| Part 1 of 3 | **ARKRAY**<br>**Mariann Amador** corelab@arkrayusa.com<br>**Minneapolis, MN**<br>**855-646-3108** www.arkrayusa.com | **ARKRAY**<br>**Mariann Amador** corelab@arkrayusa.com<br>**Minneapolis, MN**<br>**855-646-3108** www.arkrayusa.com | **ARKRAY**<br>**Mariann Amador** corelab@arkrayusa.com<br>**Minneapolis, MN**<br>**855-646-3108** www.arkrayusa.com |
|---|---|---|---|
| Name of urinalysis instrument | AUTION Eleven AE-40222† | AUTION Eye AI-4510 & AUTION Max AX-4060† | AUTION Max AX-4030† |
| Type of instrument | urine chemistry | urine chemistry and microscopy/sediment combined | urine chemistry |
| Instrument list price | — (available via purchase) | — (available via purchase) | — (available via purchase) |
| First year instrument sold in U.S. | 2017 | 2025 | 2011 |
| Approximate No. of units in clinical use in U.S./outside U.S. | 700/7,200 (worldwide) | —/200 (worldwide) | 1,600/3,600 (worldwide) |
| Foreign countries where company markets instrument | worldwide | worldwide | worldwide |
| Country where instrument designed/manufactured | Japan/Japan | Japan/Japan | Japan/Japan |
| Human languages (other than English) supported | — | — | — |
| Intended urine sample volume per day | — | >50 | >50 |
| Dimensions (H×W×D) | 6.5 × 8.3 × 12.9 in. | 26 × 42 × 24 in. | 21 × 21 × 21 in. |
| Weight fully loaded with reagents/without reagents | —/7.9 lbs.†† | —/154 lbs.†† | —/82 lbs.†† |
| Power requirements | 100–240 VAC (50–60 Hz) | 100–240 VAC (50–60 Hz) | 100–240 VAC (50–60 Hz) |
| Mean time between failure of instrument | 600 days | — | 364 days |
| Events that cause instrument to lock or stop analysis | user ID failure, result error | QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement/expiration | 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/wavelength of absorbance within an analyzer well/turbidity entered manually | refractometer/wavelength of absorbance within an analyzer well/turbidity within an analyzer well | refractometer/wavelength of absorbance within an analyzer well/turbidity within an analyzer well |
| • Urine chemistry tests available on instrument in the U.S. | bilirubin (0.5–14.0 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 (0.5–10.0 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 (10–600 mg/dL), specific gravity (1.000–>1.030), urobilinogen (2–12 mg/dL) | bilirubin (0.5–10.0 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 (10–600 mg/dL), specific gravity (1.000–>1.030), urobilinogen (2–12 mg/dL) |
| • Color compensation pad included/Flagging thresholds customizable | yes/— | yes/no | yes/no |
| • Test strip configuration | loosely packed in bottles | loosely packed in bottles | loosely packed in bottles |
| • Calibration required after each test strip lot No. change | no | no | no |
| • Frequency of customer-performed calibration/Form of calibration | — | — | — |
| • How results are displayed for urine chemistry | semiquantitative | semiquantitative | semiquantitative |
| • Reporting format customizable | no | — | no |
| • No. of results that can be held in internal memory | 520 sample and control results combined | 2,500 sample results/200 control results | 2,500 sample results/200 control results |
| • Specific gravity correction for protein/glucose | no/no | yes/yes | yes/yes |
| Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)* | | | |
| • Microscopy/sediment technology | — | digital flow morphology | — |
| • Microscopy/sediment analysis parameters | — | flagged and quantitative: pathological casts, crystals, small round cells, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts | — |
| • 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/1,000 control results | — |
| Reagent shelf life/storage temp. for unopened containers of calibrator | — | 365 days/2–8°C | 365 days/2–8°C |
| Reagent shelf life/storage temp. for opened containers of calibrator | — | 1 day/2–8°C | 1 day/2–8°C |
| Reagent shelf life/storage temp. for unopened containers of control reagent | 547 days/2–8°C | 365 days/2–8°C | 547 days/2–8°C |
| Reagent shelf life/storage temp. for opened containers of control reagent | 31 days/2–8°C | 1 day/2–8°C | 31 days/2–8°C |
| Reagent barcode-reading capability | yes, for all tests (can read Codabar [NW-7], Code 39, Code 128, PDF 417, ITF) | yes, for all tests (can read Codabar [NW-7], Code 39, Code 128, ITF) | yes, for all tests (can read Codabar [NW-7], Code 39, Code 128, PDF 417, ITF) |
