Name of instrument: i-STAT 1 analyzer
Type of instrument: combination chemistry/immunoassay
Operational type/Model type: discrete/handheld
List price/First year sold in U.S.: $2,000
Targeted hospital bed size/Targeted test volume: 30,000> 10,000
Company manufactures instrument: yes
Other models in this family of analyzers: —
No. of units in clinical use in U.S./Outside U.S. (countries): —
Dimensions (W x H x D/instrument footprint:
Weight empty/Weight fully loaded: < 2 lbs./< 2 lbs./150 lbs./150 lbs./78 lbs./78 lbs.
No. of different measured assays onboard simultaneously: —
Test throughput per hour/Assay run time: —/2–10 min.

### Chemistry:
- No. of direct ion-selective electrode channels: up to 26
- Detection methods: potentiometry, amperometry, conductivity
- Stat time until completion/specimen throughput for:
  - Ion-selective electrode: 2 min./<20–25
  - Basic metabolic panel: 2 min./<20–25
  - Complete metabolic panel: —
- Typical time delay from ordering stat test until aspiration of sample: none
- Approximate No. of tests per reagent set/Reagent type:
- Reagents refrigerated onboard/Reagents ready to use: —/—
- Reagent lot tracking/Reagent inventory: no/no
- Reagent form/Reagents barcoded: dry chemistry, liquid chemistry (closed reagent system)/yes
- Separate reagent pack for each specimen/or each test run: yes
- Walkaway capability/Walkaway duration: yes/2–10 min. or 1 specimen or up to 13 tests
- Design of sample-handling system:
  - Uses washable cuvettes/Uses disposable cuvettes: no/no
  - Min. max. sample volume that can be aspirated at one time: 17–95 μL
  - Min. reaction volume/Min. specimen volume/Min. dead volume: no
  - Dedicated pediatric sample cup: no
  - Primary tube sampling: no
- Accommodates most standard tube sizes/Accepts nonstandard tube sizes: no/no
- Pierces caps on primary tubes: yes
- Protects against probe collision: yes
- Detects clot/liquid level/short sample: yes
- Detection or quantitation for hemolysis, icterus, lipemia, clots: detection for hemolysis, icterus, lipemia, clots
- Dilutes patient samples onboard/Susceptibility to carryover: no
- Automatic rerun capability: no
- Sample volume can be diluted to run out-of-range-high results: no
- Sample volume can be concentrated to run out-of-range-low results: no
- Analyzer requires dedicated water supply: yes
- Autocalibration/Multipoint calibration supported: yes
- Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays:
  - Onsite calibration: 3 hrs./—/—/—
  - Reagent calibration: yes/yess
  - QC/Calibrants placed onboard/off-board: yes
  - QC/Calibrants stored onboard/off-board: yes
- Automatic programmable start/Automatic programmable shutdown:
- Onboard real-time QC/Onboard software capability to review QC: yes
- Sample barcode-reading capability/Autodiscrimination:
- Lab can control analyzer from remote computer: yes
- Instrument can diagnose its own malfunctions: yes
- System malfunctions can be diagnosed via remote monitoring: yes
- UPS backup power supply: yes
- Data-management capability/LS or EHR systems interfaced:
- LIS interface provided/Directional interface capability: yes
- Modern servicing provided/Service engineer on-site response time: yes (additional cost)/—
- Mean time between failures:
- Average scheduled maintenance time by lab personnel: —
- Maintenance records kept onboard for user/vendor:
- Training included with purchased/agreement for basic user training:
- Advanced operator training/Extra charge for follow-up training or advanced training:
- Warranty provided/Cost of annual service contract (24 hrs/24 hrs):
- Distinguishing features (supplied by company):
  - handheld portable analyzer; unit uses system can perform chemistry, blood gas, cardiac marker, and coagulation tests
  - CLIA- waived menu of tests, including basic metabolic panel
  - uses 2–3 drops of whole blood or plasma
- Note: a dash in lieu of an answer means company did not answer question or question is not applicable

