toxicology	qUAntify Plus Control is intended for use as an assayed quality control to monitor the precision of urinalysis test procedures.
6. What types of specimen/sample does the product employ?	Urine-based matrix	Urine-based matrix	Liquid, human urine based
7. What types of diseases, conditions, or analytes does the system detect?	Urine toxicology/drugs of abuse	Urine toxicology/drugs of abuse	Albumin, albumin-to-creatinine ratio, bilirubin, blood, clarity, creatinine, glucose, hemoglobin, ketones, leukocytes, micro-albumin, microscopics, nitrite, pH, hCG, protein (total), protein-to-creatinine ratio, specific gravity, urobilinogen
8. Where is the product used?	<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"> ■ 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 ■ 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?	Instrument dependent	Instrument dependent	This is dependent upon instrument being used
10. What are the product's maximum specimen capacity and throughput under ideal conditions?	N/A	N/A	N/A
11. Briefly describe any automation or connectivity features or options that pertain to the product.	Results can be sent to LIS systems.	N/A	This control is supported by the Unity interlaboratory quality control data management system
12. What is the typical training time for the product?	Less than 30 minutes	Less than 30 minutes	No training is required; material is run as a patient sample
13. What types of technical support are available?	Technical service staff available	Technical service staff available	Technical support is available by phone or email. Individualized customer support is provided as needed.
14. What capabilities, features, or accessories distinguish this product from others on the market?	Human urine matrix mimics patients samples. 14 different drug formulations. 20 mL size. 31 day open shelf life at 2-8° C.	Human urine matrix mimics patients samples. 22 different drug formulations. 10 mL size. 31 day open shelf life. at 2-8° C	Multi-analyte urinalysis QC for monitoring precision in chemical and microscopic urine testing. Available in 12 mL conical tubes or 120 mL flip-top bottles, ideal for dipstick and microscopic testing methods. Build confidence in patient results with QC data management and peer groups via the Unity Interlaboratory Program.



15 of the Top 20 USA Best Hospitals 2024 have Beckman Coulter Urinalysis

“...the DxU Iris Workcell has **significantly decreased the need to go to a microscope and perform a manual sediment...** it has greatly **reduced turnaround times...**”

-Hematology and Urinalysis Clinical Manager, Boston area hospital

DxU Iris Workcell



Take the Interruptions Out of Your Urinalysis Workflow with DxU Iris

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

Beckman Coulter distributes Arkray products only in the U.S. This product may not be available in your country or region at this time. Please contact your Beckman Coulter sales representative or distributor for more information.

© 2025 Beckman Coulter, Inc. All rights reserved. Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries. The Danaher trademark is a proprietary mark of Danaher Corporation. All other trademarks are the property of their respective owners.

2024-13693



Bio-Rad Laboratories

Hercules, CA
800-224-6723
www.bio-rad.com

Jant Pharmacal Corporation

Encino, CA
800-676-5565
info@jantdx.com
jantdx.com

Randox Laboratories Ltd.

Crumlin, Northern Ireland
(+) 44 2894422413
marketing@randox.com
www.randox.com

Sysmex America

Lincolnshire, IL
800-379-7639

Liquichek Urine Toxicology Control, Levels S1E Low Opiate and S2E Low Opiate	Accustrip	Acusera Urinalysis Control	UN-2000 Automated Urinalysis Solution
2004 US and 2009 OUS	Accustrip URS Reader; 2008 (US)		2020
FDA Class II, 510(k) exempt; CE mark	FDA 510(k) 09.06.06	CE Mark, 2009; FDA 510(k) clearance, 2011; Health Canada Licence, 2010; TGA Certificate (Australia), 2014	UF-5000 FDA 510(k), 2018; Siemens Clinitek Novus, FDA 510(k), 2014
N/A	3" x 6" x 8"	N/A	35" x 51" x 36"
Intended for use as a quality control urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.	Point of care applications: Screening for diabetes, metabolic abnormalities, liver diseases, biliary and hepatic obstructions and diseases of the kidneys and urinary tract	Intended as a control for urinalysis.	Integrated urine chemistry and urine particle screening device
Liquid, human urine based	Urine sample	100% human urine	Urine
11-Nor-delta-9-THC-9-COOH, amphetamines, barbituate, benzodiazepines, benzoyllecgonine, cannabinoids, cocaine, d-Methamphetamine, ethanol, lormetazepam, LSD, methadone, methaqualone, morphine, free, nortriptyline, opiates, phencyclidine, propoxyphene, secobarbital, TCA	Leukocytes, nitrite, urobilinogen, protein, pH, blood, specific gravity, ketone, bilirubin, glucose conditions: diabetes, metabolic abnormalities, liver diseases, kidney function, and urinary tract infections"	Albumin, bilirubin, blood, creatinine, glucose, hCG, ketones, leukocytes, nitrate, pH, protein (total), specific gravity, urobilinogen	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.
<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 ■ 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
This is dependent upon instrument being used	Results available in 1-2 minutes. The result is displayed on the screen.	Same as patient sample.	Time to first result varies by configuration.
N/A	The analyzer processes one specimen at a time with a throughput of up to 60 tests per hour.	N/A	80 to 250 samples onboard; urine chemistry up to 240/hr throughput; urine microscopy/sediment up to 105/hr throughput.
This control is supported by the Unity interlaboratory quality control data management system	Self-test, autocalibration, autodetection of specimens, transfer of results to interface or print, touch screen, battery or external power.	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.	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
No training is required; material is run as a patient sample	Minimal training required.		Includes 9 hours of live virtual instructor led training (VILT) as well as on-demand access to e-learning material.
Technical support is available by phone or email. Individualized customer support is provided as needed.	Telephone tech support	24/7 phone and email support, online educational material and references, onsite support (available in certain circumstances)	24-hour phone support via a technical assistance center; onsite service varies by service contract.
Multi-analyte urine toxicology QC designed for precision monitoring of drugs-of-abuse testing with at 20-25% above/below EIA cutoff levels. Offers a 3-year shelf life at 2-8°C and 30-day open-vial stability. Ideal for screening and semi-quantitative testing.	Offers automatic, hands-free testing with a clear display for all results. A user-friendly touch screen simplifies operation, with an option for a keyboard. Its compact, battery-compatible design makes it portable, and the memory stores up to 200 results for quick access and review. Easy result printing is available.	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.	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.



ADLM
2025

BRING THE

WONDER

JULY 29–31 • CHICAGO, IL • USA

PREPARE TO BE AMAZED

There's only one Expo that brings the wonder of clinical laboratory medicine to life. Join lab medicine leaders from various specialties to explore innovative solutions, cutting-edge technologies, and essential products. Don't miss this opportunity to discover what's practical—and what's possible—in the lab and beyond!

Join us at the ADLM 2025 Expo in Chicago for:

- 850+ exhibitors, 200+ product categories and live demos
- Lecture Series Presentations and Industry Workshops
- Networking opportunities to connect with industry peers and leaders
- New technologies competing for this year's Disruptive Tech Award
- Exclusive member benefits at the ADLM booth + member lounge

**FOR A LIMITED TIME,
EXPO-ONLY RATE IS
JUST \$40!**



**REGISTER NOW AT
[MEETING.MYADLM.ORG](https://meeting.myadlm.org)**



This year's meeting will be held in partnership with the Canadian Society of Clinical Chemists (CSCC).