| How often quality control samples are run | daily | — | daily |
| Sample throughput per hour/Time to first result for chemistry | 514/1 min. | 225/— | 225/1 min. |
| Sample throughput per hour/Time to first result for microscopy/sediment | — | 100/— | — |
| Analyzer has stat mode | no | yes (minimum sample volume, 2 mL for chemistry and 1 mL for microscopy/sediment) | yes (minimum sample volume, 2 mL) |
| FDA approved for body fluid analysis | no | no | no |
| Sample dilutions required for urinalysis/body fluid analysis | no/not applicable | no/not applicable | no/not applicable |
| Minimum width of sample tube/Minimum length of sample tube | — | 14–15.8 mm/95–110 mm | 14–15.8 mm/95–110 mm |
| Conditions or substances that prevent a sample from being run | blood, visible turbidity | blood, visible turbidity | blood, 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, reagent lot No. | specimen identifier, reagent lot No. | specimen identifier, reagent lot No. |
| Supports QR codes/Supports radio-frequency identification | no/no | no/no | no/no |
| Compatible with laboratory automation systems | no | planned for future | planned for future |
| How LOINC codes for results are made available | e-mail query | e-mail query | e-mail query |
| Software includes reflex testing/cross-check functionality | — | yes/yes | — |
| Instrument automatically generates consolidated report* | — | yes | — |
| Archives patient data | no | yes (test results, ID, name) | — |
| Instrument connections to transfer information | directly to LIS or via commercial middleware (Data Innovations) | data-management system that connects to LIS, directly to LIS, or via commercial middleware (Data Innovations) | directly to LIS or via commercial middleware (Data Innovations) |
| Interface standards or formats supported | ASTM 1394-91, ASTM 1381 | ASTM 1394-91, ASTM 1381 | ASTM 1394-91, ASTM 1381 |
| Bidirectional interface | no | yes, to other companies' LISs (no third-party tool or software required for interface) | yes, to other companies' LISs (no third-party tool or software required for interface) |
| Test results can be transmitted to LIS as soon as tests completed | yes | yes | yes |
| Connection to LIS/EHR to upload patient and QC results | LIS: direct serial, hospital network/EHR: option not available | LIS: direct serial, hospital network/EHR: option not available | LIS: direct serial, hospital network/EHR: option not available |
| Information included in transmission to data-management system | patient ID, specimen ID, result | patient ID, specimen ID, result | patient ID, specimen ID, result |
| Training included with instrument purchase | no | yes (3–4 days at customer site) | yes (1–2 days at customer site) |
| Approximate scheduled maintenance time required | 5 min. daily | 10 min. daily; 15 min. weekly; 20 min. monthly (maintenance records kept onboard instrument) | 5 min. daily; 5 min. weekly; 10 min. monthly |
| Onboard diagnostics for troubleshooting | no | yes | yes |
| Provide list of client sites to potential customers on request | no (information is confidential) | no (information is confidential) | yes (partial list of comparable sites but prospective client must sign a nondisclosure agreement) |
| Clients restricted from sharing their experience with company or software | no | no | no |
| Distinguishing instrument features (supplied by company) | • proven reliability with less than one unscheduled service event per year<br>• small semiautomated footprint | • images have three focal depths, similar to focusing up/down on a microscope<br>• small footprint for a complete urinalysis system | • easy to use; strips easy to load; does not require calibration<br>• abnormal color detection alerts operators to potential false-positive results |
| **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* | *†also sold via distribution partners*<br>*††reagents not kept onboard* | *†also sold via distribution partners*<br>*††urine strips kept onboard, not reagents* | *†also sold via distribution partners*<br>*††urine strips kept onboard, not reagents* |

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