### Immunology:
- Fully automated microparticle immunoassay system:
- Methodologies supported:
- Separation methodologies: no
- Stat time until completion of a 8-NOC test:
- Typical time delay from test order to aspiration of sample: none
- Stat time until completion of a cTn test:
- Typical time delay from test order to aspiration of sample: none
- Approximate No. of tests per reagent set/Reagent type:
- Reagents refrigerated onboard/Reagents ready to use: —/—
- Reagent lot tracking/Reagent inventory: no/no
- Reagent form/Reagents barcoded: dry chemistry, liquid chemistry (closed reagent system)/yes
- Separate reagent pack for each specimen/or each test run: yes
- Walkaway capability/Walkaway duration: yes/2–10 min. or 1 specimen or up to 13 tests
- Design of sample-handling system:
  - Uses washable cuvettes/Uses disposable cuvettes: no/no
  - Min. max. sample volume that can be aspirated at one time: 17–95 μL
  - Min. reaction volume/Min. specimen volume/Min. dead volume: no
  - Dedicated pediatric sample cup: no
  - Primary tube sampling: no
- Accommodates most standard tube sizes/Accepts nonstandard tube sizes: no/no
- Pierces caps on primary tubes: yes
- Detects clot/liquid level/short sample: yes
- Detection or quantitation for hemolysis, icterus, lipemia, clots: detection for hemolysis, icterus, lipemia, clots
- Dilutes patient samples onboard/Susceptibility to carryover: no
- Automatic rerun capability: no
- Sample volume can be diluted to run out-of-range-high results: no
- Sample volume can be concentrated to run out-of-range-low results: no
- Analyzer requires dedicated water supply: yes
- Autocalibration/Multipoint calibration supported: yes
- Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays:
  - Onsite calibration: 3 hrs./—/—/—
  - Reagent calibration: yes/yess
  - QC/Calibrants placed onboard/off-board: yes
  - QC/Calibrants stored onboard/off-board: yes
- Automatic programmable start/Automatic programmable shutdown:
- Onboard real-time QC/Onboard software capability to review QC: yes
- Sample barcode-reading capability/Autodiscrimination:
- Lab can control analyzer from remote computer: yes
- Instrument can diagnose its own malfunctions: yes
- System malfunctions can be diagnosed via remote monitoring: yes
- UPS backup power supply: yes
- Data-management capability/LS or EHR systems interfaced:
- LIS interface provided/Directional interface capability: yes
- Modern servicing provided/Service engineer on-site response time: yes (additional cost)/—
- Mean time between failures:
- Average scheduled maintenance time by lab personnel: —
- Maintenance records kept onboard for user/vendor:
- Training included with purchased/agreement for basic user training:
- Advanced operator training/Extra charge for follow-up training or advanced training:
- Warranty provided/Cost of annual service contract (24 hrs/24 hrs):
- Distinguishing features (supplied by company):
  - handheld portable analyzer; unit uses system can perform chemistry, blood gas, cardiac marker, and coagulation tests
  - CLIA- waived menu of tests, including basic metabolic panel
  - uses 2–3 drops of whole blood or plasma
- Note: a dash in lieu of an answer means company did not answer question or question is not applicable

### Notes:
- List all information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.
### Beckman Coulter
**Name of instrument:** Access 2
**Type of instrument:** immunoassay

<table>
<thead>
<tr>
<th>Operational type/Model type</th>
<th>continuous random access/benchtop</th>
</tr>
</thead>
<tbody>
<tr>
<td>List price/First year sold in U.S.</td>
<td>$2,001/2009</td>
</tr>
<tr>
<td>Targeted hospital bed size/Targeted test volume</td>
<td>Unlisted/Unlisted</td>
</tr>
<tr>
<td>Company manufactures instrument</td>
<td>yes (also sold by McKesson, Henry Schein)</td>
</tr>
<tr>
<td>Other models in this family of analyzers</td>
<td>DxC 700 AU, AU5800</td>
</tr>
<tr>
<td>Dimensions (H × W × D)/Instrument footprint</td>
<td>19.5 × 39 × 24 in./additional clearance of 12 in. on left, 35 in. right, 2 in. rear, 30 in. top</td>
</tr>
<tr>
<td>Weight empty/Weight fully loaded</td>
<td>200 lbs./— 926 lbs./— 253 lbs./271 lbs.</td>
</tr>
<tr>
<td>No. of different measured assays onboard simultaneously</td>
<td>24/24 can be run and calibrated at one time</td>
</tr>
<tr>
<td>No. of user-definable (open chemistry) channels</td>
<td>0</td>
</tr>
<tr>
<td>Test throughput per hour/Assay run time</td>
<td>up to 100/13–55 min.</td>
</tr>
</tbody>
</table>

#### IMMUNOASSAY:

- **Fully automated microplate immunoassay system:** no
- **Methodologies supported:** chemiluminescence
- **Separation methodologies:** magnetic particle
- **Stat time until completion of a R-ICG test:** 15 min.
- **Typical time delay from test order to aspiration of sample:** 36 sec.
- **Typical time delay from stat test order to aspiration of sample:** 36 sec.
- **Approximate No. of tests per reagent set/Reagent type:** 50 per pack or 100 per kit/self-contained multistep
- **Reagents refrigerated onboard/Reagents ready to use:** yes (2–8°C)/yes
- **Reagent form/Reagents barcoded:** no
- **Separate reagent pack for each specimen/For each test run:** no
- **Walkaway capability/Walkaway duration:** yes/180 min. or 60 specimens
- **Design of sample-handling system:** rack
- **Primary tube sampling:** yes
- **Accommodates most standard tube sizes/Accepts nonstandard tube sizes:** no/yes
- **Pierces caps on primary tubes:** no
- **Protects against probe collision:** no
- **Detects clothes/liquid/short sample:** no/yes
- **Detection or quantification for hemolysis, icterus, Lippema, clots:** yes
- **Dilutes patient samples onboard/Susceptibility to carryover:** yes
- **Automatic rerun capability:** no
- **Sample volume can be diluted to rerun out-of-linear-range high results:** yes
- **Sample volume can be concentrated to rerun out-of-linear-range low results:** yes

