

Guide to urinalysis instrumentation

It is arguably the oldest discipline in pathology, but that title likely would not be enough to generate sentimental feelings among those at the receiving end of a urinalysis test. Yet urinalysis is a Cinderella of sorts: morphing from visual observation, to taste testing, to manual dipstick tests, to sleek, state-of-the-art instrumentation that can measure numerous substances.

Showing off their features on the following pages are 10 urinalysis instruments that, collectively, represent CAP TODAY's first urinalysis systems product guide. The guide focuses on fully automated and semiautomated urine chemistry and microscopy/sediment instrumentation. We determined what information would be relevant to you, the reader, in part by discussing with industry representa-

tives what we should ask and how to ask it. A special thank you to the product specialists at Arkray, Roche, and Siemens and to our trusted CAP TODAY informatics experts, Raymond D. Aller, MD, and Hal Weiner, for their guidance. And an enormous thank you to Leslie Williams, at Sysmex America, for her invaluable assistance each step of the way. We would appreciate feedback and suggestions on how to improve future editions of the guide.

But first writer Anne Ford reports what a few company representatives say about how urinalysis technology fits into laboratory automation and the importance of urinalysis.

—Kimberly Carey, managing editor, kcarey@cap.org
Not everyone shares Lauren Foohey's idea of a good time, and she knows it.

"Performing urine sediment analysis under a microscope—I thought it was fun," Foohey says with a laugh. She spent 10 years in the laboratory before ultimately becoming senior director of global marketing for point-of-care urinalysis and diabetes at Siemens Healthcare, Point of Care Diagnostics. "I just always thought it was fun to figure out, 'What are these cells I'm looking at? Red cells, white cells, casts, crystals, amorphous phosphates, bacteria?' It wasn't often you'd see a parasite, so it was always a big deal when you did, and everybody would be screaming, 'Look at this!'"

"I loved doing it," she continues. "But as fewer and fewer people are going into the medical technology field, it's more difficult for lab managers and directors to find people who are trained to do urinalysis via microscopy and who want to do it." That, she adds, is in part why demand for automation has increased.

But even as demand rises, "there seems to be variation in how urinalysis technology fits into full automation," says Leslie Williams, urinalysis product manager for Sysmex America. "There are some urinalysis systems that have been incorporated into large automation systems, but I am not sure how common that is in practice. Usually customers will take our UF-1000i fully automated urine sediment analyzer and put it on an automation line, and then put the urine chemistry analyzer at some other point further down the line and run them that way. Our distributor, Siemens, sells the UF-1000i as part of an integrated urinalysis system, the Clinitek AUWi Pro automated urine workstation."

That workstation, Foohey says, has been available in the United States since the beginning of the year and is also for sale in Canada and Japan. "Siemens connects the UF-1000i with our Clinitek Novus urine chemistry analyzer [via] a track that moves racks of urine tubes throughout the system," she explains. "There is no doubt that automation requires a greater upfront investment...but it pays off in shorter turnaround times, speed to diagnosis, and staffing within the lab. At the end of the day, if you don't have the laboratorians to do the testing manually, you really don't have a choice. Even some of our smaller-volume customers want to go to full automation."

The Clinitek Novus automated urine chemistry analyzer, which was also introduced this year, can be loaded with up to 200 samples at a time. "The nice thing about all of our reagents is that we make them all in the same plant, and they're all the same chemistries," says Foohey. "So the chemistry that makes up a ketone pad for visual reading is the same technology that is in our high-volume Clinitek Novus analyzer, so you get very consistent results regardless of where you're running the product."

PRODUCT
GUIDE

URINALYSIS INSTRUMENTATION

Arkray, too, has been focusing on the marriage of automation and urinalysis. “Laboratories are seeking automation solutions to decrease manual tasks such as urine microscopy without compromising quality,” says marketing manager Jessica Donlan, MLS(ASCP). “Automated urinalysis minimizes hands-on time, standardizes results, and gives laboratorians the flexibility to multitask.” Arkray sells the Aution Hybrid AU-4050 fully automated and integrated urine chemistry and sediment instrument as well as the Aution Max AX-4030 fully automated urine chemistry instrument.

