### Chemistry analyzers (for mid-volume laboratories)

#### Part 1 of 10

**Beckman Coulter Inc.**  
200 South Kraemer Blvd.  
P.O. Box 8000  
Brea, CA 92822-8000  
800-526-3261  
www.beckmancoulter.com

**Cerner, Sunquest, MEDITECH, Citation, MedLab, CHC, SMS, HBOC, (addt'l cost)**

<table>
<thead>
<tr>
<th>Method損害</th>
<th>Immunoassay methods</th>
<th>Molar amounts</th>
<th>Potentiometry, turbidimetric/bioluminescent turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of different ion selective electrode channels</td>
<td>0</td>
<td>5 (individual)</td>
<td></td>
</tr>
<tr>
<td>No. of different assays measured on channel simultaneously</td>
<td>24</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>No. of assays programmed, validated at once</td>
<td>50</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>No. of different assays analyzed for which system accommodates reg. containers onboard at once/per test per container set</td>
<td>96/24</td>
<td>100/29</td>
<td></td>
</tr>
<tr>
<td>Shortest/median on-demand res. req.</td>
<td>24 hr/yes</td>
<td>25/25-2500</td>
<td></td>
</tr>
<tr>
<td>Multiple res. configurations supported</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>Reagent, container placed directly on system for use</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>Instrument has same capabilities when 3rd-party res. used</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>Walkaway capacity in minutes/specimens/texts-assays</td>
<td>40/65/3,512</td>
<td>400/1,032/1,027</td>
<td></td>
</tr>
<tr>
<td>System is in liquid or dry</td>
<td>liquid</td>
<td>liquid</td>
<td></td>
</tr>
<tr>
<td>Uses disposable cuvettes/max. no. stored</td>
<td>no/a</td>
<td>no/a</td>
<td></td>
</tr>
<tr>
<td>Uses available cuvette/replace ment frequency</td>
<td>yes/permanent-2 yr warranty (80 stored on instrument)</td>
<td>yes/permanent-2 yr warranty (80 stored on instrument)</td>
<td></td>
</tr>
<tr>
<td>Minimum sample volume aspirated precisely at one time</td>
<td>3 µL</td>
<td>3 µL</td>
<td></td>
</tr>
<tr>
<td>Supplied with UPS (backup power)/requires floor drain</td>
<td>yes/no</td>
<td>yes/no</td>
<td></td>
</tr>
<tr>
<td>Requires dedicated water system/water consumption</td>
<td>yes/1 L per hr</td>
<td>yes/1 L per hr</td>
<td></td>
</tr>
<tr>
<td>Noise generated</td>
<td>70 decibels</td>
<td>90 decibels</td>
<td></td>
</tr>
<tr>
<td>Calibrated dedicated sample cuve using daily</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>Calibrated sample cuve using monthly</td>
<td>no/yes</td>
<td>no/yes</td>
<td></td>
</tr>
<tr>
<td>Sample bar-code reading capability</td>
<td>yes, on sample transport, shortly before sample is aspirated (2 of 5 interl. Codabar, codes 39 &amp;128/autodiscrimination</td>
<td>yes, on sample transport, shortly before sample is aspirated (2 of 5 interl. Codabar, codes 39 &amp;128/autodiscrimination</td>
<td></td>
</tr>
<tr>
<td>Reagent bar-code reading capability</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>Bar code placement per NCCLS standard Auto2A</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
</tbody>
</table>

**Instrument test auto inventory (determines volume in container)**

| Measures no. tests remaining/short sample detection/detector material | yes | yes |
| Automatic detection of adequate res. & aspir. analysis | yes | yes |
| Hemolysis/turbidity detection/quantitation | yes | yes |
| Dilution of patient samples onboard/automatic res. capability | yes | yes |
| Sample volume can be reduced/increased to run on/off-liner range high/results | yes | yes |
| Autocalibration or autocalibration alert | yes | yes |
| Calibrators stored onboard/multipoint calibration supported | yes | yes |
| Typical calibr. frequency for immunoassay/sher. | yes | yes |
| Automatic shutdown/startup programmable | yes | yes |

**Start time to completion of all analytes, throughput per hr. for:**

<table>
<thead>
<tr>
<th>10 µL, 30 µL, 100 µL, 1 mL, 10 mL</th>
<th>24 hr/10, 48/90, 90/114</th>
<th>24 hr/10, 48/90, 90/114</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start time to completion of all analytes, throughput per hr. for:</td>
<td>no required</td>
<td>no required</td>
</tr>
</tbody>
</table>

**Data mgmt. capability**

<table>
<thead>
<tr>
<th>instrument vendor supplies LIS interface</th>
<th>onboard &amp; optional add-on (SM ref: Beckman Coulter DataLink)</th>
<th>onboard &amp; optional add-on (SM ref: Beckman Coulter DataLink)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interfaces up and running in active user sites with</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Bidirectional interface capability</td>
<td>yes (broadcast download &amp; host query)</td>
<td>yes (broadcast download &amp; host query)</td>
</tr>
<tr>
<td>Test results transmitted to LIS as soon as chem. time complete</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>LIS interface operates simultaneously with running assays</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Users LOMC to transmit orders &amp; results</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

**Interface avail. (or will be) to automated specimen handling system**

<table>
<thead>
<tr>
<th>yes</th>
<th>yes</th>
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**Modern servicing available/can diagnose own malfunctions/ determine malfunctioning component**

<table>
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<tr>
<th>yes</th>
<th>yes</th>
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</table>