#### Analyzer requires dedicated water supply
- **Autocalibration/Multipoint calibration supported:** no
- **Typical calibration frequency for ISE/therapeutic drugs/other drugs of abuse/general chemicals/Immunoassays:** no (calibrations are not stored onboard)/yes (recommended avg. frequency: 28 days)
- **Automatic programmable start/Automatic programmable shutdown:** no (< 5 min. start-up time)/no
- **Data-manageability capability/LIS or EHR systems interfaced:** yes (recommended instrument price)/yes (recommended instrument price)
- **Interface provided/Direct interface capability:** yes (interleaved 2 of 5; Codabar; Code 39; Code 128/no)
- **Modern servicing provided/Service engineer on-site response time:** yes (Interleaved 2 of 5; Codabar; Code 39; Code 128/no)
- **Mean time between failures:** yes (< 24 hrs.)
- **Average scheduled maintenance time by lab personnel:** yes (Interleaved 2 of 5; Codabar; Code 39; Code 128/no)
- **Maintenance records kept onboard for user/vendor:** yes (operator intervention required to order parts)
- **Maintenance training demonstration module onboard Training included with purchase/ and upgrade time for basic user training:** yes
- **Advanced operator training/Extra charge for follow-up/ or advanced training:** no
- **Warranty provided/Cost of annual service contract (24 h/7 d)**: yes (Interleaved 2 of 5; Codabar; Code 39; Code 128/no)

#### Training
- **Pierces caps on primary tubes:** no/no/yes
- **Protects against probe collision:** no/yes/yes
- **Detects clothes/liquid/short sample:** no/yes/yes
- **Detection or quantification for hemolysis, icterus, Lippema, clots:** yes/yes/yes
- **Dilutes patient samples onboard/Susceptibility to carryover:** yes/yes/yes
- **Automatic rerun capability:** no/yes/yes
- **Sample volume can be diluted to rerun out-of-linear-range high results:** yes/yes/yes
- **Sample volume can be concentrated to rerun out-of-linear-range low results:** yes/yes/yes
- **Analyzer requires dedicated water supply:** no/no/yes
- **Autocalibration/Multipoint calibration supported:** no/yes/no
- **Typical calibration frequency for ISE/therapeutic drugs/other drugs of abuse/general chemicals/Immunoassays:** no (calibrations are not stored onboard)/yes (recommended avg. frequency: 28 days)
- **Automatic programmable start/Automatic programmable shutdown:** no (< 5 min. start-up time)/no
- **Data-manageability capability/LIS or EHR systems interfaced:** yes (recommended instrument price)/yes (recommended instrument price)
- **Interface provided/Direct interface capability:** yes (interleaved 2 of 5; Codabar; Code 39; Code 128/no)
- **Modern servicing provided/Service engineer on-site response time:** yes (< 24 hrs.)
- **Mean time between failures:** yes (Interleaved 2 of 5; Codabar; Code 39; Code 128/no)
- **Average scheduled maintenance time by lab personnel:** yes (Interleaved 2 of 5; Codabar; Code 39; Code 128/no)
- **Maintenance records kept onboard for user/vendor:** yes (operator intervention required to order parts)
- **Maintenance training demonstration module onboard Training included with purchase/ and upgrade time for basic user training:** yes
- **Advanced operator training/Extra charge for follow-up/ or advanced training:** no
- **Warranty provided/Cost of annual service contract (24 h/7 d)**: yes (Interleaved 2 of 5; Codabar; Code 39; Code 128/no)

#### REFERENCES:
- **List of references:** Beckman Coulter
- **Last updated:** June 2020
**Chemistry and Immunoassay Analyzers**

### Part 3 of 7

<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>Type of instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>DS2 Automated ELISA System</td>
<td>Immunoassay</td>
</tr>
<tr>
<td>Envoy 500/Envoy 500+</td>
<td>Chemistry</td>
</tr>
<tr>
<td>Selectra ProM</td>
<td>Chemistry</td>
</tr>
</tbody>
</table>

### Dynex Technologies

**German Nunez**<br>703-803-1457, www.dynex.com

- **Operational type/Model type**: batch/benchtop
- **List price/First year sold in U.S.**: $57,607/2007
- **Targeted hospital bed size/Targeted test volume**: 32 beds/day; 105 tests/day
- **Company manufactures instrument**: yes (also sold by Fisher Scientific, Zeus Scientific, others)
- **Other models in this family of analyzers**: DSX
- **No. of units in clinical use in U.S./Outside U.S. (countries)**: 700/2,400 (Belgium, Czech Republic, Egypt, Germany, others)
- **Dimensions (H × W × D)**: 26 × 21 × 27 in./21.3 sq. ft. 105 lbs./—
- **Weight empty/Weight fully loaded**: up to 12 assays per microplate (up to 12 can be run)
- **No. of user-definable (open chemistry) channels**: —
- **Test throughput per hour/Assay run time**: 500 (40 can be active simultaneously)
- **Typical time delay from ordering test until aspiration of sample**: 4900—