The urinalysis market, in general, “is growing globally at about two percent for the urine chemistry side,” says Foohey. “But when you look at the combined automated urine chemistry and sediment market, it’s growing at more like four to five percent.”

Stressing the ongoing need for urinalysis—automated or not—Foohey adds that, “Globally, there are more than 1 billion people at risk for kidney disease, with one risk factor being [age] over 60 years,” she says. “And this is a very easily performed test. All you need is some urine, a cup, and a urine strip, whether the physician is in the outback of Australia, or the most remote parts of Canada, or Tierra del Fuego in South America.”

Williams agrees. “I think a lot of people have fallen into the trap of thinking, ‘It’s just urine,’” she says. “But if you really pay attention to what urinalysis results are telling you, specifically to what you find in the urine sediment, then I think you can appreciate that urine is still as relevant as it’s ever been.”

She points to the trend toward identifying biomarkers for kidney disease. “There have been several of these identified, but the medical community can’t seem to come to a consensus on which one is best for which condition. Once they identify a marker and can align it with a specific disease state, that’s going to be a new avenue for urine testing.”

Also supporting the growth of urinalysis, Williams says, is the trend toward increased screening for urinary tract infections, particularly those associated with catheter use. “It’s more important than ever for hospitals to catch infection early, so they can prove that a patient did not develop a hospital-acquired infection,” she says. “Otherwise, they run the risk of losing the reimbursement for the entire stay. And quite often those patients are not symptomatic, and if you let a UTI go undetected, it can lead to sepsis. Using available urine testing to make sure you capture these infections early is becoming more important as health care starts to focus on patient outcomes and test value versus the traditional pay-for-service model.”

In CAP TODAY’s guide to urinalysis instrumentation are products from the aforementioned manufacturers and from Beckman Coulter and Roche Diagnostics. Companies supplied the information listed. Readers interested in a particular product should confirm that it has the stated features and capabilities. □

Anne Ford is a writer in Evanston, Ill.

Part 1 of 4

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

Arkray

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Name of urinalysis instrument	AUTION HYBRID AU-4050
Type of instrument	urine chemistry and microscopy/sediment combined
First year instrument sold in U.S.	2013
No. of units installed in U.S./No. of units installed outside U.S.	— (also sold via Cardinal Health)
Targeted urine sample volume per day	>30
Dimensions (HxWxD)/Weight	28.3 × 31.5 × 28.3 in./265 lbs.
Power requirements	100–240 VAC (50–60 Hz)
Mean time between failure of instrument	—
Events that cause instrument to lock or stop analysis	QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement

Urine chemistry: (Information in this box is specific to urine chemistry)

- Testing methodology: Specific gravity/Color/Clarity

- Urine chemistry tests available on instrument

- Test strip configuration
- Calibration required after test strip replacement/After test strip lot No. change
- Frequency of customer-performed calibration
- Form of calibration
- How results are displayed for urine chemistry
- Reporting format customizable
- No. of sample results/Control results that can be held in internal memory
- Specific gravity correction for protein/Specific gravity correction for glucose

refractometer/wavelength of absorbance within an analyzer well/turbidity within an analyzer well
bilirubin (0–≥10 mg/dL), blood (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)
loosely packed in bottles
no/no
specific gravity only: monthly
liquid
semiquantitative
yes
10,000/300 per file, 24 files
yes/yes

Microscopy/sediment: (Information in this box is specific to microscopy/sediment)

- Microscopy/sediment technology
- Microscopy/sediment analysis parameters

- Instrument eliminates amorphous crystal interference before sample analysis
- How results are displayed for microscopy/sediment
- Reporting format customizable
- No. of sample results/Control results that can be held in internal memory

flow cytometry with fluorescent stain
pathological casts (flagged), crystals (flagged), small round cells (flagged), yeast-like cells (flagged), mucus (flagged), sperm (flagged), RBCs (quantitative), WBCs (quantitative), epithelial cells (quantitative), bacteria (quantitative), hyaline casts (quantitative)
yes
numeric values, scattergrams
yes
10,000/300 per file, 24 files

