URINALYSIS INSTRUMENTATION

Part 1 of 2

See **captodayonline.com/productguides** for an interactive version of guide

	ARKRAY **Angie Howe** howea@arkrayusa.com **Edina, MN** **877-538-8872** www.arkrayusa.com/clinical-diagnostics	**ARKRAY** **Jessica Donlan** donlanj@arkrayusa.com **Edina, MN** **877-538-8872** www.arkrayusa.com/clinical-diagnostics	**Beckman Coulter** **Shallon Hagen** smhagen@beckman.com **Miami, FL** **305-380-3800** www.beckmancoulter.com
Name of urinalysis instrument	AUTION ELEVEN AE-4022	AUTION MAX AX-4030	iQ200SELECT, iQ200ELITE, iQ200SPRINT†
Type of instrument	urine chemistry	urine chemistry	microscopy/sediment
First year instrument sold in U.S.	2017	2011	2003
No. of units installed in U.S./No. of units installed outside U.S.	— (also sold via Cardinal, Beckman Coulter, Medline Industries)	— (also sold via Cardinal, Beckman Coulter, Medline Industries)	>1,000††/>4,000†† globally (also sold via McKesson)
Intended urine sample volume per day	—	>15	100–199
Dimensions (HxWxD)/Weight	6.5 × 8.3 × 12.9 in./7.9 lbs.	21 × 21 × 21 in./82 lbs.	22 × 21 × 24 in./100 lbs.
Power requirements	100–240 VAC (50–60 Hz)	100–240 VAC (50–60 Hz)	90–240 VAC
Mean time between failure of instrument	1,230 days	less than one per year	—
Events that cause instrument to lock or stop analysis	user ID failure, result error	short sample, result error, sampling error	QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement/expiration
Urine chemistry: *(Information in this box is specific to urine chemistry)*			
• Testing methodology: Specific gravity/Color/Clarity	test strip/test strip/visual read, manual entry	refractometer/wavelength of absorbance within an analyzer well/turbidity within an analyzer well	—
• Urine chemistry tests available on instrument	bilirubin (0.5–14 mg/dL), hemoglobin (0.03–1.0 mg/dL), glucose (30–1,000 mg/dL), ketone (5–150 mg/dL), leukocyte esterase (25–500 leukocytes/µL), nitrite (0.08–0.5 mg/dL), pH (5–9), protein (10–1,000 mg/dL), specific gravity (1.005–1.030), urobilinogen (2–16 mg/dL)	bilirubin (0–≥10 mg/dL), hemoglobin (0–≥1 mg/dL), glucose (0–≥1,000 mg/dL), ketone (0–≥150 mg/dL), leukocyte esterase (0–500 leukocytes/µL), nitrite (–, 1+, 2+), pH (5–9), protein (0–≥600 mg/dL), specific gravity (1.000–1.050), urobilinogen (0–≥12 mg/dL)	—
• Color compensation pad included	yes	yes	—
• Flagging thresholds customizable	—	no	—
• Test strip configuration	loosely packed in bottles	loosely packed in bottles	—
• Calibration required after each test strip lot No. change	no	no	—
• Frequency of customer-performed calibration	—	—	—
• Form of calibration	—	—	—
• How results are displayed for urine chemistry	semiquantitative	semiquantitative	—
• Reporting format customizable	no	no	—
• No. of results that can be held in internal memory	520 (sample results and control results combined)	2,500 sample results/200 control results	—
• Specific gravity correction for protein/glucose	no (protein)/no (glucose)	yes (protein)/yes (glucose)	—
Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)*			
• Microscopy/sediment technology	—	—	digital flow morphology (digital imaging)
• Microscopy/sediment analysis parameters	—	—	all of the following quantitative: pathological casts, crystals, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts, white blood cell clumps, yeast, squamous and nonsquamous epithelial cells, cast subtyping, crystal subtyping, RBC subtyping
• Flagging thresholds customizable	—	—	yes
• Instrument eliminates amorphous crystal interference before sample analysis	—	—	no
• How results are displayed for microscopy/sediment	—	—	numeric values
• Reporting format customizable	—	—	yes
• No. of results that can be held in internal memory	—	—	10,000 sample results/~200 control results
Reagent shelf life/storage temperature for unopened containers	2 years/1–30°C	—	varies based on reagent type