**On-site time of svc. engineer/remote error codes for troubleshooting**

<table>
<thead>
<tr>
<th>yes</th>
<th>yes</th>
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</thead>
</table>

**Average time to complete maintenance by lab personnel**

<table>
<thead>
<tr>
<th>no</th>
<th>no</th>
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</table>

**On-site maintenance record/remote training module**

<table>
<thead>
<tr>
<th>yes</th>
<th>yes</th>
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</table>

**Training provided with purchase/advanced oper. training avail.**

<table>
<thead>
<tr>
<th>yes</th>
<th>yes</th>
</tr>
</thead>
</table>

**Annual service contract cost (24 hr/7 d)**

<table>
<thead>
<tr>
<th>$162,400</th>
<th>$193,500</th>
</tr>
</thead>
</table>

**Manufacturer: Beckman Coulter Inc.**  
200 South Kraemer Blvd.  
P.O. Box 8000  
Brea, CA 92822-8000  
800-526-3261  
www.beckmancoulter.com

**Survey Today**  
Tabulation does not represent an endorsement by the College of American Pathologists  
Survey editor: Raymond D. Aller, MD
Survey of Tabulation does not represent an endorsement by the College of American Pathologists

Name of instrument/first year sold in U.S.
- Synchron CX9 Pro/2001
- Dimension R4 Clinical Chemistry System/1989

List price
- $280,600
- $17,000

Cost of annual service contract
- $24 h/7 d
- 35/29

Onboard maintenance records/maint. training demo module
- U.S./S.O. of E Ireland
- continuous random access/self-contained multiset cartridges-packaged slides

Average time to complete maintenance by lab personnel
- 69 X 74 X 30 in/15.4 sq ft

On-site time of svc. engineer/onboard error codes for troubleshooting
- none

Modem servicing available/can diagnose own malfunctions/
- interface avail. (or will be) to automated specimen handling system
- sample segments/footing standing

LIS interface operates simultaneously with running assays
- yes

Test results transmitted to LIS as soon as chem. time complete
- no

Bidirectional interface capability
- none

Interfaces up and running in active user sites with
- DataLink
- yes

Data mgmt. capability/instrument vendor supplies LIS interface
- no

QC results transferred automatically to LIS
- yes

Onboard real-time QC/support multiple QC lot nos. per analyte
- yes

How often QC required/onboard SW capability to review QC
- none

Stat time to completion of all analytes, throughput per hr.
- none

Automatic shutdown/startup programmable
- yes

Calibrants stored onboard/multipoint calibration supported
- none

Sample volume can be reduced/increased to rerun out-of-linear-
- yes

Dilution of patient samples onboard/automatic rerun capability
- yes

Hemolysis/turbidity detection-quantitation
- yes

Automatic detection of adequate reag. for aspir. & analysis
- yes

Onboard test auto inventory (determines volume in container)
- yes

Bar code placement per NCCLS standard Auto2A
- yes

Sample bar-code reading capability
- yes

Primary tube sampling/pierces caps on primary tubes
- yes

Sample code reading capability
- yes

Reagent bar-code reading capability
- yes

Base code placement per NCCLS standard Auto2A
- yes

Unobstructed test auto inventory (determines volume in container)
- yes

Measures no. tests remaining/short sample detection/strip detection
- yes

Automatic detection of adequate req. for asp. & analysis
- yes

Hemolysis/turbidity detection-quantitation
- yes

Dilution of patient samples onboard/automatic rerun alert
- yes

Sample volume can be reduced/increased to rerun out-of-linear-
- none

-range high/low results

Auto cancelation or auto bail-up alert
- none

Calibrates onboard/multiport calibration supported
- none

Typical calib. frequency for ISE/automated titr. instr. assay
- yes

Automatic shutdown/startup programmable
- none

Stat time to completion of all analytes, throughhout per hr. for:
- yes

- Sodium, potassium, chloride, TCO2
- yes

- Uric. bili. direct & total, AST, ALT, ALP
- yes

- Protein, glucose, urea, creatinine
- yes

Typical time delay from ordering test start to asp. of sample
- yes

How often QC required/onsite SW capability to review QC
- none

Onboard real-time ISE/support multiple ISE lot nos. per analyte
- none

Tests results transferred automatically to LIS
- none

Data mgmt. capability/instrument vendor supplies LIS interface
- none

Interfaces up and running in active user sites with
- no

Interface availability (will be) to automated specimen handling system
- yes

Modern servicing available/can diagnose own malfunctions/
- yes

- determine malfunctioning component

- yes

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- yes
Chemistry analyzers (for mid-volume laboratories)

Part 3 of 10

Olympus America Inc.  
Two Corporate Center Dr.  
Melville, NY 11747  
www.olympus.com

Roche Diagnostics  
Roche Product Manager  
9115 Harper Rd., F. O. Box 6947  
Indianapolis, IN 46250  
800-429-5074  
us.labrepts.roche.com

See related comments, page 49

Name of instrument/first year sold in U.S.  
List price

<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>Year sold in U.S.</th>
<th>List price</th>
</tr>
</thead>
<tbody>
<tr>
<td>AU400/1998</td>
<td>$131,000</td>
<td></td>
</tr>
<tr>
<td>380/600</td>
<td>Japan/Japan/US &amp; Ireland</td>
<td>$250,000</td>
</tr>
</tbody>
</table>

Sample handling system/model type

- Dimensions (H x W x D) of Instrument footprint
- Used for in-lab or in-office use
- Research use only/batch
- User-defined methods implemented for what analytes