- Reagent storage and stability requirements for unopened containers
- Reagent storage and stability requirements for opened containers
- Reagent barcode-reading capability

—
—
yes

- How often quality control samples run/Can use other vendors’ QC products
- Sample throughput per hour/Time to first result
- Analyzer has stat mode
- Sample dilutions required for urinalysis
- Sample dilutions required for body fluid analysis
- Special sample handling required for body fluid analysis
- Minimum width of sample tube/Minimum height of sample tube
- Conditions or substances that prevent sample from being run
- Means of sample ID entry

per lab requirements/no
100–200/2 min. 15 sec.
no
no
—
—
14 mm/95 mm
—
barcode scan, bidirectional download from host, worklist download from host, manual entry
yes

- Built-in liquid-level sensing for samples

yes

- Information that can be barcode scanned on instrument
- Instrument compatible with lab automation systems
- How LOINC codes for results are made available
- Software includes reflex testing functionality/Includes cross-check functionality
- Instrument automatically generates consolidated report
- Instrument connections to transfer information

specimen identifier, reagent lot No.
no
—
yes/yes
yes
directly to LIS/HIS/lab automation system or via commercial middleware
ASTM 1394, proprietary Sysmex
device unique identifier, patient ID, specimen ID, result, QC identifier

- Interface standards supported
- Information included in transmission from instrument to data-management software

- No. of days of on-site training with purchase
- No. of days of training at vendor office
- Approximate scheduled maintenance time required

varies
2
<1 min. of hands-on time daily, shutdown (automated cleaning cycle) approx. 10 min. daily; 2 min. every 3 days; <5 min. weekly; <10 min. monthly

- Maintenance records kept on instrument
- Instrument list price
- Cost of annual service contract/Length of warranty

yes
\$146,590
—/1 year

- Provide list of client sites to potential customers on request
- Clients restricted from sharing their experience with company or software

—
—

- Distinguishing features (supplied by company)

- smallest footprint in the market (30–50 percent smaller than the competition)
- accurately enumerates bacteria using nucleic acid stain with anti-carryover function and amorphous crystal removal
- easy-to-load strips with no calibration