Reagent shelf life/storage temperature for opened containers	31 days/1–30°C	—	varies based on reagent type
Reagent barcode-reading capability	no	no	yes
How often quality control samples are run	daily	daily	daily
Ability to use other vendors' quality control products	yes	yes	no
Sample throughput per hour/time to first result for chemistry	514/1 min.	225/1 min. cycle time	—
Sample throughput per hour/time to first result for microscopy/sediment	—	—	—/<2 min.
Analyzer has stat mode	no	yes (minimum sample volume, 2 mL)	—
Sample dilutions required for urinalysis/body fluid analysis	no (urinalysis)/— (body fluid analysis)	no (urinalysis)/— (body fluid analysis)	no (urinalysis)/yes (body fluid analysis)
• Special sample handling required for body fluid analysis	—	—	yes (Lyse reagent)
Minimum width of sample tube/Minimum length of sample tube	—	15.8 mm/105 mm	16 mm/100 mm
Conditions or substances that prevent a sample from being run	preservatives	—	grossly visible turbidity
Means of sample ID entry	barcode scan, manual entry	barcode scan, manual entry	barcode scan, manual entry
Built-in liquid-level sensing for samples	no	yes	yes
Information that can be barcode scanned on instrument	operator identifier, specimen identifier	specimen identifier	specimen identifier, reagent lot No., reagent expiration
How LOINC codes for results are made available	customer should call ARKRAY to obtain information	e-mail query	manual transmission
Software includes reflex testing/cross-check functionality	no (reflex testing)/no (cross-check functionality)	no (reflex testing)/no (cross-check functionality)	yes (reflex testing)/yes (cross-check functionality)
Instrument automatically generates consolidated report*	no	no	yes
Instrument connections to transfer information	directly to LIS or via commercial middleware (Data Innovations)	directly to LIS or via commercial middleware	directly to LIS and EHR
Interface standards supported	ASTM 1394-91, ASTM 1381	ASTM 1394-91, ASTM 1381	ASTM 1381 with proprietary message layer
Bidirectional interface	no	yes (to other companies' LISs–Cerner, Epic, Meditech, Orchard, SCC Soft Computer, Sunquest)	yes (to other companies' LISs)
Connection to LIS or EHR to upload patient and QC results	direct serial or hospital network (both for LIS); option not available for EHR	direct serial or hospital network (both for LIS)	direct serial (for LIS and EHR)
Information included in transmission from instrument to data-management software	device unique identifier, specimen ID, result, QC identifier	device unique identifier, specimen ID, result	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier
No. of days of training with purchase	0	1–2 days at customer site	1 day at customer site/3 days at vendor office
Approximate scheduled maintenance time required	5 min. daily	<5 min. daily; 2 min. every 3 days; <5 min. weekly; <10 min. monthly	—
Instrument list price	$9,100	$42,000	—
Provide list of client sites to potential customers on request	no (information is confidential)	yes (partial list of comparable sites)	yes
Clients restricted from sharing their experience with company or software	no	no	no
Distinguishing instrument features (supplied by company)	• standardized test strip technology across all ARKRAY platforms • clinically significant reporting ranges • small semi-automated footprint	• proven reliability with less than one unscheduled service event per year • abnormal color detection alerts operators to potential false-positive results • easy to use; strips are easy to load; does not require calibration	• advances urinalysis and body fluid testing through digital flow morphology using auto-particle–recognition software for standardization • increased productivity through improved workflow, reduced urine cultures, lower review rates, and review by exception • advanced technology allows for testing of body fluids and urine samples in a preservative tube