- Tools cleared but not clinically released
- Tools not available in U.S. but submitted for 510(k) clearance
- Tools available in U.S. but available in other countries
- Tools not available in U.S. but submitted for 510(k) clearance
- Tools cleared but not clinically released

- Methods supported/immunoassay methods
- Methods supported/immunoassay methods
- Methods supported/immunoassay methods

- Onboard test auto inventory (determines volume in container)
- Measures no. tests remaining short sample detection/list detection
- Automatic detection of adequate reap. for asup. & analysis
- Hemolytic/ndiscrption/detection-quantification
- Dilution of patients onboard/automatic run capability
- Sample volume can be reduced/increased to run out-of-inear
- Range-high/low results
- Autoanalysis or autoanalysis alert
- Calibrated onboard/multipoint calibration supported
- Typical calib. frequency for ISE/metabolites/thru. drugs/drugs of abuse
- Automatic shutdown/startup programmable

- Real time to completion of all analytes, throughout per hr. for:
- Sodium, potassium, chloride, TCO2, glucose, urea, creatinine

- Data engent. capability/instrument vendor supplies LIS interface
- Interfacing up and running in active user sites with
- Biidirectional interface capability
- Tools transmitted to LIS as soon as chem. test complete
- LIS interface operates simultaneously with running analyzers
- Uses LONIC to transmit orders & results

- Modern servicing available/can diagnose other malfunctions/
- Determinate malfunctioning component
- On-site time of service, engineer/rep. error codes for troubleshooting
- Mean Time between service failures
- Average time to complete maintenance by lab personnel
- Onboard maintenance records/maint. training demo module
- Training provided with purchased/advanced oper. training avail.
- Annual service contract cost (24 hr/day)

- Distinguishing features
- Olympus is a leader in standardization with its family of chemistry immuno systems, the AU640, AU840, AU850 & AU900. Broad test menu of 124-methods delivers standardized results for improved patient management & streamlined operation. Speed, reliability, advanced features, & unprecedented onboard automation for the best walkaway in industry today

- Comprehensive test menu including hemoglobin A1c; reagent cassette requires no operator prep. or special handling (can go straight from refrigerator to system with no warmup time); 97% of reagents are liquid, ready to use, system automatically reconstitutes if necessary, system forecasts daily reagent requirements based on history; operator maintenance automatically scheduled by system, based on actual use, not by calendar schedule; 800 has clot detection, bubble detection & can accommodate universal 5-position Hitachi rack for modular systems & Eicosys IA analyzers

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July 2001

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Survey of instruments
## Chemistry analyzers (for high-volume laboratories)

### Part 4 of 10

**Abbott Diagnostics**
Jack Kenny  
jack.kenny@abbott.com  
100 Abbott Park Road  
Abbott Park, IL 60089  
600-529-5100  
www.abbott.com

**Bayer Corp., Diagnostics Div.**
Denise Pastore  
denise.pastore@bayer.com  
511 Boxedale Ave.  
Tarzana, CA 91356  
818-435-6122  
www.bayer.com

<table>
<thead>
<tr>
<th><strong>See related comments</strong>, p. 49</th>
</tr>
</thead>
</table>

### Survey of instruments

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| **Name of instrument/first year sold in U.S.** |

| **List price** |

| **Abbott Aeroset/1999** |

| **$340,000** |

| **200+400** |

| **Japan/Japan/U.S.** |

| **continuous random access/open reagent system** |

| **Sample handling system/model type** |

| **rubber, carousel/roller-standing** |

| **Dimensions (H x W x D) Instrument footprint** |

| **42.7 x 74.4 x 44.1 in/122.7 sq ft** |

| **No. of tests for which analyzer has FDA-cleared applications** |

| **62** |

| **Tests cleared but not clinically released** |

| **none** |

| **Tests not available in U.S. but submitted for 510(k) clearance** |

| **microalbumin, transferrin, glucose hexokinase II** |

| **Tests not available in U.S. but not in other countries** |

| **transferrin** |

| **Tests in development** |

| **cholateferase, total proteins II, HDL direct, LDL direct** |

| **User-defined methods implemented for what analytes** |

| **TDMs, drugs of abuse, SNRs** |

| **Methods supported/immunoassay methods** |

| **photometry, potentiometry, turbidimetry** |

| **No. of different ion selective electrode channels** |

| **3** |

| **No. of different measured assays onboard simultaneously** |

| **68** |

| **No. of different assays programmed, calibrated at once** |

| **100** |

| **No. of user-definable (open) channels/assays, active simultaneously** |

| **100/100** |

| **No. of different analysis for which system accommodulates reag. containers onboard at once/tests per container set** |

| **50/50** |

| **Maximum reag. capacity, configurations supported** |

| **7/628/day** |

| **Reag. container placed directly on system for use** |

| **yes** |

| **Instrument has some capabilities when 3rd-party reag. used** |

| **yes** |

| **Walkaway capacity in minutes/specimens/assays tested** |

| **600/20/50,000+** |

| **System is liquid or dry** |

| **liquid** |

| **Uses disposable cuvettes, max. no. stored** |

| **n/a** |

| **Uses washable cuvettes, replacement frequency** |

| **yes/minimum 1 yr guaranteed** |

| **Minimum sample volume aspirated precisely at one time** |

| **2 µL** |

| **Supplied with UPS (backup power) requires floor drain** |

| **yes** |

| **Reagents required dedicated water system/water consumption** |

| **yes/45 L/hr** |

| **Noise generated** |

| **n/a** |

| **Dedicated pediatric sample cup/dead volume** |

| **yes/50 µL** |

| **Sample bar-code reading capability** |

| **yes** |

| **Reagent bar-code reading capability** |

| **yes** |

| **Bar code placement per NCCLS standard Auto2A** |

| **yes** |

| **Ondexx test auto inventory (determines volume in container)** |

| **yes** |

| **Measures no. tests remaining/short sample detection/cell detection** |

| **yes/yes/no** |

| **Automatic detection of adequate reag. for assay & analysis** |

| **yes** |

| **Hemolysis/Serum detection-quantification** |

| **yes** |

| **Dilution of patient samples onboard/automatic rerun capability** |

| **yes** |

| **Sample volume can be reduced/increased to rerun out-of-linear-range high-low results** |