| Part 2 of 3 | **Beckman Coulter**<br>**Kanochia Johnson** kjohnson05@beckman.com<br>**Brea, CA**<br>www.beckmancoulter.com/urinalysis | **Beckman Coulter**<br>**Kanochia Johnson** kjohnson05@beckman.com<br>**Brea, CA**<br>www.beckmancoulter.com/urinalysis | **Sciteck Diagnostics**<br>**Kerstin Lanier** kerstinlanier@sciteck.org<br>**Fletcher, NC**<br>**800-749-4537** myautoua.com |
|---|---|---|---|
| Name of urinalysis instrument | DxU Iris Workcell: DxU 850 Iris, DxU 840 Iris† | DxU Microscopy Series: DxU 850m Iris, DxU 840m Iris† | AUA-450 Clinical Chemistry Analyzer |
| Type of instrument | urine chemistry and microscopy/sediment combined | microscopy/sediment | urine chemistry |
| Instrument list price | — | — (available via purchase or lease) | $40,000–$45,000 (price based on location; available via purchase or lease) |
| First year instrument sold in U.S. | 2021 (also sold by McKesson, Henry Schein in U.S.) | 2021 (also sold by McKesson, Henry Schein in U.S.) | 2022 |
| Approximate No. of units in clinical use in U.S./outside U.S. | >800/>120 (worldwide) | >800/>150 (worldwide) | 12/2,400 (in Japan) |
| Foreign countries where company markets instrument | worldwide | worldwide | none |
| Country where instrument designed/manufactured | U.S./U.S. and Japan | U.S./U.S. | Japan/Japan |
| Human languages (other than English) supported | French, German, Spanish, Portuguese, Italian, many more | French, German, Spanish, Portuguese, Italian, many more | Japanese |
| Intended urine sample volume per day | 50–600+ | 50–600+ | 50–1,000 |
| Dimensions (H×W×D) | 23 × 21 × 60 in. | 23 × 21 × 25 in. | 24 × 34 × 26 in. |
| Weight fully loaded with reagents/without reagents | 238 lbs./214 lbs. | 100 lbs./85 lbs. | 255 lbs./250 lbs. |
| Power requirements | 100–240 VAC (50–60 Hz) | 100–240 VAC (50–60 Hz) | 120 VAC |
| Mean time between failure of instrument | 305 days | 305 days | 0 days |
| Events that cause instrument to lock or stop analysis | QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement/expiration | QC failure, short sample, barcode/sample ID misread, result error, sampling error, consumables replacement/expiration | user ID failure, QC failure, sampling error, consumables replacement/expiration |
| 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 | — | colorimetric/wavelength of absorbance within an analyzer well/turbidity within an analyzer well |
| • Urine chemistry tests available on instrument in the U.S. | 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 (1.0–1.5), urobilinogen (0–≥12 mg/dL) | — | albumin/microalbumin (0.5–100 mg/dL), creatinine (0–1,000 mg/dL), albumin/creatinine ratio (<30 mg/g), protein/creatinine ratio (<150 mg/g), bilirubin (0–300 mg/dL), hemoglobin (0–5,000 µg/dL), glucose (0–1,000 mg/dL), ketone (0–200 mg/dL), leukocyte esterase (0–200 leukocytes/L), nitrite (0–200 mg/dL), pH (3–11), protein (0–30 mg/dL), specific gravity (1.00–1.07), urobilinogen (0–30 mg/dL) |
| • Color compensation pad included/Flagging thresholds customizable | yes/no | — | no/yes |
| • Test strip configuration | loosely packed in bottles | — | no test strip |
| • Calibration required after each test strip lot No. change | no | — | — |
| • Frequency of customer-performed calibration/Form of calibration | — | — | daily/liquid |
| • How results are displayed for urine chemistry | semiquantitative | — | true values, calculated values |
| • Reporting format customizable | no | — | yes |
| • No. of results that can be held in internal memory | 2,500 sample results/200 control results | — | 1,000 sample results/1,000 control results |
| • Specific gravity correction for protein/glucose | yes/yes | — | yes/yes |
| Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)* | | | |
| • Microscopy/sediment technology | digital flow morphology using auto particle-recognition software | digital flow morphology using auto particle-recognition software | — |
| • Microscopy/sediment analysis parameters | qualitative and quantitative: pathological casts, crystals, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts, WBC clumps | qualitative and quantitative: pathological casts, crystals, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts, WBC clumps | — |
| • Flagging thresholds customizable | yes | yes | — |
| • Instrument eliminates amorphous crystal interference before sample analysis | no | no | — |
| • How results are displayed for microscopy/sediment | numeric values | numeric values | — |
| • Reporting format customizable | yes | yes | — |