**chemistry and microscopy results in one report*

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

†answers in listing apply to all three systems unless otherwise indicated

††combined total

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.

Product guide editors: Raymond D. Aller, MD, and Hal Weiner

Part 2 of 2

See **captodayonline.com/productguides** for an interactive version of guide

	Roche Diagnostics **Brittany Greiner** brittany.greiner@roche.com **Indianapolis, IN** go.roche.com/cobasu-411	**Roche Diagnostics** **Brittany Greiner** brittany.greiner@roche.com **Indianapolis, IN** usdiagnostics.roche.com/en/core_laboratory/instrument/urisys-2400.html	**Siemens Healthineers** **Maya Daaboul** maya.daaboul@siemens-healthineers.com **Norwood, MA** **781-269-3000** siemens-healthineers.us/poc
Name of urinalysis instrument	cobas u 411	Urisys 2400	CLINITEK AUWi PRO Automated Urinalysis System†
Type of instrument	urine chemistry	urine chemistry	urine chemistry and microscopy/sediment combined
First year instrument sold in U.S.	2006	2002	2015
No. of units installed in U.S./No. of units installed outside U.S.	>400/>2,300	>150/>800	— (also sold via distribution partners)
Intended urine sample volume per day	40–100	>100	75–500
Dimensions (HxWxD)/Weight	10.24 × 16.73 × 13.34 in./26 lbs.	28 × 21 × 26 in./187 lbs.	27 × 63 × 35 in./397 lbs.
Power requirements	110 VAC	110 VAC	120–240 VAC (50–60 Hz)
Mean time between failure of instrument	—	—	—
Events that cause instrument to lock or stop analysis	opening front cover	opening front cover	user ID failure, QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement/expiration, calibration failure, other events
Urine chemistry: *(Information in this box is specific to urine chemistry)*			
• Testing methodology: Specific gravity/Color/Clarity	—/test strip/turbidity within an analyzer well	—/test strip/turbidity within an analyzer well	refractometer/test strip/turbidity within an analyzer well
• Urine chemistry tests available on instrument	bilirubin (neg.–6 mg/dL), red blood cells (neg.–250 erythrocyte/µL), hemoglobin (neg.–250 erythrocyte/µL), glucose (normal–1,000 mg/dL), ketone (neg.–150 mg/dL), leukocyte esterase (neg.–500 leukocytes/µL), nitrite (positive/negative), pH (5–9), protein (neg.–500 mg/dL), urobilinogen (normal–12 mg/dL)	bilirubin (neg.–6 mg/dL), red blood cells (neg.–250 erythrocyte/µL), hemoglobin (neg.–250 erythrocyte/µL), glucose (normal–1,000 mg/dL), ketone (neg.–150 mg/dL), leukocyte esterase (neg.–500 leukocytes/µL), nitrite (positive/negative), pH (5–9), protein (neg.–500 mg/dL), urobilinogen (normal–12 mg/dL)	bilirubin (0.5–2.7 mg/dL), red blood cells (trace level), hemoglobin (0.013–0.3 mg/dL), glucose (36–820 mg/dL), ketone (3.6–156 mg/dL), leukocyte esterase (6.0–91 cells/µL), nitrite (positive and negative; >0.06 mg/dL), pH (5.3–8.7), protein (10.8–1,000 mg/dL), specific gravity (1.000–1.099), urobilinogen (0.24–6.24 mg/dL)††
• Color compensation pad included	yes	yes	yes
• Flagging thresholds customizable	no	no	yes
• Test strip configuration	loosely packed in bottles	cartridge	cartridge
• Calibration required after each test strip lot No. change	yes	yes	yes
• Frequency of customer-performed calibration	monthly	monthly	with every Novus cassette change or every 24 hours when multiple same-lot Novus cassettes are used within 24 hours
• Form of calibration	dry	dry	liquid and dry
• How results are displayed for urine chemistry	semiquantitative	semiquantitative	semiquantitative
• Reporting format customizable	yes	yes	yes
• No. of results that can be held in internal memory	1,000 sample results/900 control results	1,000 sample results/900 control results	7,500 sample results/400 control results
• Specific gravity correction for protein/glucose	—	—	no (protein)/no (glucose)
Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)*			
• Microscopy/sediment technology	—	—	flow cytometry with fluorescent stain
• Microscopy/sediment analysis parameters	—	—	flagged: pathological casts, crystals, small round cells, yeast-like cells, mucus, sperm; quantitative: RBCs, WBCs, epithelial cells, bacteria, hyaline casts
• Flagging thresholds customizable	—	—	yes
• Instrument eliminates amorphous crystal interference before sample analysis	—	—	yes
• How results are displayed for microscopy/sediment	—	—	numeric values, scattergrams
• Reporting format customizable	—	—	yes
• No. of results that can be held in internal memory	—	—	2 years worth of data, all sample results/2 years worth of data, all control results
Reagent shelf life/storage temperature for unopened containers	—/2–30°C	—/2–30°C	365 days/15–30°C
Reagent shelf life/storage temperature for opened containers	—/2–30°C	14 days/2–30°C	—
Reagent barcode-reading capability	yes	yes	yes
How often quality control samples are run	minimum of daily	minimum of daily	daily