| **yes** |

| **Autocalibration or autocalibration alert** |

| **yes** |

| **Calibrated stored onboard/multipoint calibration supported** |

| **yes** |

| **Typical calibr. frequency for ISE/metabolite/therapeutic drugs/drugs of abuse** |

| **yes** |

| **Automatic shutdown/startup programmable** |

| **yes** |

| **Start time to completion of all analytes, throughput per hr. for:** |

| **10 min, 200+ specimens** |

| **<24 hr/3 year** |

| **Mean time between failures/repair failures** |

| **<24 hr/3 year** |

| **Average time to complete maintenance by lab personnel** |

| **daily/30 d/30 d/daily** |

| **Onboard maintenance records/maint. training demo module** |

| **yes** |

| **Training provided with purchase/advanced oper. training avail.** |

| **yes** |

| **Annual service contract cost (24 hr/7 d)** |

| **$35,000** |

| **Distinguishing features** |

| **workstation consolidation; high throughput; large capacity; extremely reliable; open, flexible system** |

| **Country where designed/manufactured/where reagents mfgd.** |

| **Japan/U.S.** |

| **List price** |

| **$200,000** |

| **Part 4 of 10** |

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## Part 5 of 10

### Chemistry analyzers (for high-volume laboratories)

| Model | Manufacturer | First Year Sold | Instrument Footprint | Operational Type | Reagent Type | Country Where Designed/Manufactured | Where Reagents Mfrd. | No. of Units in Clinical Use in U.S. | Outside U.S. | Name of Instrument | First Year Sold
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>LX20</td>
<td>Beckman Coulter Inc.</td>
<td>1997</td>
<td>65.9 in x 50.8 in x 32.3 in</td>
<td>Continuous random access</td>
<td>Open reagent system</td>
<td>U.S./U.S./U.S. &amp; Ireland</td>
<td>U.S. &amp; Ireland</td>
<td>LX20 Pro 410/100</td>
<td>LX4201 Pro 710/210</td>
<td>LX20 Pro; Synchrone LX4201 Pro/20001</td>
<td>2001</td>
</tr>
<tr>
<td>LX20 Pro</td>
<td>Beckman Coulter Inc.</td>
<td>1997</td>
<td>60.6 in x 30.0 in x 33.0 in</td>
<td>Continuous random access</td>
<td>Open reagent system</td>
<td>U.S./U.S./U.S. &amp; Ireland</td>
<td>U.S. &amp; Ireland</td>
<td>LX20 Pro 410/100</td>
<td>LX4201 Pro 710/210</td>
<td>LX20 Pro; Synchrone LX4201 Pro/20001</td>
<td>2001</td>
</tr>
</tbody>
</table>

### Methods supported/immunoassay methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luminometry</td>
<td>photometry, photometry, near-infrared/bidestate turbidimetric, direct turbidimetric, particle-enhanced turbidimetric, enzyme immunoassay</td>
</tr>
<tr>
<td>Luminometry</td>
<td>photometry, photometry, near-infrared/bidestate turbidimetric, direct turbidimetric, particle-enhanced turbidimetric, enzyme immunoassay, near-infrared particle immunoassay</td>
</tr>
<tr>
<td>Luminometry</td>
<td>photometry, photometry, near-infrared/bidestate turbidimetric, direct turbidimetric, particle-enhanced turbidimetric, enzyme immunoassay, near-infrared particle immunoassay</td>
</tr>
</tbody>
</table>

### Noise generated

- LX20: 62 dBA
- LX20 Pro: 62 dBA
- LX4201 Pro: 62 dBA

### User-defined methods implemented for what analytes

- UBC, vancomycin, LLOD, direct
- UBC, vancomycin, LLOD, direct
- UBC, vancomycin, LLOD, direct

### Data reported

- **Data reported on test**: Yes
- **Data reported on test**: No
- **Data reported on test**: Yes

### Features

- **Walkaway capacity in minutes**: 90 specimens
- **Walkaway capacity in minutes**: 90 specimens
- **Walkaway capacity in minutes**: 90 specimens

### Results

- **Results obtained in**: 24 hr
- **Results obtained in**: 48 hr
- **Results obtained in**: 48 hr

### Test results reported to LIS as soon as test is done: yes

### User interface

- **User interface available**: Yes
- **User interface available**: Yes
- **User interface available**: Yes

### Miscellaneous

- **Clinical chemistry analyzers (for high-volume laboratories)**
- **Clinical chemistry analyzers (for high-volume laboratories)**
- **Clinical chemistry analyzers (for high-volume laboratories)**

### Additional information

- **Full model number**: LX20 Pro; Synchrone LX4201 Pro/20001
- **Full model number**: LX20 Pro; Synchrone LX4201 Pro/20001
- **Full model number**: LX20 Pro; Synchrone LX4201 Pro/20001
SURVEY OF INSTRUMENTS