| • No. of results that can be held in internal memory | 10,000 sample results/200 control results | 10,000 sample results/200 control results | — |
| Reagent shelf life/storage temp. for unopened containers of calibrator | both vary based on reagent type | 240 days/2–8°C | 720 days/8°C |
| Reagent shelf life/storage temp. for opened containers of calibrator | both vary based on reagent type | 1 day/2–8°C | 30 days/8°C |
| Reagent shelf life/storage temp. for unopened containers of control reagent | both vary based on reagent type | 240 days/2–8°C (focus and positive); 28°C (negative) | 720 days/8°C |
| Reagent shelf life/storage temp. for opened containers of control reagent | both vary based on reagent type | 30 days/2–8°C | 30 days/8°C |
| Reagent barcode-reading capability | yes, for some tests (can read Code 39, Code 128, more) | yes, for some tests (can read Code 39, Code 128, more) | yes, for all tests (can read Code 39, Code 128, more) |
| How often quality control samples are run | daily | daily | daily |
| Sample throughput per hour/Time to first result for chemistry | 225/1 min. | — | 22/13 min. |
| Sample throughput per hour/Time to first result for microscopy/sediment | DxU 840: 70/<2 min.; DxU 850: 101/<2 min. | DxU 840m: 70/<2 min.; DxU 850m: 101/<2 min. | — |
| Analyzer has stat mode | no (min. sample volume for sampler or track mode, 2 mL for chemistry and 3 mL for microscopy/sediment) | no (minimum sample volume for sampler or track mode, 3 mL) | yes (minimum sample volume, 0.25 mL) |
| FDA approved for body fluid analysis | yes (for CSF, pleural, peritoneal, synovial, more) | yes (for CSF, pleural, peritoneal, synovial, more) | yes (for urine) |
| Sample dilutions required for urinalysis/body fluid analysis | no/yes (lyse reagent required) | no/yes (lyse reagent required) | no/no |
| Minimum width of sample tube/Minimum length of sample tube | 16 mm/100 mm | 16 mm/100 mm | 14 mm/25 mm |
| Conditions or substances that prevent a sample from being run | grossly visible turbidity | grossly visible turbidity | none |
| Means of sample ID entry | barcode scan, manual entry | barcode scan, manual entry | barcode scan, manual entry, worklist download from host |
| Built-in liquid-level sensing for samples | yes | yes | yes |
| Information that can be barcode scanned on instrument | specimen identifier, reagent lot No., reagent expiration, dilution barcodes | specimen identifier, reagent lot No., reagent expiration, dilution barcodes | operator identifier, specimen identifier, reagent lot No. |
| Supports QR codes/Supports radio-frequency identification | no/no | no/no | no/no |
| Compatible with laboratory automation systems | no | no | no |
| How LOINC codes for results are made available | website | website | e-mail query, transmitted to LIS with each result |
| Software includes reflex testing/cross-check functionality | yes/no | yes/no | no/no |
| Instrument automatically generates consolidated report* | yes | yes | no |
| Archives patient data | yes (patient results) | yes (up to 10,000 patient results) | yes |
| Instrument connections to transfer information | directly to LIS | directly to LIS | directly to LIS, EHR |
| Interface standards or formats supported | ASTM 1381, ASTM 1238-95, Iris-defined XML | ASTM 1381, ASTM 1238-95, Iris-defined XML | ASTM 1394-91, ASTM 1381, ASTM 1238-95, HL7 version 2, HL7 version 3 |
| Bidirectional interface | yes, to other companies' LISs | yes, to other companies' LISs | yes, to other companies' LISs and EHRs (requires interface engine with LIS) |
| Test results can be transmitted to LIS as soon as tests completed | yes | yes | yes |
| Connection to LIS/EHR to upload patient and QC results | LIS: direct serial/EHR: — | LIS: direct serial/EHR: — | LIS and EHR: direct serial, hospital network |
| Information included in transmission to data-management system | device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier | device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier | device unique identifier, operator ID, patient ID, specimen ID, result, LOINC codes |
| Training included with instrument purchase | yes (1 day at customer site, 3 days of e-learning; follow-up training available for an extra charge) | yes (1 day at customer site, 3 days of e-learning; follow-up training available for an extra charge) | yes (2.5 days at customer or vendor site [optional]; follow-up training available for an extra charge) |
