URINALYSIS INSTRUMENTATION

Part 1 of 3

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Name of urinalysis instrument
Type of instrument
Instrument list price
First year instrument sold in U.S.
No. of units installed in U.S./No. of units installed outside U.S.
Country where instrument designed/manufactured
Country where instrument manufactured
Foreign countries where company markets instrument
Power requirements
Dimensions (HxWxD)/Weight fully loaded with reagents
Mean time between failure of instrument
Events that cause instrument to lock or stop analysis

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

• Testing methodology: specific gravity/color/clarity
• Urine chemistry tests available on instrument in the U.S.

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

Reagent shelf life/storage temperature for unopened containers
Reagent shelf life/storage temperature for opened containers
Reagent barcode-reading capability

How often quality control samples are run
Sample throughput per hour/Time to first result for chemistry
Sample throughput per hour/Time to first result for microscopy/sediment
Analyzer has stat mode
Sample dilutions required for urinalysis/body fluid analysis
Special sample handling required for body fluid analysis
Minimum width of sample tube/Minimum length of sample tube
Conditions or substances that prevent a sample from being run
Means of sample ID entry
Built-In liquid-level sensing for samples

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

Interface standards supported
Bidirectional interface

Test results can be transmitted to LIS as soon as tests completed
Connection to LIS to upload patient and QC results
Connection to EHR to upload patient and QC results

No. of days of training with instrument purchase
Approximate scheduled maintenance time required
Maintenance records kept onboard instrument

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

Distinguishing instrument features (supplied by company)

*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

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

Product guide editor: Raymond D. Aller, MD
### URINALYSIS INSTRUMENTATION

<table>
<thead>
<tr>
<th>Part 2 of 3</th>
<th>Beckman Coulter</th>
<th>Roche Diagnostics</th>
<th>Roche Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of urinalysis instrument</td>
<td>DxU Iris Workcell, DxU Iris 850, DxU Iris 840²</td>
<td>cobas u 411</td>
<td>cobas u 601</td>
</tr>
<tr>
<td>Type of instrument</td>
<td>urine chemistry and microscopy/sediment combined</td>
<td>urine chemistry</td>
<td>urine chemistry</td>
</tr>
<tr>
<td>Instrument list price</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>First year instrument sold in U.S.</td>
<td>2021</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>No. of units installed in U.S./No. of units installed outside U.S.</td>
<td>&gt;50/70 globally for both systems combined (also sold via Molson and Henry Schein in the U.S.)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Foreign countries where company markets instrument</td>
<td>worldwide</td>
<td>worldwide</td>
<td>worldwide</td>
</tr>
<tr>
<td>Country where instrument designed/manufactured</td>
<td>U.S. and Japan/U.S. and Japan</td>
<td>Switzerland/Switzerland</td>
<td>Hungary/Hungary</td>
</tr>
<tr>
<td>Intended urinalysis sample volume per day</td>
<td>50–400+</td>
<td>10–100</td>
<td>25–35.52 ± 42.8 ± 20.94 ±20.75 ±</td>
</tr>
<tr>
<td>Dimensions (HxWxD/Weight fully loaded with reagents</td>
<td>23 × 21 × 60 in./23 lbs.</td>
<td>10.24 × 16.73 × 13.34 in./26 lbs</td>
<td>110 VAC</td>
</tr>
<tr>
<td>Power requirements</td>
<td>90–240 VAC (50–60 Hz)</td>
<td>100–125 VAC</td>
<td>126 days</td>
</tr>
<tr>
<td>Mean time between failure of instrument</td>
<td>QC failure, short sample, barcode/sample ID mismatch, result error, sampling error, consumables replacement/expiration</td>
<td>opening front cover</td>
<td>—</td>
</tr>
</tbody>
</table>