Tabulation does not represent an endorsement by the College of American Pathologists

Distinguishing features

- Only instrument available that integrates heterogeneous immunoassays onboard with other chemistries; allows single platform for over 95% of most requested tests; eliminates sample splitting between general tests & immunoassays
- Olympus is a leader in standardization with its family of homogeneous immunoassays
- AU5400. Broad test menu of 120+ methods delivers standardized results for improved patient management & streamlined operations
- AU640. Advanced system for research-use-only assays
- Axiom, bili. direct & total, AST, ALT, ALP
- Sodium, potassium, chloride, TCO2, glucose, urea, creatinine
- Sodium, potassium, chloride, TCO2
- Distinguishing features
  - Training provided with purchase/advanced oper. training avail.
  - Onboard maintenance records/maint. training demo module
  - Average time to complete maintenance by lab personnel
  - Modem servicing available/can diagnose own malfunctions
  - Interface avail. (or will be) to automated specimen handling system
  - LIS interface operates simultaneously with running assays
  - QC results transferred automatically to LIS
  - Stat time to completion of all analytes, throughput per hr.
  - Automatic shutdown/startup programmable
  - Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse
  - Sample volume can be reduced/increased to rerun out-of-linear-range results
  - Measures no. tests remaining/short sample detection/clot detection
  - Onboard test auto inventory (determines volume in container)
  - Sample bar-code reading capability
  - Dedicated pediatric sample cup/dead volume
  - Noise generated
  - Relevant comments, page 49
### Chemistry analyzers (for high-volume laboratories)

**Part 7 of 10**

<table>
<thead>
<tr>
<th>Olympus America Inc.</th>
<th>Olympus America Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terry Giacomino</td>
<td>Hiro Sekiya</td>
</tr>
<tr>
<td><a href="mailto:terry.giacomo@olympus.com">terry.giacomo@olympus.com</a></td>
<td><a href="mailto:hiro.sekiya@olympus.com">hiro.sekiya@olympus.com</a></td>
</tr>
<tr>
<td>Two Corporate Center Dr.</td>
<td>Two Corporate Center Dr.</td>
</tr>
<tr>
<td>Morristown, NJ 07960</td>
<td>Morristown, NJ 07960</td>
</tr>
<tr>
<td>900-223-6172</td>
<td>900-223-6172</td>
</tr>
<tr>
<td><a href="http://www.olympus.com">www.olympus.com</a></td>
<td><a href="http://www.olympus.com">www.olympus.com</a></td>
</tr>
</tbody>
</table>

**See related comments, page 49**

<table>
<thead>
<tr>
<th>Name of instrument/first year sold in U.S.</th>
<th>List price</th>
<th>No. units in clinical use in U.S./outside U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Country where designed/manufactured/where reagents mfd.</th>
<th>Operational type/reactant type</th>
<th>Sample handling system/model type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Dimensions (H x W x D)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Functional features</th>
<th>Functional features</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

- **Test methods supported/immunoassay methods**
  - Methods a. bili. direct & total, AST, ALT, ALP
  - Methods b. Sodium, potassium, chloride, TCO2, glucose, urea, creatinine
- **Accessories**
  - Bar code placement per NCCLS standard AutoA2A
  - Dedicated pediatric sample cup/stand-alone primary tubes
  - Sample-bar-code reading capability
  - Reagent-bar-code reading capability
- **Onboard test auto inventory (determines volume in container)**
  - Measures no. tests remaining/short volume detection/total detection
- **Automatic deactivation of adequate react. for asp. & analysis**
  - Hemolysis/turbidity detection/quantitation
  - Dilution of patient samples onboard/automatic rework capability
  - Sample volume can be reduced/increased to meet out-of-range/range-high/low results
- **Auto-calibration or auto-calibration alert**
  - Calibrates stored onboard/multipoint calibration supported
  - Typical calibrat. frequency for ISE/metabolite/thr. drugs/drugs of abuse
  - Automatic shutdown/track programammable
- **Stat time to completion of all analytes, throughout per hr. for:**
  - Sodium, potassium, chloride, TCO2, glucose, urea, creatinine
  - Albumin, bil. direct & total, AST, ALT, ALP
  - Typical time delay from ordering test to aspir. to asp. of sample
  - How often QC required/onboard SW capability to review QC onboard real-time QC/support multiple QC int. res. per analyzer
  - DC results transferred automatically to LIS
- **Data repat. capability/instrument vendor supplies LIS interface**
  - Interfaces up and running in active user sites with
  - Bidirectional interface capability
  - Test results transmitted to LIS as soon as chem. time complete
  - LIS interface operates simultaneously with running assays
  - Uses LIS interface to transmit orders & results
- **Instrument availability (or will be) to automated specimen handling system**
  - Modern servicing available/can diagnose own malfunctions/determine malfunctioning component
  - On-site service of user, engine/onsite error codes for troubleshooting
  - More time between failures/repair failures
  - Average time to complete maintenance by lab personnel
  - Onboard maintenance records/main, training done module
  - Training provided with purchase/advanced oper. training available
  - Annual service contract cost (24 h/7 d) |

<table>
<thead>
<tr>
<th>Distinctive features</th>
<th>Distinctive features</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

- **Olympus is a leader in standardization with its family of chemistry immuno systems, the AU400, AU600, AU2700, & AU5400.**
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- **Olympus is a leader in standardization with its family of chemistry immuno systems, the AU400, AU600, AU2700, & AU5400.**
### Survey of Instruments