| Approximate scheduled maintenance time required | — (maintenance records kept onboard instrument) | — (maintenance records kept onboard instrument) | 30 min. monthly |
| Onboard diagnostics for troubleshooting | yes | yes | yes (can perform diagnostics via remote access) |
| Provide list of client sites to potential customers on request | yes (complete list with no restrictions regarding its use) | yes (complete list with no restrictions regarding its use) | yes (partial list of comparable sites but prospective client must sign a nondisclosure agreement) |
| Clients restricted from sharing their experience with company or software | no | no | no |
| Distinguishing instrument features (supplied by company) | • auto-classifies 12 urine particles based on size, shape, contrast, texture to provide digital images for all samples<br>• iQ Body Fluids Module analyzes RBC count and nucleated cell count in cerebrospinal, synovial, and serous fluids | • auto-classifies 12 urine particles based on size, shape, contrast, texture to provide digital images for all samples<br>• iQ Body Fluids Module analyzes RBC count and nucleated cell count in cerebrospinal, synovial, and serous fluids | • AutoUA is an FDA-cleared quantitative urinalysis system; superior test results<br>• sample size of 2–3 µL provides stoichiometric advantages, reducing interferents that affect test strips |

**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*

*†formerly iQ Workcell; all answers apply to DxU 850 Iris and 840 Iris systems unless otherwise indicated*

*†formerly iQ200 series; all answers apply to DxU 850m Iris and 840m Iris systems unless otherwise indicated*

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

| Part 3 of 3 | **Siemens Healthcare Diagnostics**<br>**Aohua Sang** aohua.sang@siemens-healthineers.com<br>**Tarrytown, NY**<br>**914-631-8000** www.siemens-healthineers.com | **Sysmex America**<br>**Pinak Patel** patelpi@sysmex.com<br>**Lincolnshire, IL**<br>**888-879-7639** www.sysmex.com/us | **Sysmex America**<br>**Pinak Patel** patelpi@sysmex.com<br>**Lincolnshire, IL**<br>**888-879-7639** www.sysmex.com/us |
|---|---|---|---|
| Name of urinalysis instrument | CLINITEK Advantus Analyzer† | Clinitek Novus Automated Urine Chemistry Analyzer† | UN-Series Automated Urinalysis Solution (UN-2000, UN-3000, UN-9000)† |
| Type of instrument | urine chemistry | urine chemistry | urine chemistry and microscopy/sediment combined |
| Instrument list price | $7,392 (avail. via purchase or reagent rental agreement) | — (available via purchase or lease) | based on configuration (avail. via purchase or lease) |
| First year instrument sold in U.S. | 2006 | 2015 | UN-2000: 2019; UN-3000 and UN-9000: 2020 |
| Approximate No. of units in clinical use in U.S./outside U.S. | 3,000/2,000 (in Europe, Asia–Pacific, Latin America, Canada) | >600/>57 (in Canada) | >600/— (in Canada) |
| Foreign countries where company markets instrument | Europe, Asia–Pacific, Latin America, Canada | Canada | Canada |
| Country where instrument designed/manufactured | U.S. and United Kingdom/Poland | U.S. and United Kingdom/U.S. and United Kingdom | Japan/Japan |
| Human languages (other than English) supported | French, German, Italian, Japanese, Spanish, more | — | — |
| Intended urine sample volume per day | 36–50 | >50 | >80 |
| Dimensions (H×W×D) | 12.75 × 15.75 × 13.75 in. | 21 × 25 × 27 in. | varies based on configuration |
| Weight fully loaded with reagents/without reagents | 17 lbs./16 lbs. | —/93 lbs. | both vary based on configuration |
| Power requirements | 100–240 VAC (50–60 Hz) | 100–240 VAC | varies based on configuration |
| Mean time between failure of instrument | 81 days | 120 days | 90 days |
| Events that cause instrument to lock or stop analysis | QC failure, short sample, barcode/sample ID misread, result error, sampling error, hardware failure, more | user ID failure, sampling error, consumables replacement/expiration, calibration failure | user ID failure, consumables replacement/expiration |
| Urine chemistry: *(Information in this box is specific to urine chemistry)* | | | |
| • Testing methodology: specific gravity/color/clarity | test strip/test strip/test strip | refractometer/wavelength of absorbance within an analyzer well/turbidity within an analyzer well | refractometer/wavelength of absorbance within an analyzer well/turbidity within an analyzer well |