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

- **Testing methodology:** specific gravity/color/clarity
- **Urine chemistry tests available on instrument in the U.S.**
  - refractometer/wavelength of absorbance within an analyzer-wavelength absorbance within an analyzer
  - bilirubin (0–10 mg/dL), hemoglobin (0–10 mg/dL), glucose (0–1,000 mg/dL), ketone (0–150 mg/dL), leukocyte esterase (0–500 leukocytes/µL), nitrite (1+, 2+, 3+), pH (5–9), protein (0–600 mg/dL), specific gravity (1.000–1.500), urobilinogen (0–12 mg/dL)
- **Color compensation pad included** yes
- **Flagging thresholds customizable** no
- **Calibration required after each test strip lot No. change** —
- **Frequency of customer-performed calibration** 28 days
- **Form of calibration** dry
- **How results are displayed for urine chemistry** qualitative and quantitative: pathological casts, crystals, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts, WBC clumps
- **Reporting format customizable** yes
- **No. of results that can be held in internal memory** 2,500 sample results/200 control results
- **Specific gravity correction for protein/glucose** yes
- **Microscopy/sediment (Information in this box is specific to microscopy/sediment)**
  - digital flow morphology using auto particle recognition software
  - qualitative and quantitative: pathological casts, crystals, yeast-like cells, mucus, sperm, RBCs, WBCs, epithelial cells, bacteria, hyaline casts, WBC clumps
- **Sample throughput per hour/Time to first result for microscopy/sediment**
  - DxU 840: 70, DxU 850: 101/<2 min.
- **Built-in liquid-level sensing for samples** yes
- **Information that can be barcode scanned on instrument**
  - specimen identifier, reagent lot No., reagent expiration manual transmission
  - yes (reflex testing)/yes (cross-check functionality)
  - directly to LIS or EHR
- **Interface standards supported**
  - with proprietary message layer
  - yes (to other companies’ LISs)
  - yes (to other companies’ LISs and EHRs)
  - hospital network
  - direct serial connection
  - device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier
- **No. of days of training with instrument purchase**
  - 1 day at customer site, 2.5 days at vendor office
  - yes
  - 5 min. daily; 10 min. monthly
- **Provide list of client sites to potential customers on request**
  - yes (complete list with no restrictions regarding its use)
  - yes (information is confidential)
  - no
- **Distinguishing instrument features (supplied by company)**
  - streamlines urinalysis workflow to achieve manual review rates of 4%
  - auto-classifies 12 urine particles based on size, shape, contrast, texture to provide digital images for samples
  - urinalysis system FDA-cleared body fluids module
  - paperless digital layout
  - Urobilinogen/microscopy questions in one report
  - formerly ID Workcell answers in listing apply to both systems unless otherwise indicated
  - fast, efficient processing of urine strips; analyzer ready to test every six seconds
  - Chemiluminescence (CL) technology with virtually no interference with ascorbic acid, minimizing false-negative glucose and hemoglobin results
  - flexible sample ID entry options let user choose barcode scan, download from host, or manual entry options
  - no (information is confidential)
  - no
  - no
  - no
  - no
  - no

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²formerly iQ Workcell; answers in listing apply to both systems unless otherwise indicated

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### Table: Clinitek Novus Automated Urine Chemistry Analyzer

<table>
<thead>
<tr>
<th>Feature</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of urinalysis instrument</td>
<td>Clinitek Novus Automated Urine Chemistry Analyzer</td>
</tr>
<tr>
<td>Type of instrument</td>
<td>urine chemistry</td>
</tr>
<tr>
<td>Instrument list price</td>
<td>$104,995</td>
</tr>
<tr>
<td>First year instrument sold in U.S.</td>
<td>2015</td>
</tr>
<tr>
<td>No. of units installed in U.S., No. of units installed outside U.S.</td>
<td>3000–57 (in Canada)&lt;sup&gt;1&lt;/sup&gt; for chemistry/sediment</td>
</tr>
<tr>
<td>Foreign countries where company markets instrument</td>
<td>Canada&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Country where instrument designed/manufactured</td>
<td>U.S. and United Kingdom/U. and United Kingdom</td>
</tr>
<tr>
<td>Intended urine sample volume per day</td>
<td>&gt;50 tests</td>
</tr>
<tr>
<td>Dimensions (HxWxD)/Weight fully loaded with reagents</td>
<td>21 x 25 x 27 in./100 lbs.</td>
</tr>
<tr>
<td>Power requirements</td>
<td>100–240 VAC (48–62 Hz)</td>
</tr>
<tr>
<td>Mean time between failure of instrument</td>
<td>120 days</td>
</tr>
<tr>
<td>Events that cause instrument to lock or stop analysis</td>
<td>user ID failure, sampling error, consumables replacement/calibration failure</td>
</tr>
</tbody>
</table>

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

- **Sampling volume:** 2 mL
- **Wavelengths:** 360–500 nm
- **Refractometer/wavelength of absorbance in an analyzer well or test strip/turbidity within an analyzer well:**
  - bilirubin (0.5–2.7 mg/dL), red blood cells (trace level), hemoglobin (0.013–0.3 mg/dL), glucose (36–620 mg/dL), ketone (0.6–156 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 (0.24–2.4 mg/dL)

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

- **Specific gravity correction for protein/glucose:** no (protein)/no (glucose)
- **Color compensation pad included:** yes
- **Flagging thresholds customizable:** yes
- **Test strip configuration:** cartridge
- **Calibration required after each test strip lot No. change:** yes
- **Frequency of customer-performed calibration:** daily
- **Form of calibration:** semiquantitative
- **How results are displayed for urine chemistry:** yes
- **Reporting format customizable:** yes
- **No. of results that can be held in internal memory:** 7,500 sample results/400 control results