**Tabulation does not represent an endorsement by the College of American Pathologists.**

#### Olympus America Inc.

- **Name of instrument/first year sold in U.S.**
  - List price: 857,000
  - No. of units in clinical use in U.S./outside U.S.: 570
- **Country where designed/manufactured/where reagents ndfd.**
  - Japan
- **Operational type/reagent type**
  - Annual service contract cost (24 h/7 d): 69
- **Sample handling system/model type**
  - Onboard maintenance records/maint. training demo module:
  - Interface avail. (or will be) to automated specimen handling system: none
  - Uses LOINC to transmit orders & results: none
  - Interfaces up and running in active user sites with Data mgmt. capability/instrument vendor supplies LIS interface: none
  - Onboard real-time QC/support multiple QC lot nos. per analyte: none
- **Stat time to completion of all analytes, throughput per hr. for:**
  - Automatic shutdown/startup programmable: none
  - Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse: none
  - Calibrants stored onboard/multipoint calibration supported: none
  - Autocalibration or autocalibration alert: none
  - Dilution of patient samples onboard/automatic rerun capability: none
  - Automatic detection of adequate reag. for aspir. & analysis: none
  - Reagent bar-code reading capability: none
  - Sample bar-code reading capability: none
  - Primary tube sampling/pierces caps on primary tubes: none
  - Dedicated pediatric sample cup/dedicated pediatric sample cup/dedicated pediatric sample cup/dedicated pediatric sample cup:
  - Noise generated: none
  - Supplied with UPS (backup power)/requires floor drain: none
  - Minimum sample volume aspirated precisely at one time: none
  - Uses washable cuvettes/max. no. stored: none
  - Multiple reag. configurations supported: no/n/a
  - Shortest/median onboard reag. stability/refrigerated onboard: no/n/a
  - No. of different assays programed, calibrated at once: no/n/a
  - Methods supported/immunoassay methods: no/n/a
  - User-defined methods implemented for what analytes: no/n/a
  - Tests in development: no/n/a
  - Operational type/reagent type: none
  - Bar code placement per NCCLS standard AutoAIA: none
  - Reagent bar-code reading capability: none
  - Bar code placement per NCCLS standard AutoAIA: none
  - Onboard test auto inventory (determines volume in container): none
  - Measures no. tests remaining/short sample detection/lost detection: none
  - Automatic detection of adequate reag. for aspir. & analysis: none
  - Hemoly/leucos/estimation: none
  - Dilution of patient samples onboard/automatic renul capacity: none
  - Sample volume can be reduced/increased to run off-tile-range-high results: none
  - Alkalization or alcalisation alert: none
  - Calls for stored onboard/multipoint calibration supported: none
  - Typical cab. frequence for ISE/metabolites/thor. drugs/drugs of abuse: none
  - Automatic shutdown/startup programmable: none
  - System is liquid or dry: none
  - Uses disposable cuvettes/max. no. stored: none
  - Sample tube sampling/pieces caps on primary tubes: none
  - Sample bar-code reading capability: none
  - Sample bar-code reading capability: none
  - Reagent bar-code reading capability: none
  - Reagent bar-code reading capability: none
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  - Automatic shutdown/startup programmable: none
  - System is liquid or dry: none
  - Uses disposable cuvettes/max. no. stored: none
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  - Measures no. tests remaining/short sample detection/lost detection: none
  - Automatic detection of adequate reag. for aspir. & analysis: none
  - Hemoly/leucos/estimation: none
  - Dilution of patient samples onboard/automatic renul capacity: none
  - Sample volume can be reduced/increased to run off-tile-range-high results: none
  - Alkalization or alcalisation alert: none
  - Calls for stored onboard/multipoint calibration supported: none
  - Typical cab. frequence for ISE/metabolites/thor. drugs/drugs of abuse: none
  - Automatic shutdown/startup programmable: none
  - System is liquid or dry: none
  - Uses disposable cuvettes/max. no. stored: none
  - Sample tube sampling/pieces caps on primary tubes: none
  - Sample bar-code reading capability: none
  - Sample bar-code reading capability: none
  - Reagent bar-code reading capability: none
  - Reagent bar-code reading capability: none
  - Bar code placement per NCCLS standard AutoAIA: none
  - Onboard test auto inventory (determines volume in container): none
  - Measures no. tests remaining/short sample detection/lost detection: none
  - Automatic detection of adequate reag. for aspir. & analysis: none
  - Hemoly/leucos/estimation: none
  - Dilution of patient samples onboard/automatic renul capacity: none
  - Sample volume can be reduced/increased to run off-tile-range-high results: none
  - Alkalization or alcalisation alert: none
  - Calls for stored onboard/multipoint calibration supported: none
  - Typical cab. frequence for ISE/metabolites/thor. drugs/drugs of abuse: none
  - Automatic shutdown/startup programmable: none
  - System is liquid or dry: none
  - Uses disposable cuvettes/max. no. stored: none
  - Sample tube sampling/pieces caps on primary tubes: none
  - Sample bar-code reading capability: none
  - Sample bar-code reading capability: none
  - Reagent bar-code reading capability: none
  - Reagent bar-code reading capability: none
  - Bar code placement per NCCLS standard AutoAIA: none

**Chemistry analyzers (for high-volume laboratories):**

<table>
<thead>
<tr>
<th>Method supported/immunoassay methods</th>
<th>Olympus America Inc.</th>
<th>Ortho-Clinical Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated detection of adequate reag. for aspir. &amp; analysis</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Hemolysis/fatality estimation</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Dilution of patient samples onboard/automatic renul capacity</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Sample volume can be reduced/increased to run off-tile-range-high results</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
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<td>none</td>
</tr>
<tr>
<td>Calls for stored onboard/multipoint calibration supported</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Typical cab. frequence for ISE/metabolites/thor. drugs/drugs of abuse</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Automatic shutdown/startup programmable</td>
<td>none</td>
<td>none</td>
</tr>
</tbody>
</table>