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

URINALYSIS INSTRUMENTATION

Part 2 of 4	Arkray Jessica Donlan donlanj@arkrayusa.com 5198 W. 76th St. Edina, MN 55439 952-646-3231 www.arkraylab.com	Beckman Coulter Michelle Dumonceaux mddumonceaux@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 800-526-3821 www.beckmancoulter.com	Beckman Coulter Michelle Dumonceaux mddumonceaux@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 800-526-3821 www.beckmancoulter.com
See captodayonline.com/productguides for an interactive version of guide			
Name of urinalysis instrument	AUTION MAX AX-4030	iChemVELOCITY	iQ200ELITE, iQ200SELECT, iQ200SPRINT [†]
Type of instrument	urine chemistry	urine chemistry	microscopy/sediment
First year instrument sold in U.S.	2011	2012	2003
No. of units installed in U.S./No. of units installed outside U.S.	— (also sold via Cardinal Health)	>1,000/>2,000 (also sold via McKesson)	>1,000/>4,000 (answers for all 3 instruments combined; also sold via McKesson)
Targeted urine sample volume per day	>15	0–500	iQ200ELITE: 100–199; iQ200SELECT: <100; iQ200SPRINT: >200
Dimensions (HxWxD)/Weight	21 × 21 × 21 in./82 lbs.	22 × 21 × 24 in./100 lbs.	22 × 21 × 24 in./100 lbs.
Power requirements	100–240 VAC (50–60 Hz)	100–240 VAC (50–60 Hz, 150 watts max.)	90–240 VAC (50–60 Hz, 150 watts max.)
Mean time between failure of instrument	—	—	—
Events that cause instrument to lock or stop analysis	short sample, result error, sampling error	QC failure, short sample, barcode/sample ID misread, result error, sampling error, expired consumables	QC failure, short sample, barcode/sample ID misread, result error, sampling error, expired consumables
Urine chemistry: (Information in this box is specific to urine chemistry)			
• Testing methodology: Specific gravity/Color/Clarity	refractometer/wavelength of absorbance within an analyzer well/turbidity within an analyzer well	refractometer/wavelength of absorbance within an analyzer well/measured directly from scattered light	—
• Urine chemistry tests available on instrument	bilirubin (0–≥10 mg/dL), blood (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)	ascorbic acid (0–40 mg/dL), bilirubin (0–4 mg/dL), blood (0–≥1 mg/dL), glucose (0–≥500 mg/dL), ketone (0–80 mg/dL), leukocyte esterase (0–500 WBCs/μL), nitrite (positive and negative), pH (5–9), protein (0–≥500 mg/dL), specific gravity (1.000–1.060), urobilinogen (0–4 mg/dL)	—
• Test strip configuration	loosely packed in bottles	loosely packed in bottles	—
• Calibration required after test strip replacement/After test strip lot No. change	no/no	no/no	—
• Frequency of customer-performed calibration	specific gravity only: monthly	quarterly	—
• Form of calibration	liquid	liquid	—
• How results are displayed for urine chemistry	semiquantitative	true values, calculated values, semiquantitative	—
• Reporting format customizable	yes	yes	—
• No. of sample results/Control results that can be held in internal memory	2,500/200	10,000/3	—
• Specific gravity correction for protein/Specific gravity correction for glucose	yes/yes	no/no	—
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 qualitative or quantitative (user's option): pathological casts, crystals, small round cells, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts
• Instrument eliminates amorphous crystal interference before sample analysis	—	—	no
• How results are displayed for microscopy/sediment	—	—	numeric values
• Reporting format customizable	—	—	yes
• No. of sample results/Control results that can be held in internal memory	—	—	10,000/~200