### ELTechGroup

**Brandon Elggren**<br>401-642-8400, www.elttechgroup.com

- **List price/First year sold in U.S.**: $85,000/2005
- **Avg. frequency: 28 days**
- **Separate reagent pack for each specimen/for each test run**: no/yes
- **Uses washable cuvettes/Uses disposable cuvettes**: yes/no (can store up to 34 cuvettes) yes/no (can store up to 48 cuvettes)
- **Min.–max. sample volume that can be aspirated at one time**: 10–300 µL
- **Sample barcode-reading capability/Autodiscrimination**: yes/no
- **Sample volume can be concentrated to rerun out-of-linear-range analysis**: yes
- **Analyzer requires dedicated water supply**: no
- **Sample barcode-reading capability/Autodiscrimination**: yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)
- **Sample volume can be concentrated to rerun out-of-linear-range analysis**: yes
- **Mean time between failures**: 250 days (displays error codes for troubleshooting)
- **Distinguishing features (supplied by company)**: runs any assay from any vendor—fully automated open system

### Smithfield

**Selectra ProM**<br>25,000

- **List price/First year sold in U.S.**: $64,375/2012
- **Avg. frequency: 28 days**
- **Separate reagent pack for each specimen/for each test run**: no/yes
- **Uses washable cuvettes/Uses disposable cuvettes**: yes/no (can store up to 34 cuvettes) yes/no (can store up to 48 cuvettes)
- **Min.–max. sample volume that can be aspirated at one time**: 10–300 µL
- **Sample barcode-reading capability/Autodiscrimination**: yes/no
- **Sample volume can be concentrated to rerun out-of-linear-range analysis**: yes
- **Mean time between failures**: 250 days (displays error codes for troubleshooting)
- **Distinguishing features (supplied by company)**: runs any assay from any vendor—fully automated open system

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**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. See captodayonline.com/chem-immuno-poc-low for an interactive version of guide.
<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>Type of instrument</th>
<th>Gold Standard Diagnostics</th>
<th>Pentrace C400</th>
<th>Yumizen C1200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operational type/Model type</td>
<td>batch/benchtop</td>
<td>batch, random access, continuous random access, discrete/ benchtop</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>List price/First year sold in U.S.</td>
<td>$100,000/2006</td>
<td>$179,800/2020</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Targeted hospital bed size/Targeted test volume</td>
<td>---</td>
<td>&lt; 300; daily: 9,520; monthly: 17,000; annual: 2 million</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Company manufacturing instrument</td>
<td>---</td>
<td>yes (also sold by distribution partners)</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dimensions (H × W × D)/Instrument footprint</td>
<td>22 × 19 × 21 in./8 sq. ft.</td>
<td>---</td>
<td>44 × 48 × 33.5 in.---</td>
<td>---</td>
</tr>
<tr>
<td>Weight empty/Weight fully loaded</td>
<td>60 lbs./110 lbs.</td>
<td>---</td>
<td>992 lbs.---</td>
<td>---</td>
</tr>
<tr>
<td>No. of different assays onboard simultaneously</td>
<td>open EA platform (up to 12 plus 2 with a single wash, nine neons and common incubation temperature, plate frame type)</td>
<td>---</td>
<td>45 (can be run and calibrated at any time)</td>
<td>---</td>
</tr>
<tr>
<td>No. of user-definable (open chemistry) channels</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Test throughput per hour/Assay run time</td>
<td>assay dependent (96 tests in throughput/20 min.-4 hr. (avg. 2 hr.)</td>
<td>420 (4 tests in throughput/1–10 min. (avg. 5 min.)</td>
<td>---</td>
<td></td>
</tr>
</tbody>
</table>

**Chemistry:**

| No. of direct ion-electrode select channels | --- | --- | --- |
| Detection methods | --- | --- | --- |
| Stat time until completion/specimen throughput for: | --- | --- | --- |
| ″Ion-selective electrode″ | --- | --- | --- |
| Basic metabolic panel | --- | --- | --- |
| Complete metabolic panel | --- | --- | --- |
| Typical time delay from ordering start test until aspiration of sample | --- | --- | --- |

**Immunassay:**

| Fully automated microparticle immunassay system | yes (96 tests per unit; 96 wells per microplate) | 3 photometry, potentiometry, enzyme immunassay | 3 photometry, potentiometry, immunoturbidimetry |
| Methodologies supported | --- | --- | --- |
| Separation methodologies | --- | --- | --- |
| Stat time until completion of a R-HCG test | --- | --- | --- |
| Stat time until completion of a 24- hr. test | --- | --- | --- |
| Typical time delay from test order to aspiration of sample | --- | --- | --- |

**Approximate No. of tests per quarter set/Reagent type**

| Reagents refrigerated onboard/Reagents ready to use | --- | 100–400/self-contained multilane; open reagent system | 500–2,200/self-contained multilane; open reagent system |
| Reagent lot tracking/Reagent inventory | --- | yes (2–8°C); variable; reagent specific | yes (2–8°C); variable; reagent specific |
| Reagent form/Reagents barcoded | --- | yes (liquid chemistry open reagent system)/no | yes (liquid chemistry open reagent system)/yes |
| Separate reagent pack for each specimen/for each test run | --- | no/yes | no/yes |
| Walkaway capability/Walkaway duration | --- | --- | --- |