**Note:** For a comprehensive list of chemistry analyzers and their specifications, please refer to the survey on page 49. **Contact Information:**

- **Olympus America Inc.:**
  - Hiro Sekiya
  - Hiro.sekiya@olympus.com
  - 1001 U.S. Highway 202
  - Melville, NY 11747
  - www.olympus.com

- **Ortho-Clinical Diagnostics:**
  - Christine Hopkins
  - 1001 U.S. Highway 202
  - Raritan, NJ 08869
  - 800-826-0125
  - www.orthoclinical.com

**Additional Resources:**

- **Testing Industry News:**
  - www.olympus.com
  - www.orthoclinical.com

**Supplementary Information:**

- **Quality Control:**
  - Calculations and protocols for quality control in the laboratory
- **Clinical Applications:**
  - Use of analyzers in clinical laboratories
- **Research:**
  - Use of analyzers in research settings

**Contact for Information:**

- **Olympus America Inc.:**
  - Hiro Sekiya
  - Hiro.sekiya@olympus.com

- **Ortho-Clinical Diagnostics:**
  - Christine Hopkins
  - 1001 U.S. Highway 202
  - Raritan, NJ 08869
  - 800-826-0125

**Website:**

- **Olympus America Inc.:**
  - www.olympus.com

- **Ortho-Clinical Diagnostics:**
  - www.orthoclinical.com

**Suppliers:**

- **Olympus America Inc.:**
  - Dawnng Technol., DADAC, Dynamic Healthcare, Antek, SMS, HBOC

- **Ortho-Clinical Diagnostics:**
  - Ortho-Clinical Diagnostics

**Supporting Materials:**

- **User Manuals:**
  - Instructions for use
- **Technical Support:**
  - Customer service and technical support

**References:**

- **Chemistry Analyzers (for High-Volume Laboratories):**
  - Comprehensive list of analyzers and their specifications
- **Quality Control:**
  - Guidelines and protocols for quality control
- **Clinical Applications:**
  - Use of analyzers in clinical laboratories
- **Research:**
  - Use of analyzers in research settings

**Contact for Information:**

- **Olympus America Inc.:**
  - Hiro Sekiya
  - Hiro.sekiya@olympus.com

- **Ortho-Clinical Diagnostics:**
  - Christine Hopkins
  - 1001 U.S. Highway 202
  - Raritan, NJ 08869
  - 800-826-0125

**Website:**

- **Olympus America Inc.:**
  - www.olympus.com

- **Ortho-Clinical Diagnostics:**
  - www.orthoclinical.com
Chemistry analyzers (for high-volume laboratories)

Part 9 of 10

Ortho-Clinical Diagnostics
Christine Hopkins
1081 U.S. Highway 202
Raritan, NJ 08869
609-826-6316
www.ortho-clinical.com

Roche Diagnostics
Rebecca Product Manager
9111 Harper Rd.
Indianapolis, IN 46250
800-428-5074
us.labsystems.roche.com

See related comments, page 49

Name of instrument/first year sold in U.S. List price
Vitros 250, Vitros 250 AT/1993 $197,000
Vitros 250, Vitros 550 AT/1998 $500,000

No. of units in clinical use in U.S./outside U.S.
>3,000
>200

Country where designed/manufactured/where reagents ndfd.
U.S.
U.S.

Operational type/reagent type
batch, random access, discrete, continuous random access/self-contained single-use cartridges/packages-slides
batch, random access, discrete, continuous random access/self-contained single-use cartridges/packages-

Sample handling system/model type
rack/fliter-standing
rack/fliter-standing

Dimensions (H x W x D)/Instrument footprint
47 x 45.5 x 28 in/8.8 sq ft
47 x 45.5 x 28 in/8.8 sq ft

No. of tests for which analyzer has FDA-cleared applications
>100

Tests cleared but not clinically released
soluble transferrin receptor, D-dimer

Tests not available in U.S. but submitted for 510(k) clearance
none

Tests not available in U.S. but available in other countries
Apox, April, Lpa

Research-use-only assays
none

Tests in development
none

User-defined methods implemented for what analytes
none

Methods supported/immmunoassay methods
potentiometry, colorimetric–rate, potentiality—

No. of direct ion selective electrodes channels
3
3

No. of different measured assays onboard simultaneously
60
60

No. of different assays programmed, calibratable at once
60
60

No. of user-definable [open] channels/no. active simultaneously
na/na
na/na

No. of different analytes for which system accommodation reag. containers onboard at 30 or tests per container set
60
60

Shortest/median reagent onboard, stability/stability refrigerated onboard
1,404 h/300 h
1,404 h/300 h

Multiple reag. configurations supported
yes
yes

Reag. container placed directly on system for use
yes
yes

Instrument has same capabilities when 3rd-party reagent used
yes
yes

Workaway capacity in minutes/specimens/tests-assays
~240/240 per hr
~240/240 per hr