| • Urine chemistry tests available on instrument in the U.S. | bilirubin (negative–large), hemoglobin (negative–large), glucose (negative–≥1,000 mg/dL), ketone (negative–≥80 mg/dL), leukocyte esterase (negative–large), nitrite (positive/negative), pH (5.0–≥9.0), protein (negative–300 mg/dL), specific gravity (≤1.005–≥1.030), urobilinogen (0.2–≥8.0 EU/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 (6–91 cells/µL), nitrite (positive/negative), 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) | bilirubin (0.5–2.7 mg/dL), red blood cells (trace levels), hemoglobin (0.013–0.3 mg/dL), glucose (36–820 mg/dL), ketone (3.6–156 mg/dL), leukocyte esterase (6–91 cells/µL), nitrite (positive/negative), 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/Flagging thresholds customizable | yes/yes | yes/yes | yes/yes |
| • Test strip configuration | loosely packed in bottles | cartridge | cartridge |
| • Calibration required after each test strip lot No. change | no | yes | yes |
| • Frequency of customer-performed calibration/Form of calibration | instrument self-calibrates for every strip/dry | with every new lot No. of Novus cassette loaded or same lot No. loaded and calibration is > 24 hours old/liquid | with every new lot No. of Novus cassette loaded or same lot No. loaded and calibration is > 24 hours old/liquid |
| • 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 | 500 sample results/200 control results | 7,500 sample results/400 control results | 7,500 sample results/400 control results |
| • Specific gravity correction for protein/glucose | no/no | no/no | no/no |
| Microscopy/sediment: *(Information in this box is specific to microscopy/sediment)* | | | |
| • Microscopy/sediment technology | — | — | flow cytometry with fluorescent stain |
| • Microscopy/sediment analysis parameters | — | — | flagged and qualitative: pathological casts, crystals, yeast-like cells, mucus, sperm; qualitative and quantitative: RBCs; quantitative: WBCs, epithelial cells, bacteria, casts |
| • Flagging thresholds customizable | — | — | yes |
| • Instrument eliminates amorphous crystal interference before sample analysis | — | — | yes |
| • How results are displayed for microscopy/sediment | — | — | numeric values or scattergrams |
| • Reporting format customizable | — | — | yes |
| • No. of results that can be held in internal memory | — | — | 100,000 sample results (in the urinalysis data manager)/2 concentrations × 3 lots (120 plots/lot) for control results |
| Reagent shelf life/storage temp. for unopened containers of calibrator | — (no calibrator needed) | —/2–8°C | — |
| Reagent shelf life/storage temp. for opened containers of calibrator | — (no calibrator needed) | — | — |
| Reagent shelf life/storage temp. for unopened containers of control reagent | 730 days/2–8°C | —/QC: 2–8°C; cassette: 15–30°C | —/2–8°C |
| Reagent shelf life/storage temp. for opened containers of control reagent | 30 days/20–25°C | — | — |
| Reagent barcode-reading capability | yes, for all tests (can read Data Matrix, more) | yes, for all tests (can read Code 39, Code 128, more) | yes, for all tests (can read Code 39, Code 128, more) |
| How often quality control samples are run | configurable: 1 hour to 99 days (can use other companies' QC products) | follow government regulations or accreditation requirements (can use other companies' QC products) | daily |
| Sample throughput per hour/Time to first result for chemistry | 500/62 seconds, then every 7 seconds | 240/— | 240/— |
| Sample throughput per hour/Time to first result for microscopy/sediment | — | — | varies based on configuration/— |
| Analyzer has stat mode | yes | no | yes (min. sample vol., 1.6 mL for microscopy/sediment) |
| FDA approved for body fluid analysis | yes (for urine) | no | no |
| Sample dilutions required for urinalysis/body fluid analysis | no/not applicable | no/not applicable | no/not applicable |
| Minimum width of sample tube/Minimum length of sample tube | 7 mm/76 mm | 16 mm/95 mm | 16 mm/95 mm |
| Conditions or substances that prevent a sample from being run | none | — | — |
| Means of sample ID entry | barcode scan, manual entry, worklist download from host | barcode scan, manual entry, worklist download from host, RFID for authentic entry of cassette lot | barcode scan, manual entry, worklist download from host, RFID for authentic entry of cassette lot |
