Advance the potential of your cell culture
Cedex Bio and Cedex Bio HT Analyzers
The value of certainty
Cedex Bio and Cedex Bio HT Analyzers

Understanding the challenges of bioprocess monitoring

Whether you are working in the pharmaceutical or biotech industry, you always value the safety and confidence of monitoring and analyzing cell culture with state of the art solutions.

As one of the leaders in the diagnostics and pharmaceutical field, Roche has first-hand experience with challenges in biomanufacturing. That knowledge, plus many years of competence in designing diagnostic tests and engineering analyzer systems, are the foundation for the Cedex Bio Analyzer family from Roche CustomBiotech.

The Cedex metabolite analyzers are based on enzymatic assays, enabling high robustness and sensitivity as well as optimized measurement ranges, adapted to the particular demands of cell culture and fermentation processes. Thus, you can rely on one instrument family to capture useful and timely insights into your bioprocess and make the right decisions for optimal manufacturing outcomes.

We continuously improve the performance and level of integration of our analyzers to support you with reliable and up-to-date instruments. Moreover we are offering a comprehensive test menu we are constantly evolving according to the user needs, so you can flexibly monitor multiple and modern parameters in your bioprocess without having to develop new assays on your own or purchase additional instruments.

Act on predictability and accuracy

Ultimately, having a bioprocess under control means pre-dicting changes in cell cultivation and fermentation that can impact product yield and quality. This is especially true when running the bioprocess within narrow specifications, such as under substrate-limiting conditions. High predictability requires precise and accurate data that reflect the actual conditions in a bioreactor, even at low analyte concentrations. Compared to membrane-based analyzers, the Cedex Bio Analyzers offer significantly higher reproducibility, accuracy and precision (Figure 1). For example, you can rely on the monitoring results to indicate the right time points for substrate bolus shots or harvest.

Figure 1: Recovery of glucose concentration was determined in parallel using the Cedex Bio HT Analyzer and a membrane analyzer (Roche evaluation data).
See relevant information in time

Information about the conditions in a cell culture must be available in time to enable controlled processing with optimal manufacturing outcome. Thus, the Cedex Bio Analyzers offer an assortment of assays, some designed specifically to determine the product yield and quality throughout the fermentation process. Quantify IgG levels in minutes and with the same accuracy as the gold standard HPLC (Figure 2).

In addition, determine lactate dehydrogenase (LDH) as a sensitive control for cell integrity. A rising LDH activity in the culture medium is an early indicator of cell lysis, which is combined with the release of intracellular proteases, glucosidases and other degrading proteins, generating a considerable risk for the yield and quality of the valuable product.

Count on answers, every time

Cedex Bio Analyzers were developed based on industry-proven diagnostic technology. Adapted to support process development and large-scale production at Roche Pharmaceuticals, each instrument withstands the demanding conditions in the daily bioprocessing, with need for high robustness and minimal manual interaction.

The flexible capabilities for automated sample pre-dilution, the long on-board stabilities of the reagents and the long calibration intervals, the dedicated multi-analyte calibrators and controls, and the identification of reagents and samples via barcodes, make Cedex Bio Analyzers a perfect match for highly efficient process monitoring.
Powerful, flexible and comprehensive cell culture profiling
Cedex Bio and Cedex Bio HT Assays

Find answers you need, with a comprehensive test panel

Each available assay facilitates tight control of biopharmaceutical manufacturing, and new assays are consecutively added to the menu based on industry knowledge and requests from customers. Thus, with a single platform, you have continuously increasing testing flexibility and insights to optimize your bioprocess.

Culture control for mammalian cells, bacteria, yeast & insect cells

Substrates
- Ala-Gln (GlutaMAX)
- Calcium
- Cholesterol
- Ethanol
- Galactose
- Glucose
- Glutamate
- Glutamine
- Glycerol
- Iron
- Magnesium
- Phosphate
- Potassium
- Pyruvate
- Sodium
- Sucrose

Metabolites
- Acetate
- Ammonia
- Formate
- Lactate
- LDH
- Osmolality calc.