**Design of sample-handling system**

| Uses washable cuvettes/Uses disposable cuvettes | yes/no | --- | --- |
| Min. -max. sample volume that can be aspirated at one time | 1–300 µL | --- | --- |
| Min. reaction volume/Min. specimen volume/Min. dead volume | 25 μL/150 µL/150 μL | --- | --- |
| Dedicated pediatric sample cup | no | no | --- |

**Primary tube sampling**

| Accommodates most standard tube sizes/Accepts nonstandard tube sizes | --- | --- | --- |
| Pierces caps on primary tubes | yes/no | --- | --- |
| Protects against probe collision | yes/no | --- | --- |
| Detects clots/liquid level/short sample | yes/no | --- | --- |
| Detection or quantification for hemolysis, icterus, lipemia, clots | yes/no | --- | --- |
| Dilutes patient samples onboard/Susceptibility to carryover | yes/no | --- | --- |

**Automatic rerun capability**

| Sample volume can be diluted to rerun out-of-line-range high results | --- | --- | --- |
| Sample volume can be concentrated to rerun out-of-line-range low results | --- | --- | --- |

**Analyzer requires dedicated water supply**

| Water management | --- | --- | --- |
| Autocalibration/ Multipoint calibration supported | --- | --- | --- |

**Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemicals/Immunoassays**

| Automatic programmable start/ Automatic programmable shutdown | no (5 min. start-up time)/no | --- | --- |
| Onboard real-time QC/Onboard software capability to review QC | yes | --- | --- |

**Sample barcode-reading capability/Autodiscrimination Lab**

| Sample barcode-reading capability/Autodiscrimination Lab | yes/unspecific/no | --- | --- |
| Test throughput per hour/Assay run time | yes/48 hrs. | --- | --- |

**Mean time between failures**

| Average scheduled maintenance time by lab personnel | --- | --- | --- |
| Maintenance records kept onboard for user/vendor Maintenance training demonstration module onboard Training included with purchase/Avg. time for basic user training | --- | --- | --- |
| Advanced operator training/Extra charge for full-up or advanced training Warranty provided/ Cost of annual service contract (24-hr) service | --- | --- | --- |

**Distinguishing features (supplied by company)**

- open architecture; program any EIA or CLIA protocol, fully customizable with flexible, intuitive software
- space saving: high capacity (96 samples) in 2 ft. × 2 ft. footprint
- cost saving: low instrument price with no routine consumables required
- can run up to 55 assays onboard with 420 results/hr.
- no requirement for external water system; no drain or special electrical required; remote diagnostics available for real-time troubleshooting
- flexible, open-channel system capable of running ≤ 40 third-party reagents onboard; self-contained disposable reaction cuvettes ensure low exposure to infectious waste

**Additional Information:**

- big lab automation in a small footprint; processes 1,200 tests per hour, up to 2 million tests annually
- 100 user-definable channels
- flexible maintenance schedule

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.
**Name of instrument**
HYTEC 288 PLUS

**Type of instrument**
immunassay

**Operational type/Model type**
batch/benchtop

**Last price/First year sold in U.S.**
$85,000/1999

**Targeted hospital bed size/Targeted test volume**
200/variable

**Company manufactures instrument**
no (yes also sold by distribution partners)

**Other models in this family of analyzers**

**No. of units in clinical use in U.S./Outside U.S. (countries)**
> 100–200 (Canada, Europe, Middle East, South America)

**Dimensions (ft × W × D)/Instrument footprint**
29.5 × 42.5 × 27.5 in./8 sq. ft.

**Weight empty/Weight fully loaded**
198 lbs./198 lbs.

**No. of different measured assays onboard simultaneously**
up to 288 (up to 288 can be run and calibrated at one time)

**Test throughput per hour/Assay run time**
48 (288 tests in throughput)/6 hrs.

**Chemistry**

| No. of direct ion-selective electrode channels | — |
| Detection methods | — |
| Stat time until completion/specimen throughput for: | — |
| • Ion-selective electrode | — |
| • Basic metabolic panel | — |
| • Complete metabolic panel | — |

**Typical time delay from ordering stat test until aspiration of sample**
1 min.

**Immunassay:**

| Fully automated microplate immunassay system | no |
| Methodologies supported | enzyme immunassay |