Reagent storage and stability requirements for unopened containers	—	—	—
Reagent storage and stability requirements for opened containers	—	—	—
Reagent barcode-reading capability	—	yes	yes
How often quality control samples run/Can use other vendors' QC products	per lab requirements/yes	daily/no	daily/yes
Sample throughput per hour/Time to first result	225/1 min. cycle time	210 chemistry/2 min.	iQ200ELITE: 70 microscopic; iQ200SELECT: 40 microscopic; iQ200SPRINT: 101 microscopic/~2 min.
Analyzer has stat mode	yes (minimum sample volume, 2 mL)	no	no
Sample dilutions required for urinalysis	no	yes	yes
Sample dilutions required for body fluid analysis	—	yes	yes
• Special sample handling required for body fluid analysis	—	yes	yes
Minimum width of sample tube/Minimum height of sample tube	14 mm/95 mm	16 mm/100 mm	16 mm/100 mm
Conditions or substances that prevent sample from being run	—	blood, mucus	grossly visible turbidity
Means of sample ID entry	barcode scan, manual entry	barcode scan, bidirectional download from host, manual entry	barcode scan, bidirectional download from host, manual entry
Built-in liquid-level sensing for samples	yes	no	no
Information that can be barcode scanned on instrument	specimen identifier	specimen identifier, reagent lot No., reagent expiration	specimen identifier, reagent lot No., reagent expiration
Instrument compatible with lab automation systems	no	no	no
How LOINC codes for results are made available	—	manual transmission	manual transmission
Software includes reflex testing functionality/Includes cross-check functionality	—	yes/no	yes/no
Instrument automatically generates consolidated report	—	yes	yes
Instrument connections to transfer information	directly to LIS/HIS/lab automation system or via commercial middleware	data-management system, which connects to LIS/HIS, or directly to LIS/HIS/lab automation system	data-management system, which connects to LIS/HIS, or directly to LIS/HIS/lab automation system
Interface standards supported	ASTM 1394	ASTM 1381 with proprietary message layer	ASTM 1381 with proprietary message layer
Information included in transmission from instrument to data-management software	device unique identifier, specimen ID, result	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier
No. of days of on-site training with purchase	—	1	1
No. of days of training at vendor office	—	0	3.5
Approximate scheduled maintenance time required	<5 min. daily; 2 min. every 3 days; <5 min. weekly; <10 min. monthly	10 min. daily; 12 min. weekly; 21 min. monthly	—
Maintenance records kept on instrument	yes	—	no
Instrument list price	\$42,000	—	—
Cost of annual service contract/Length of warranty	—/1 year	—/1 year	—/1 year
Provide list of client sites to potential customers on request	—	yes	yes
Clients restricted from sharing their experience with company or software	—	no	no
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> easy-to-load strips with no calibration delivers quality results with color compensation pad and corrected specific gravity for elevated glucose and protein wide reportable ranges with no dilutions required 	<ul style="list-style-type: none"> ascorbic acid test pad identifies possible ascorbic acid interference with key chemistry assays offers high capacity and ease of use to maximize lab performance and productivity evaluates nine standard urine chemistries plus ascorbic acid, as well as color, clarity, and specific gravity 	<ul style="list-style-type: none"> advances urinalysis and body fluid testing through digital flow morphology using APR 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