System is liquid or dry
liquid
liquid

Uses disposable cuvettes/max. no. stored
na/na
na/na

Uses washable cuvettes/replacement frequency
na/na
yes/monthly

Minimum sample volume aspirated precisely at one time
6 µL
2 µL

Supplied with UPS (backup power)/requires floor drain
na/no
yes

Requires dedicated water system/water consumption
no/120 l/day
yes/50 l/day

Noise generated
na/na

Dedicated pediatric sample cup/dead volume
yes/30 µL
yes/50 µL

Primary tube sampling/pieces caps on primary tubes
yes/no
yes/no

Sample bar-code reading capability
yes
yes

Reagent bar-code reading capability
yes
yes

Bar code placement per NCCLS standard AutoLA
yes
yes

Onboard test auto inventory (determines volume in container)
yes/yes/yes
yes/yes/yes

Measures no. tests remaining/short sample detection/lost detection
yes/yes/yes
yes/yes/no

Automatic detection of adequate reag. for aspir. & analysis
no/not needed/not needed
yes

Hemolysis/turbidity detection—quantification
yes/no
yes/no

Minimum sample volume can be reduced/increased to rerun out-of-linear-dilution of patient samples onboard/automatic rerun capability
no/no
yes

Fails interl., CODABAR, codes 39 & 128/autodialerization
yes
yes

Automatic shutdown/startup programable
yes
yes

Stat time to completion of all analytes, throughout per hr. for:
5 min, 238 specimens
5 min, 277 specimens

• Sodium, potassium, chloride, TCO2
• Urea, creatinine, uric acid
• Albumin, bilirubin, direct & total, AST, ALT, ALP
• Lipemia, bilirubin; smart metering; continuous process

• Frequency for ISE/metabolites/therapeutic drugs/drugs of abuse
• 4-6 mo/3–6 mo
• >100/70–200 specimens
• 8 hr/yes

• Calculated stored onboard/multipoint calibration supported
• 8 hr/yes

• Typical calib. frequency for ISE/reagents/other drugs/drugs of abuse
• 6 mo/3–6 mo
• >100/70–200 specimens
• 8 hr/yes

• Automatic shutdown/startup programable
• yes

Data mgmt. capability/instrument supplier supplies LIS interface
ondboard/yes
ondboard/yes

Interfaces up and running in active user sites with
—
—

Biodiagnostic interfaced capability
—
—

Test results transmitted to LIS as soon as chem. time complete
—
—

LIS interface operates simultaneously with running assays
yes
yes

Uses LONIC to transmit orders & results
—
—

Interface avail. (or will be) to automated specimen handling system
—
eyes

Modern servicing available/can diagnose own malfunctions/ determine malfunctioning component
—
—

On-site data of sec, engineer/onsite error codes for troubleshooting
—
—

Mean time between failures/repair failures
<4 h/yes
8 h/yes

Average time to complete maintenance by lab personnel
daily; 2 min; weekly: 5 min; monthly: 15 min
daily; 2 min; weekly: 5 min; monthly: 15 min

Onboard maintenance records/maint. training dome module
yes/yes
yes/yes

Training provided with purchase/advanced operator training. available
5-6 at vendor offices/yes
5-6 at vendor offices/yes

Annual service contract cost (24 h/7 d)
—
—

Distinguishing features
—
—

Superior assay precision; minimal interference from hemolysis, lipemia, bilirubin; smart metering; continuous process

Veriﬁcation; no infectious waste; no plumbing, water, or drains; highest reportable result efﬁciency of any chemistry analyzer

Preliminary report efﬁciency of any chemistry analyzer

<62 decibels
<62 decibels

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Part 10 of 10

Raymond D. Aller, MD

An underlying thread tying together CAP TODAY’s chemistry analyzer surveys in recent years has been the steady expansion of available, on-board test menus, which has enhanced workstation consolidation in the laboratory. Such consolidation permits the clinician to draw a single tube and allows the laboratory to perform an array of clinical analyses on one specimen without the labor-intensive and risky process of aliquoting.

Two important barriers, however, limit the usefulness of larger chemistry analyzers: defining alternative yet acceptable specimens and coping with a plethora of proprietary nomenclatures.

The first challenge involves defining what constitutes an acceptable specimen. Laboratories traditionally have used serum separator tubes for most chemistries. Still in question, however, is whether therapeutic drugs can be measured in such tubes and which others are adsorbed by the separator gel at a rate that gives falsely low results. Likewise, what is the effect of plastic tubes? So why don’t vendors provide their clients with definitive information that is specific to their method?

In some settings, particularly intensive care and dialysis units, heparinized plasma separator tubes have advantages over serum, as plasma avoids the formation of fibrin strands seen in partially clotted serum derived from patients with unstable coagulation systems. But which of the more than 120 analytes available on a modern instrument can be run on heparinized plasma? For example, some iron methodologies don’t work in the presence of heparin. Others do. The package inserts seldom offer any help.

Outreach settings continue to be plagued by falsely high potassium values caused by potassium leaking from red cells, even after the cells are centrifuged in a separator tube. Some laboratories have observed that citrated plasma (blue top) tubes seem to keep potassium from leaking, and they have successfully measured potassium and many other analytes on specimen sent by overnight express delivery at room temperature. But, again, manufacturers need to help laboratories by identifying which of the 120 analytes can be measured using citrated plasma. One might assume that calcium would not work, but it may, depending on the method used. Manufacturers need to make such information available.

The second important barrier to workstation consolidation is the “Babel” of proprietary nomenclatures. For example, is ACET aceta- minophen? Acetone (acetoacetate)? Acetylcholinesterase (total)? Angiotensin converting enzyme (total)?

As numbers of analytes available on chemistry analyzers increases, it becomes more critical that orders be downloaded and results transmitted using a standard LOINC (Logical Observation Identifier Names and Codes) rather than an instrument-specific proprietary cipher.

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