**Separation methodologies**

**Stat time until completion of a CBC test**

**Typical time from test to result of aspiration of sample**

**Stat time until completion of a C7 test**

**Typical time from test to result of aspiration of sample**

**Approximate No. of tests per reagent set/Reagent type**
20 or 10/self-contained multiuse

**Reagents refrigerated onboard/Reagents ready to use**
no/yes

**Reagent lot tracking/Reagent inventory**
yes/no

**Uses washable cuvettes/Uses disposable cuvettes**
no/yes

**Min.–max. sample volume that can be aspirated at one time**
50 µL maximum

**Min. reaction volume/Min. specimen volume/Min. dead volume**
10 µL/50 µL/100 µL

**Max.–max. sample volume that can be aspirated at one time**
2–25 µL

**Min. reaction volume/Max. specimen volume/Max. dead volume**
150 µL/2 µL/100 µL

**Dilutes patient samples onboard/Susceptibility to carryover**
yes/no

**Complete metabolic panel**
yes/no

**Pierce caps on primary tubes**
yes/no

**Detects clinical/liquid level/short sample**
no/no

**Hemosiderin, icterus, lipemia, clots not available**
yes/no

**Can be programmed to perform dilutions prior to analysis/≤ 1 part per 10,000**
yes/no

**Automatic phosphatase capability**
yes/no

**Analyzer requires dedicated water supply**
yes/no

**Autocalibration/Multipoint calibration supported**
no

**Typical calibration frequency for ISE/therapeutic drugs**
no/yes (recommended avg. frequency: monthly)

**Supports multiple ISE lot numbers per analyte**
no

**Waste management**

**Sample barcode-reading capability/Autodiscrimination**

**Lab can control analyzer from remote computer**
yes

**Instrument can diagnose its own malfunctions**
no

**System malfunctions can be diagnosed via remote monitoring**
no

**UPS backup power supply**
yes

**Data-management capability/LIS or EHR systems interfaced**
no

**LIS interface provided/8-directional interface capability**
no

**Modem servicing provided/Service engineer on-site response time**
o

**Mean time between failures**
210 days (displays error codes for troubleshooting)

**Average scheduled maintenance time by lab personnel**

**Maintenance training demonstration module onboard**
no

**Training included with purchase/Avg. time for basic user training**
yes (2 training slots)/2 days (at customer site)

**Advanced operator training/Extra charge for follow-up or advanced training**
no

**Warranty provided/Cost of annual service contract**
yes (1 year)

**Distinguishing features (supplied by company)**

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

**Maintenance records kept onboard for user/vendor**
yes/no

**NIST traceability**
no

**Prime ES**

| Approximate No. of tests per reagent set/Reagent type | 20 or 10/self-contained multiuse |
| Uses washable cuvettes/Uses disposable cuvettes | no/yes |
| Min.–max. sample volume that can be aspirated at one time | 50 µL maximum |
| Min. reaction volume/Max. specimen volume/Max. dead volume | 10 µL/50 µL/100 µL |
| Dilutes patient samples onboard/Susceptibility to carryover | yes/no |
| Analyzer requires dedicated water supply | no |
| Autocalibration/Multipoint calibration supported | no |
| Typical calibration frequency for ISE/therapeutic drugs | yes (recommended avg. frequency: monthly) |
| Supports multiple ISE lot numbers per analyte | no |
| Waste management | no |
| Sample barcode-reading capability/Autodiscrimination | yes (Codabar, Code 39) |
| Lab can control analyzer from remote computer | yes |
| Instrument can diagnose its own malfunctions | no |
| System malfunctions can be diagnosed via remote monitoring | no |
| UPS backup power supply | yes |
| Data-management capability/LIS or EHR systems interfaced | no |
| LIS interface provided/8-directional interface capability | yes (additional costs/yes host query) |
| Modem servicing provided/Service engineer on-site response time | no/within 48 hrs. |
| Mean time between failures | 210 days (displays error codes for troubleshooting) |
| Average scheduled maintenance time by lab personnel | daily: 10–15 min.; weekly: 20–25 min.; monthly: 20–25 min. |
| Maintenance training demonstration module onboard | no |
| Training included with purchase/Avg. time for basic user training | yes (2 training slots)/2 days (at customer site) |
| Advanced operator training/Extra charge for follow-up or advanced training | no |
| Warranty provided/Cost of annual service contract | yes (1 year) |
| Distinguishing features (supplied by company) | • menu • ease of use • quality of results • easy to learn and use icon-driven touchscreen user interface • read and write radio frequency identification of reagents for automated tracking of stability and calibrations • limited maintenance and user-serviceable parts • maintenance-free MicroSensor Card and disposable cartridge technology for sensors and reagents • broad menu including 8µg, BUN, creatinine, non-lyzing CO-oximetry • automated, liquid QC and supplemental quality monitoring for EP23A compliance and real-time verification of all analytical components during calibration, sample analysis, QC analysis |

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

**Name of instrument**

| HYCOR Biomedical | Medica Corp. | Nova Biomedical |
| Lorraine Damico | Charlene Soley | info@novabiomedical.com |
| 800-382-2527 | 781-275-4892 | 800-458-5813 |

**Description**

- All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.
- See captodayonline.com/chem-immuno-poc-low for an interactive version of this.
### Chemistry and Immunoassay Analyzers

**Name of instrument**: VITROS XT 3400 Chemistry Systems chemistry  
**Type of instrument**: chemistry  
**Company**: Ortho Clinical Diagnostics  
**Address**: Raritan, NJ  
**Website**: www.orthoclinicaldiagnostics.com