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

URINALYSIS INSTRUMENTATION

Part 3 of 4	Beckman Coulter Michelle Dumonceaux mddumonceaux@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 800-526-3821 www.beckmancoulter.com	Roche Diagnostics Mark Sprunger mark.sprunger@roche.com 9115 Hague Road Indianapolis, IN 46250 317-521-4975 www.usdiagnostics.roche.com	Roche Diagnostics Mark Sprunger mark.sprunger@roche.com 9115 Hague Road Indianapolis, IN 46250 317-521-4975 www.usdiagnostics.roche.com
See captodayonline.com/productguides for an interactive version of guide			
Name of urinalysis instrument Type of instrument First year instrument sold in U.S. No. of units installed in U.S./No. of units installed outside U.S.	iRICELL1500, iRICELL2000, iRICELL3000† urine chemistry and microscopy/sediment combined 2003 >1,000/>2,000 (answers for all 3 instruments combined; also sold via McKesson)	cobas u 411 analyzer urine chemistry 2006 >400/>2,300	Urisys 2400 analyzer urine chemistry 2002 >150/>800
Targeted urine sample volume per day	iRICELL1500: <100; iRICELL2000: 100–199; iRICELL3000: >200	40–100	>100
Dimensions (HxWxD)/Weight Power requirements	22 × 45 × 24 in./200 lbs. microscopy/sediment module: 90–240 VAC (50–60 Hz, 150 watts max.); chemistry module: 100–240 VAC (50–60 Hz, 150 watts max.)	10.24 × 16.73 × 13.34 in./26 lbs. 110 V	28 × 21 × 26 in./187 lbs. 110 V
Mean time between failure of instrument Events that cause instrument to lock or stop analysis	— QC failure, short sample, barcode/sample ID misread, result error, sampling error, expired consumables	>365 days opening of front cover	>180 days opening of cover
Urine chemistry: (Information in this box is specific to urine chemistry) • Testing methodology: Specific gravity/Color/Clarity • Urine chemistry tests available on instrument	refractometer/wavelength of absorbance within an analyzer well/measured directly from scattered light ascorbic acid (0–40 mg/dL), bilirubin (0–4 mg/dL), blood (0–≥1 mg/dL), glucose (0–≥500 mg/dL), ketone (0–80 mg/dL), leukocyte esterase (0–500 WBCs/μL), nitrite (positive and negative), pH (5–9), protein (0–≥500 mg/dL), specific gravity (1.000–1.060), urobilinogen (0–4 mg/dL)	test strip/test strip/visual detection bilirubin, blood, glucose, ketone, leukocyte esterase, nitrite, pH, protein, specific gravity, urobilinogen	refractometer/test strip/turbidity within an analyzer well bilirubin, blood, glucose, ketone, leukocyte esterase, nitrite, pH, protein, specific gravity, urobilinogen
• Test strip configuration • Calibration required after test strip replacement/After test strip lot No. change • Frequency of customer-performed calibration • Form of calibration • How results are displayed for urine chemistry • Reporting format customizable • No. of sample results/Control results that can be held in internal memory • Specific gravity correction for protein/Specific gravity correction for glucose	loosely packed in bottles no/no quarterly liquid true values, calculated values, semiquantitative yes 10,000/5 no/no	loosely packed in bottles no/yes monthly dry semiquantitative yes 1,000/900 no/no	cartridge no/yes monthly dry semiquantitative yes 1,000/900 no/no
Microscopy/sediment: (Information in this box is specific to microscopy/sediment) • Microscopy/sediment technology • Microscopy/sediment analysis parameters • Instrument eliminates amorphous crystal interference before sample analysis • How results are displayed for microscopy/sediment • Reporting format customizable • No. of sample results/Control results that can be held in internal memory	digital flow morphology (digital imaging) all of the following qualitative or quantitative (user's option): pathological casts, crystals, small round cells, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts no numeric values yes 10,000/~200	— — — — — —	— — — — — —
Reagent storage and stability requirements for unopened containers Reagent storage and stability requirements for opened containers Reagent barcode-reading capability	— — yes	2–30°C 2–30°C yes	2–30°C 2–30°C yes
How often quality control samples run/Can use other vendors' QC products Sample throughput per hour/Time to first result	daily/yes iRICELL1500: 40 microscopic, 210 chemistry; iRICELL2000: 70 microscopic, 210 chemistry; iRICELL3000: 101 microscopic, 210 chemistry/~4 min.	minimum of daily/yes 600/<1 min.	minimum of daily/yes 240/4 min.
Analyzer has stat mode	no	yes (minimum sample volume is minimum amount necessary to immerse pads)	yes (minimum sample volume, 1.5 mL)
Sample dilutions required for urinalysis Sample dilutions required for body fluid analysis • Special sample handling required for body fluid analysis Minimum width of sample tube/Minimum height of sample tube Conditions or substances that prevent sample from being run	yes yes yes 16 mm/100 mm extreme amount of blood or mucus, grossly visible turbidity	no no no — preservatives	no no no 13–66 mm/100–115 mm preservatives
Means of sample ID entry	barcode scan, bidirectional download from host, manual 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
Built-in liquid-level sensing for samples	no	no	yes
Information that can be barcode scanned on instrument Instrument compatible with lab automation systems How LOINC codes for results are made available Software includes reflex testing functionality/Includes cross-check functionality Instrument automatically generates consolidated report Instrument connections to transfer information	specimen identifier, reagent lot No., reagent expiration no manual transmission yes/no yes data-management system, which connects to LIS/HIS, or directly to LIS/HIS/lab automation system	specimen identifier no website, e-mail query no/no no data-management system, which connects to LIS/HIS, or directly to LIS/HIS/lab automation system, or via commercial middleware (Data Innovations)	specimen identifier no website, e-mail query no/no no data-management system, which connects to LIS/HIS, or directly to LIS/HIS/lab automation system, or via commercial middleware (Data Innovations)
Interface standards supported Information included in transmission from instrument to data-management software	ASTM 1381 with proprietary message layer device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier	ASTM 1394, ASTM 1238 specimen ID, result	ASTM 1394, ASTM 1238 specimen ID, result
No. of days of on-site training with purchase No. of days of training at vendor office Approximate scheduled maintenance time required Maintenance records kept on instrument Instrument list price Cost of annual service contract/Length of warranty	1 3.5 — no — —/1 year	0 0 5 min. daily; 10 min. monthly; replace main fuse as needed no \$13,500 —/1 year	2 3–4 10 min. daily; 15 min. weekly; 10 min. monthly no \$49,750 —/1 year
Provide list of client sites to potential customers on request Clients restricted from sharing their experience with company or software	yes no	no (information is confidential) no	no (information is confidential) no
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> digital flow morphology using APR 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 		