Products
- Ig Fab (human)
- IgG (human)
- Mouse IgG
- Optical Density (bio mass)
- Total Protein

Additional assays are in development.
Visit custombiotech.roche.com/cedex for updates or contact your local CustomBiotech team.
Select the right analyzer to optimize your bioprocess workflow

**Different specifications, identical test results**

<table>
<thead>
<tr>
<th>Cedex Bio Analyzer</th>
<th>Cedex Bio HT Analyzer</th>
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<tbody>
<tr>
<td><strong>Throughput</strong></td>
<td></td>
</tr>
<tr>
<td>50 - 100 tests per hour</td>
<td>200 - 400 tests per hour</td>
</tr>
<tr>
<td><strong>Sample capacity</strong></td>
<td></td>
</tr>
<tr>
<td>up to 8 samples at once (continuous loading)</td>
<td>up to 96 + 30 samples at once (continuous loading)</td>
</tr>
<tr>
<td><strong>Test kit capacity</strong></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>32</td>
</tr>
<tr>
<td><strong>Daily maintenance</strong></td>
<td></td>
</tr>
<tr>
<td>&quot;semi-automated&quot;, &lt; 5 min minutes hands on</td>
<td>automated</td>
</tr>
<tr>
<td><strong>Automated on-board sample dilution</strong></td>
<td></td>
</tr>
<tr>
<td>selectable dilution</td>
<td>freely programmable</td>
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</table>

*Cedex Bio and Cedex Bio HT Analyzers deliver consistent results*

Although the two analyzers differ in throughput and certain aspects you can rely on equivalent results. High correlation between the Cedex Bio and the Cedex Bio HT Analyzer has been proven for all assays.

![Figure 3: Comparison of the Cedex Bio and Cedex Bio HT Analyzer showing the same recovery of glucose (Roche evaluation data).](image-url)
Cedex Bio Analyzer
Small footprint, big impact

A reliable, high-quality instrument for small sample throughput

- **Small size**: Benchtop system suitable for any space
- **Easy handling**: Sophisticated and intuitive operating software
- **Integrated processing unit**: Built-in touchscreen reduces qualification effort
- **Reliable answers**: Robust and proven technology
- **Efficiency**: Low maintenance effort and frequency save time and money

Cedex Bio and Bio HT Analyzer

- Same menu of enzymatic assays with high specificity and sensitivity
- LIMS connectivity through middleware systems with complete traceability and regulatory compliance
Cedex Bio HT Analyzer

High efficiency, fast action

*The right instrument for improved workflow efficiency*

- **High throughput:** Numerous samples can be processed simultaneously with minimal manual intervention
- **Enhanced flexibility with the 96-well Upgrade Kit:**
  - Use 96-well plates or conventional racks (total capacity: up to 96 + 30 samples)
  - Boosts processing safety and efficiency, minimizing overall hands-on time (e.g., 96 glucose assays in 35 min)
  - Designed for manual or robotic loading of 96-well plates
- **Long-term operation:** Long time on-board stability of reagents and assay cal
- **Flexible dilution:** Automated sample dilution capabilities save time and accuracy
- **Full automation:** Online integration with automated systems to optimize measurement points and timelines

**Figure 4:** Process integration and automation capabilities with Cedex Bio HT and Cedex HiRes Analyzer

*Various integration systems are available. **Sm@rtline Data Cockpit is provided by AGU, Leverkusen, Germany*
Ordering information

<table>
<thead>
<tr>
<th>Product</th>
<th>Catalog number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cedex Bio Analyzer</td>
<td>06 395 554 001</td>
</tr>
<tr>
<td>Cedex Bio HT Analyzer</td>
<td>06 608 116 001</td>
</tr>
<tr>
<td>Kit 96-well plate Cedex</td>
<td>09 181 687 001</td>
</tr>
<tr>
<td>Rack 96-well plate Cedex</td>
<td>09 241 400 001</td>
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The ordering information for all Cedex Bio Analyzer and Cedex Bio HT Analyzer assays is available on custombiotech.roche.com

Regulatory disclaimer
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