<table>
<thead>
<tr>
<th>Operational type/Model type</th>
<th>batch, random access, continuous random access, discrete/standing</th>
<th>random access, continuous random access/standing</th>
</tr>
</thead>
<tbody>
<tr>
<td>List price/First year sold in U.S.</td>
<td>—/2019</td>
<td>2009</td>
</tr>
<tr>
<td>Targeted hospital bed size/Targeted test volume</td>
<td>no (manufactured by JERL; also sold by Cardinal, McKesson, more)</td>
<td>no (manufactured by Hitachi High-Technologies)</td>
</tr>
<tr>
<td>Other models in this family of analyzers</td>
<td>VITROS 4600 Chemistry System, VITROS 350 Chemistry System</td>
<td>—</td>
</tr>
<tr>
<td>No. of units in clinical use in U.S./Outside U.S. (countries)</td>
<td>&gt; 30/0</td>
<td>&gt; 30/0</td>
</tr>
<tr>
<td>Dimensions (H × W × D)/Instrument footprint</td>
<td>53 in. × 58 in. × 34 in.</td>
<td>50 in. × 32 in. × 8.5 ft.</td>
</tr>
<tr>
<td>Weight empty/Weight fully loaded</td>
<td>1,150 lbs.</td>
<td>551 lbs.</td>
</tr>
<tr>
<td>No. of different measured assays onboard simultaneously</td>
<td>89</td>
<td>42</td>
</tr>
<tr>
<td>Test throughput per hour/Assay run time</td>
<td>1,130/5-9 min. (avg. 5 min.)</td>
<td>up to 300/300 tests in throughput/3–10 min. (avg. 7 min.)</td>
</tr>
</tbody>
</table>

**Chemistry**

| No. of direct ion-selective electrode channels | 3 | 3 |
| Detection methods | photometry, potentiometry, turbidimetric | photometry, potentiometry |
| Time interval between calibration | 5 min./726 samples per hr. | 5 min./150 samples per hr. |
| Typical time delay from ordering stat test until aspiration of sample | 1 min. | < 1 min. |

**Immunoassay**

| Fully automated microplate immunoassay system | — | — |
| Methodologies supported | — | — |
| Separation methodologies | — | — |
| Time until completion of a 8-HCg test | — | — |
| Typical time delay from test to order aspiration of sample | — | — |
| Time until completion of an AFT test | — | — |
| Typical time delay from order to aspiration of sample | — | — |

**Design of sample-handling system**

| Use washable cuvettes/Use disposable cuvettes | yes | yes |
| Min. vs. min. volume that can be aspirated at one time | 2–200 µL | 1–35 µL |
| Min. reaction volume/Min. specimen volume/Min. dead volume | yes (dead volume: 35 µL) | yes (dead volume: 50 µL) |
| Dedicated pediatric sample cup | yes | yes |
| Primary tube sampling | yes | yes |
| Accommodates most standard tube sizes/Accepts nonstandard tube sizes | yesyes (micro sample cups, micro collection containers, 10.25 × 5 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, more) | yesyes (12 × 100 mm) |
| Piers caps on primary tubes | no | no |
| Protects against probe collision | yes | yes |
| Detects clots/liquid level/short sample | yes | yes |
| Detection or quantitation for heme, icterus, icterus, icterus | yes | yes |
| Dilutes patient samples onboard/Susceptibility to carryover | — | — |

**Automatic rerun capability**

| Sample volume can be clipped to rerun out-of-line-range high results | yes | yes |
| Sample volume can be concentrated to rerun out-of-line-range low results | yes | yes |

**Analyzer requires dedicated water supply**

| Water supply supported | no | yes |
| Water supply supported | no | yes |

**Typical calibration frequency for ISE/therapeutic drugs**

| Typical calibration frequency for ISE | 6 months or lot change | 24 hrs. [ISE]; once per lot [chemistry] |
| Typical calibration frequency for therapeutic drugs | 6 months/6 months/6 months/6 months/6 months/6 months/6 months/6 months | 24 hrs./per lot/6 per lot/6 per lot |

**Sample barcode-reading capability/Autodiscrimination**

| Sample barcode-reading capability | yes | yes |
| Sample barcode-reading capability | yes | yes |
| Sample barcode-reading capability | yes | yes |

**Manual cleaning/disinfection capability**

| Manual cleaning/disinfection capability supported | yes | yes |

**Waste management**

| Waste management | yes | yes |

**Sample processing time**

| Mean time between failures | — | 24 hrs. |
| Average scheduled maintenance time by lab personnel | — | 24 hrs. |
| Maintenance records kept onboard for user/vendor | — | 24 hrs. |
| Maintenance training demonstration module onboard | — | 24 hrs. |
| Training included with purchase/Aug. time for basic user training | yes (training slot)/4 days (at both vendor and customer sites) | yes (1 training slot)/1 day (at both vendor and customer sites) |