**Microscopy/sediment analysis parameters**:

- **Reagent cassette format with RFID that provides complete traceability and 14-day onboard stability:** yes
- **Digital color camera:** yes
- **sold as a standalone system or can be configured as part of modular integration with the Sysmex UN-2000, UN-3000, or UN-9000:** yes
- **Powerful combination of urine chemistry, fluorescent flow cytometry, and digital image analysis for rapid screening of urine:** yes
- **Modular and scalable configurations:** yes
- **BeyondCare quality monitor for urinalysis provides a device unique identifier, operator ID, patient ID, specimen ID, result:** yes

**Sample throughput per hour/Time to first result for chemistry**:

- **Sample throughput per hour/Time to first result for microscopy/sediment Analyzer:** 365 days/15–30°C
- **Onboard stability of cassette, 14 days/15–30°C:** varies based on reagent type

**Reagent shelf life/storage temperature**:

- **For opened containers onboard stability of cassette, 14 days/15–30°C:** varies based on reagent type
- **For unopened containers:** 365 days/15–30°C
- **Reagent shelf life/storage temperature for opened containers onboard stability of cassette, 14 days/15–30°C:** varies based on reagent type

**Dimensions (HxWxD)/Weight fully loaded with reagents**:

- **21 x 25 x 27 in./100 lbs.**
- **21 x 25 x 27 in./100 lbs.**

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

- **Sample dilutions required for urinalysis/body fluid analysis:** no (urinalysis)/— (body fluid analysis)
- **Specific gravity correction for protein/glucose:** no (protein)/no (glucose)
- **Color compensation pad included:** yes
- **Flagging thresholds customizable:** yes
- **Instrument eliminates amorphous crystal interference before sample analysis:** yes
- **Microscopy/sediment technology:** flow cytometry with fluorescent stain, digital image analysis with UN-3000 and UN-9000 configurations flagged and qualitative: pathological casts, crystals, yeast-like cells, mucus, sperm; quantitative: RBCs, WBCs, epithelial cells, bacteria, hyaline casts
- **Microscope eliminates amorphous crystal interference before sample analysis:** yes
- **Microscopy/sediment analysis parameters**:
  - **Color compensation pad included:** yes
  - **Flagging thresholds customizable:** yes
  - **Instrument eliminates amorphous crystal interference before sample analysis:** yes
  - **Microscopy/sediment technology:** flow cytometry with fluorescent stain, digital image analysis with UN-3000 and UN-9000 configurations flagged and qualitative: pathological casts, crystals, yeast-like cells, mucus, sperm; quantitative: RBCs, WBCs, epithelial cells, bacteria, hyaline casts

**Reagent shelf life/storage temperature**:

- **For opened containers onboard stability of cassette, 14 days/15–30°C:** varies based on reagent type
- **For unopened containers:** 365 days/15–30°C
- **Reagent shelf life/storage temperature for opened containers onboard stability of cassette, 14 days/15–30°C:** varies based on reagent type

**Microscopy/sediment analysis parameters**:

- **Reagent cassette format with RFID that provides complete traceability and 14-day onboard stability:** yes
- **Digital color camera:** yes
- **sold as a standalone system or can be configured as part of modular integration with the Sysmex UN-2000, UN-3000, or UN-9000:** yes
- **Powerful combination of urine chemistry, fluorescent flow cytometry, and digital image analysis for rapid screening of urine:** yes
- **Modular and scalable configurations:** yes
- **BeyondCare quality monitor for urinalysis provides a device unique identifier, operator ID, patient ID, specimen ID, result:** yes

**Dimensions (HxWxD)/Weight fully loaded with reagents**:

- **21 x 25 x 27 in./100 lbs.**
- **21 x 25 x 27 in./100 lbs.**

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

- **Sample dilutions required for urinalysis/body fluid analysis:** no (urinalysis)/— (body fluid analysis)
- **Specific gravity correction for protein/glucose:** no (protein)/no (glucose)
- **Color compensation pad included:** yes
- **Flagging thresholds customizable:** yes
- **Instrument eliminates amorphous crystal interference before sample analysis:** yes
- **Microscopy/sediment technology:** flow cytometry with fluorescent stain, digital image analysis with UN-3000 and UN-9000 configurations flagged and qualitative: pathological casts, crystals, yeast-like cells, mucus, sperm; quantitative: RBCs, WBCs, epithelial cells, bacteria, hyaline casts
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