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

URINALYSIS INSTRUMENTATION

Part 4 of 4	Siemens Healthcare, Point of Care Diagnostics Michelle Zhang mengxi.zhang@siemens.com 2 Edgewater Drive Norwood, MA 02062 781-269-3000 www.siemens.com/poc	Siemens Healthcare, Point of Care Diagnostics Michelle Zhang mengxi.zhang@siemens.com 2 Edgewater Drive Norwood, MA 02062 781-269-3000 www.siemens.com/poc	Sysmex America Leslie Williams williamsl@sysmex.com 577 Aptakisc Road Lincolnshire, IL 60069 800-379-7639 www.sysmex.com
See captodayonline.com/productguides for an interactive version of guide			
Name of urinalysis instrument Type of instrument First year instrument sold in U.S. No. of units installed in U.S./No. of units installed outside U.S.	CLINITEK AUWi PRO Automated Urine Workstation [†] urine chemistry and microscopy/sediment combined 2015 58 (also sold via Labsco)/— (available in Canada)	CLINITEK Novus Automated Urine Chemistry Analyzer urine chemistry 2015 25/308 (Canada, Japan, Europe, others)	UF-1000i Fully Automated Urine Sediment Analyzer [†] microscopy/sediment 2006 520 ^{††} /2,968 (China, Japan, Africa, Middle East, Europe, Asia Pacific)
Targeted urine sample volume per day Dimensions (HxWxD)/Weight Power requirements Mean time between failure of instrument Events that cause instrument to lock or stop analysis	— (for high- and mid-volume labs) 27 × 63 × 35 in./397 lbs. 120 V (50–60 Hz) 2 months user ID failure, short sample, barcode/sample ID misread, result error, sampling error, background cleaning for the UF-1000i flow cell, other events	>40 21 × 25 × 27 in./93 lbs. 100–240 VAC (48–62 Hz) 3 months user ID failure, short sample, barcode/sample ID misread, result error, sampling error, hardware failure, unloading area full, other events	>75 24.2 × 22.8 × 27 in./148 lbs. 100–240 VAC 1.5 months short sample, barcode/sample ID misread, result error, sampling error, customer-defined parameters
Urine chemistry: (Information in this box is specific to urine chemistry) • Testing methodology: Specific gravity/Color/Clarity • Urine chemistry tests available on instrument	refractometer/test strip/turbidity within an analyzer well bilirubin (0.5–2.7 mg/dL), blood (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 (>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) cartridge no/yes with every Novus cassette change or every 24 hours when multiple same-lot Novus cassettes are used within 24 hours liquid semiquantitative yes 7,500/400 no/no	refractometer/test strip/turbidity within an analyzer well bilirubin (0.5–2.7 mg/dL), blood (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 (>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) cartridge no/yes with every Novus cassette change or every 24 hours when multiple same-lot Novus cassettes are used within 24 hours liquid semiquantitative yes 7,500/400 no/no	— — — — — — — —
• Test strip configuration • Calibration required after test strip replacement/After test strip lot No. change • Frequency of customer-performed calibration			
• Form of calibration • How results are displayed for urine chemistry • Reporting format customizable • No. of sample results/Control results that can be held in internal memory • Specific gravity correction for protein/Specific gravity correction for glucose			
Microscopy/sediment: (Information in this box is specific to microscopy/sediment) • Microscopy/sediment technology • Microscopy/sediment analysis parameters	flow cytometry with fluorescent stain pathological casts (flagged), crystals (flagged), small round cells (flagged), yeast-like cells (flagged), mucus (flagged), sperm (flagged), RBCs (quantitative), WBCs (quantitative), epithelial cells (quantitative), bacteria (quantitative), hyaline casts (quantitative) yes numeric values, scattergrams yes 2 years worth of data/2 years worth of data	— — — — —	flow cytometry with fluorescent stain pathological casts (flagged), crystals (flagged), small round cells (flagged), yeast-like cells (flagged), sperm (flagged), RBCs (quantitative), WBCs (quantitative), epithelial cells (quantitative), bacteria (quantitative), hyaline casts (quantitative) yes numeric values, scattergrams yes 10,000/24 QC files, 300 results per file
• Instrument eliminates amorphous crystal interference before sample analysis • How results are displayed for microscopy/sediment • Reporting format customizable • No. of sample results/Control results that can be held in internal memory			
Reagent storage and stability requirements for unopened containers Reagent storage and stability requirements for opened containers Reagent barcode-reading capability	— 60-day shelf life yes	180-day shelf life 14-day shelf life yes	12-month shelf life 60-day shelf life yes