**Choosing features (supplied by company)**

| Incorporates digital reflectometry to process two unique chem assays simultaneously on one XT Microslide | yes (1 training slot)/1 day (at both vendor and customer sites) | yes (1 year)/configuration dependent |
| Waterless system with single-use disposable tips for sample and reagent mixing/eliminates sample and reagent carryover | yes (at vendor site)/yes | yes (1 year)/configuration dependent |
| Microsensor technology detects HIL and turbidity without using reagents or additional sample and time | yes (at vendor site)/yes | yes (1 year)/configuration dependent |

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

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See captodayonline.com/chem-immuno-poc-low for an interactive version of guide.
### Name of instrument
- **FastPack IP Immunoassay Analyzer**
- **AA-360**

### Type of instrument
- Immunoassay
- Immunoassay

### Operational type/Model type
- random access/benchtop
- continuous random access/benchtop

### List price:
- $29,137/29,137
- $24,900/24,900

### Targeted hospital bed size:
- 12
- 21

### Targeted test volume:
- 12.5 L
- 12.5 L

### Company manufactures instrument:
- no (manufactured by Qualigen)
- no (manufactured by Tosoh Corp.)

### Other models in this family of analyzers:
- no
- no

### Dimensions (ft x W x D/instrument footprint):
- 13 x 9 x 12 in.
- "6 x 18 in.

### Weight empty/Weight fully loaded:
- 100 lbs.
- 100 lbs.

### No. of different measured assays onboard simultaneously:
- 1
- 1

### No. of user-definable (open chemistry) channels:
- 1
- 1

### Test throughput per hour/Assay run time:
- 4/12 min.
- 4/10 min.

### Chemistry:
- No. of direct ion-selective electrode channels:
- —
- —

### Detection methods:
- —
- —

### Stat time until completion/specimen throughput for:
- No.
- No.

### Stat time until completion of a C/I test:
- 12 min.
- 20 min.

### Typical time delay from test order to aspiration of sample:
- —
- —

### Typical time delay from stat test until aspiration of sample:
- —
- —

### Approximate No. of tests per reagent set/Reagent type:
- 30/self-contained single use
- 100 (20 tests per tray/unit dose test cup)

### Reagents refrigerated onboard/Reagents ready to use:
- yes
- yes

### Reagent lot tracking/Reagent inventory:
- no
- no

### Reagents refrigerated onboard/Reagents ready to use:
- yes
- yes

### Reagent form/Reagents barcoded:
- liquid chemistry (closed reagent system)/yes
- dry chemistry (closed reagent system)/yes
dry chemistry (closed reagent system)/yes

### Design of sample-handling system:
- test pack
- carousal

### Uses washable cuvettes/Uses disposable cuvettes:
- no
- no

### Min.-max. sample volume that can be aspirated at one time:
- 100 µL
- 10–500 µL

### Min. reaction volume/Min. specimen volume/Min. dead volume:
- 100 µL
- 100 µL

### Min.–max. sample volume that can be aspirated at one time:
- 100 µL 10– 500 µL

### Detection or quantitation for hemolysis, icterus, lipemia, clots:
- hemolysis, icterus, lipemia, clots not available
- yes/no

### protects against probe collision:
- no
- yes

### Dilutes patient samples onboard/Susceptibility to carryover:
- no/no/no/no
- yes/no/yes/yes

### Sample volume can be diluted to rerun out-of-linear-range high results:
- yes
- no

### Sample volume can be concentrated to rerun out-of-linear-range low results:
- no
- —

### Analyzer requires dedicated water supply:
- no
- no

### AutoCalibration/Reagent calibration supported:
- no
- no (calibrants are not stored onboard/yes (recommended avg. frequency: 4 weeks)

### Typical calibration frequency for ISE/therapeutic drugs/diagnosis:
- no
- yes

### Min.
- yes
- yes

### Min. sample volume:
- yes
- yes

### System malfunctions can be diagnosed via remote monitoring:
- no
- yes

### UPS backup power supply:
- —
- yes

### Data-management capability/LIS or EHR systems interfaced:
- optional add-on
- yes

### Reagent form/Reagents barcoded:
- liquid chemistry (closed reagent system)/yes
- dry chemistry (closed reagent system)/yes

### Supports multiple QC lot numbers per analyte:
- no
- no

### Onboard real-time QC/Onboard software capability to review QC:
- no
- no

### See chemistry and immunoassay analyzers.
- yes
- yes

### Min. reaction volume:
- 100 µL
- 100 µL

### Average scheduled maintenance time by lab personnel:
- yes
- yes

### Maintenance records kept onboard for user/vendor:
- yes
- yes

### Maintenance training demonstration module onboard:
- no
- no

### Training included with purchase:
- yes
- yes

### Advanced operator training:
- no
- yes

### Warranty provided/End-of-life support:
- yes
- 1 year

### Mean time between failures:
- —
- > 6 months

### Average scheduled maintenance time by lab personnel:
- —
- 6 months

### Maintenance records kept onboard for user/vendor:
- —
- 6 months

### Maintenance training demonstration module onboard:
- —
- 6 months

### Training included with purchase:
- —
- 6 months

### Advanced operator training:
- —
- 6 months

### Warranty provided:
- yes
- yes

### Distinguishing features (supplied by company):
- designed for physician office laboratory use
- designed for physician office laboratory use

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