| Built-in liquid-level sensing for samples | no | yes | yes |
| Information that can be barcode scanned on instrument | operator and specimen identifier, reagent lot No., more | operator identifier, specimen identifier, reagent lot No. | operator identifier, specimen identifier, reagent lot No. |
| Supports QR codes/Supports radio-frequency identification | no/no | no/yes | no/yes |
| Compatible with laboratory automation systems | no | yes (Siemens Aptio, Abbott Accelerator a3600) | yes (Siemens Aptio, Abbott Accelerator a3600) |
| How LOINC codes for results are made available | functionality not provided | website, e-mail query | website, e-mail query |
| Software includes reflex testing/cross-check functionality | no/no | yes/yes | yes/yes |
| Instrument automatically generates consolidated report* | yes | no | yes |
| Archives patient data | no | yes (sample ID, test results) | yes (patient demographics, test results, sample ID) |
| Instrument connections to transfer information | data-management system that connects to LIS or EHR, directly to LIS or EHR, via commercial middleware, more | data-management system that connects to LIS or EHR, or directly to LIS, EHR, or lab automation system | data-management system that connects to LIS or EHR, or directly to LIS or EHR |
| Interface standards or formats supported | ASTM 1394-91, Siemens proprietary protocol | ASTM 1394-91, ASTM 1381, HL7 version 3 | ASTM 1394-91, ASTM 1381, HL7 version 3 |
| Bidirectional interface | yes, to other companies' LISs (no third-party tool or software required for interface) | yes, to other companies' LISs and EHRs | yes, to other companies' LISs and EHRs |
| Test results can be transmitted to LIS as soon as tests completed | yes | yes | yes |
| Connection to LIS/EHR to upload patient and QC results | LIS and EHR: direct serial, hospital network | LIS and EHR: direct serial, hospital network | LIS and EHR: hospital network |
| Information included in transmission to data-management system | device unique identifier, operator ID, specimen ID, result, QC identifier, strip type, reagent lot and expiration | device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier | device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier |
| Training included with instrument purchase | yes (4 hours at choice of customer or vendor site; follow-up training available for no extra charge) | yes (virtual instructor-led training at customer site) | yes (7 hours of virtual instructor-led training at customer site) |
| Approximate scheduled maintenance time required | 30 min. per shift; 30 min. daily; 90 min. weekly; 270 min. monthly | 5–10 min. daily | 20 min. daily; 10 min. weekly (maintenance records kept onboard instrument) |
| Onboard diagnostics for troubleshooting | yes | yes | yes (can perform diagnostics via remote access) |
| Provide list of client sites to potential customers on request | yes (partial list of comparable sites but prospective client must sign a nondisclosure agreement) | yes (partial list of comparable sites with no restrictions regarding its use) | yes (partial list of comparable sites with no restrictions regarding its use) |
| Clients restricted from sharing their experience with company or software | no | no | no |
| Distinguishing instrument features (supplied by company) | • broad test menu: routine UA testing for kidney functions, CKD, AKI, UTI, diabetes mellitus, more<br>• auto-checks proprietary technology for humidity exposure, sample interference, auto. strip ID | • reagent cassette format with RFID that provides complete traceability and 14-day onboard stability<br>• digital color camera that takes images of full light spectrum | • combines urine chemistry, fluorescence flow cytometry, and digital image analysis for rapid urine screening<br>• BeyondCare quality monitor for urinalysis provides a streamlined and automated QC experience |
| **chemistry and microscopy results in one report*<br>*Note: a dash in lieu of an answer means company did not answer question or question is not applicable* | *†also sold via distribution partners* | *†marketed in the U.S. and Canada by Sysmex; marketed in other countries by Siemens Healthineers* | *†modular systems: UN-2000, two modules; UN-3000, three modules; UN-9000, four or more modules* |

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