How often quality control samples run/Can use other vendors' QC products Sample throughput per hour/Time to first result Analyzer has stat mode	daily/no 80/— yes (minimum sample volume, 2 mL for urine chemistry, 1 mL for sediment)	daily/yes up to 240/— yes (minimum sample volume, 2 mL)	once per shift/yes up to 100/2 min. yes (minimum sample volume, 1 mL)
Sample dilutions required for urinalysis Sample dilutions required for body fluid analysis • Special sample handling required for body fluid analysis Minimum width of sample tube/Minimum height of sample tube Conditions or substances that prevent sample from being run	no no no 15–16 mm outer diameter/100–104 mm blood, mucus, turbidity, preservatives	no no no 16 mm/95–106 mm blood, mucus, preservatives, turbidity	no — — 12–15 mm/95–120 mm blood, mucus, high fluorescence, preservatives, any sample with potential to clog the sample filter or reaction chamber due to excessive cellular or mucoid content or interfere with the fluorescent stain barcode scan, bidirectional download from host, worklist download from host, manual entry yes
Means of sample ID entry	barcode scan, manual entry	barcode scan, worklist download from host, manual entry	barcode scan, bidirectional download from host, worklist download from host, manual entry
Built-in liquid-level sensing for samples	yes	yes	yes
Information that can be barcode scanned on instrument	operator identifier, specimen identifier, reagent lot No.	operator identifier, specimen identifier, reagent lot No.	specimen identifier, reagent lot No., QC lot No. and target values
Instrument compatible with lab automation systems How LOINC codes for results are made available Software includes reflex testing functionality/Includes cross-check functionality Instrument automatically generates consolidated report Instrument connections to transfer information	no e-mail query yes/yes yes data-management system, which connects to LIS/HIS, or directly to LIS/HIS/lab automation system	no e-mail query no/no no data-management system, which in turn connects to LIS/HIS, or data-management system, which cannot further transmit data, or directly to LIS/HIS/lab automation system, or via commercial middleware	yes (Siemens) website, e-mail query no/no yes data-management system, which in turn connects to LIS/HIS, or directly to LIS/HIS/lab automation system, or via commercial middleware (Data Innovations)
Interface standards supported Information included in transmission from instrument to data-management software	ASTM 1394, ASTM 1238, HL7 operator ID, patient ID, specimen ID, result, QC identifier	ASTM 1394, ASTM 1238, HL7 operator ID, patient ID, specimen ID, result, QC identifier	ASTM 1394, ASTM 1238, HL7 device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier
No. of days of on-site training with purchase No. of days of training at vendor office Approximate scheduled maintenance time required	1–3 — 10–20 min. per shift; 10–20 min. based on 1 shift daily; 10 min. weekly; 10 min. monthly	1–2 — 5–10 min. per shift; 5–10 min. based on 1 shift daily; 5–10 min. weekly; 5–10 min. monthly	3–5 5 5 min. per shift; 20 min. daily; 20 min. monthly
Maintenance records kept on instrument Instrument list price Cost of annual service contract/Length of warranty	no — —/1 year	no — —/3 years	no \$125,000 \$9,223 for standard business hours coverage/1 year
Provide list of client sites to potential customers on request Clients restricted from sharing their experience with company or software	yes (partial list) no	yes (partial list) —	yes (partial list) no
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> accurate results: separate bacteria channel that dissolves amorphous crystals in the sample streamlined workflow: automatically transports samples, reflexes samples, and verifies results maximum productivity: one-time loading of 100 samples; load-and-go capability 	<ul style="list-style-type: none"> reagent cassette: radio-frequency identification tag enables automated entry of lot number and expiration date; cassette protects reagent from moisture contamination digital camera: new generation optical system that provides trusted results and reduces false-positive bilirubin high throughput; maximum one-time loading of 200 samples; processing speed up to 240 samples per hour 	<ul style="list-style-type: none"> superior bacteria detection via use of an RNA-specific stain that eliminates staining of debris review-by-exception design fluorescent flow cytometry for accurate, standardized, and reproducible results and fewer visual reviews
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		[†] also sold as part of the Siemens CLINITEK AUWi and AUWi PRO ^{††} including Siemens CLINITEK AUWi placements