Ability to use other vendors' quality control products	yes	yes	no
Sample throughput per hour/time to first result for chemistry	600/—	240/—	—
Sample throughput per hour/time to first result for microscopy/sediment	—	—	80 at 100% sediment/—
Analyzer has stat mode	yes (minimum sample volume is minimum amount necessary to immerse pads)	yes (minimum sample volume, 1.5 mL)	yes (minimum sample volume, 2 mL for chemistry/1 mL for sediment)
Sample dilutions required for urinalysis/body fluid analysis	no (urinalysis)/no (body fluid analysis)	no (urinalysis)/no (body fluid analysis)	no (urinalysis)/— (body fluid analysis)
• Special sample handling required for body fluid analysis	no	no	—
Minimum width of sample tube/Minimum length of sample tube	—	13–66 mm/100–115 mm	16 mm/ 95–106 mm
Conditions or substances that prevent a sample from being run	preservatives	preservatives	mucus, high fluorescence, visible turbidity, samples containing pyridium, grossly bloody samples
Means of sample ID entry	barcode scan, bidirectional download from host, worklist download from host, manual entry	barcode scan, bidirectional download from host, worklist download from host, manual entry	barcode scan, worklist download from host, manual entry
Built-in liquid-level sensing for samples	no	yes	yes
Information that can be barcode scanned on instrument	specimen identifier	specimen identifier	specimen identifier, reagent lot No., operator ID only for CLINITEK Novus system
How LOINC codes for results are made available	website, e-mail query	website, e-mail query	website, e-mail query, other customer communication
Software includes reflex testing/cross-check functionality	no (reflex testing)/no (cross-check functionality)	no (reflex testing)/no (cross-check functionality)	— (reflex testing)/yes (cross-check functionality)
Instrument automatically generates consolidated report*	no	no	yes
Instrument connections to transfer information	data-management system, which connects to LIS/EHR, or directly to LIS/EHR/lab automation system, or via commercial middleware (Data Innovations)	data-management system, which connects to LIS/EHR, or directly to LIS/EHR/lab automation system, or via commercial middleware (Data Innovations)	data-management system, which connects to LIS/EHR, or data-management system that cannot further transmit data
Interface standards supported	ASTM 1394-91, ASTM 1238-95	ASTM 1394-91, ASTM 1238-95	ASTM 1394-91, HL7
Bidirectional interface	—	—	yes (to other companies' LISs and EHRs [requires third-party interfacing tool for LIS interface])
Connection to LIS or EHR to upload patient and QC results	direct serial (for LIS and EHR)	direct serial (for LIS and EHR)	direct serial or hospital network (both for LIS and EHR)
Information included in transmission from instrument to data-management software	specimen ID, result	specimen ID, result	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier
No. of days of training with purchase	0	2 days at customer site/3–4 days at vendor office	1–3 days at customer site/4 days at vendor office
Approximate scheduled maintenance time required	5 min. daily; 10 min. monthly	10 min. daily; 15 min. weekly; 10 min. monthly	10 min. daily; 10 min. weekly; 10 min. monthly
Instrument list price	$13,500	$49,750	—
Provide list of client sites to potential customers on request	no (information is confidential)	no (information is confidential)	yes (partial list of comparable sites)
Clients restricted from sharing their experience with company or software	no	no	no
Distinguishing instrument features (supplied by company)	• fast, efficient processing of urine strips; analyzer ready to test every six seconds • Chemstrip 10UA strip has virtually no interference with ascorbic acid, minimizing false-negative glucose results • flexible sample ID entry options let user choose barcode scan, download from host, or manual entry options onboard	• adjusts easily to different workloads with continuous rack or batch loading • maintains quality with fully automated wash procedures and QC due to definable control racks • eliminates manual sample mixing and improves efficiency with automatic sample mixing onboard	• can upgrade CLINITEK Atlas to CLINITEK Novus and have CLINITEK solution for dry pad chemistry • operational efficiency, with no pretreatment of samples or on-screen review required • fluorescent flow cell technology with dedicated channels for bacteria and sediment to drive clinical outcomes

**chemistry and microscopy results in one report*

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

†system comprises CLINITEK Novus and Sysmex UF-1000i analyzers

††instrument does not report numeric values for most tests; it reports such terms as negative, trace, small, moderate, and large (variable by test)

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.