



Advance the  
potential of your  
cell culture

Cedex® Bio and  
Cedex® Bio HT Analyzers

# The value of certainty with the Cedex<sup>®</sup> Bio and Cedex<sup>®</sup> 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.

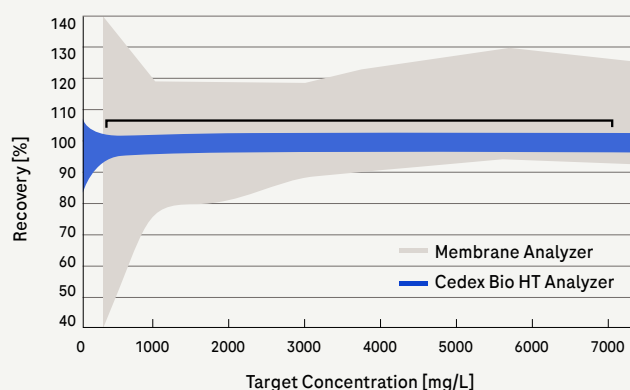
As one of the leaders in the diagnostics and pharmaceutical field, Roche has first-hand experience with challenges in biomanufacturing. That knowledge, plus many years of competence in designing diagnostic tests and engineering analyzer systems, are the foundation for the Cedex Bio Analyzer family from 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 predicting 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 (Fig. 01). For example, you can rely on the monitoring results to indicate the right time points for substrate bolus shots or harvest.



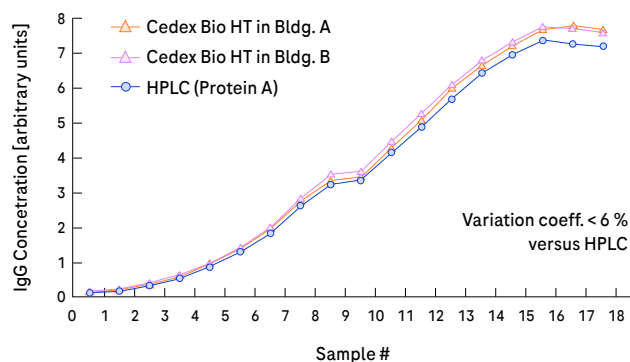
01

**Precision in metabolite testing - comparison with membrane technology in glucose analysis:** 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 (Fig. 02).

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.



02

**IgG: Cedex Bio HT vs HPLC:** Results comparable to HPLC. The IgG titer in the culture medium was monitored over a production period of 18 days. Samples were analyzed in parallel using HPLC (Protein A) and two Cedex Bio HT Analyzers in separate locations (bldg. A/B). The consistent results represent the perfect precision and the equivalence of the methods (Roche evaluation data).

### 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

## 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		Metabolites	Products
Ala-Gln (GlutaMAX)	Glycerol	Acetate	Ig Fab (human)
Arabinose	Iron	Ammonia	IgG (human)
Asparagine	Magnesium	Formate	Mouse IgG
Aspartate	Methanol	Lactate	Optical Density (bio mass)
Calcium	Nitrate	LDH	Total Protein
Cholesterol	Phosphate	Osmolality calc.	
Ethanol	Potassium	Urea	
Galactose	Pyruvate		
Glucose	Sodium		
Glutamate	Sucrose		
Glutamine			

Additional assays are in development.

Visit [custombiotech.roche.com/cedex](https://custombiotech.roche.com/cedex) for updates or  
contact your local CustomBiotech team representative.

Select the right analyzer to optimize your bioprocess workflow. Different specifications, identical test results.



#### Cedex® Bio Analyzer

50 – 100 tests per hour

up to 8 samples at once  
(continuous loading)

13

“semi-automated”  
< 5 min minutes hands on

selectable dilution

#### Throughput

#### Sample capacity

#### Test kit capacity

#### Daily maintenance

#### Automated on-board sample dilution

#### Cedex® Bio HT Analyzer

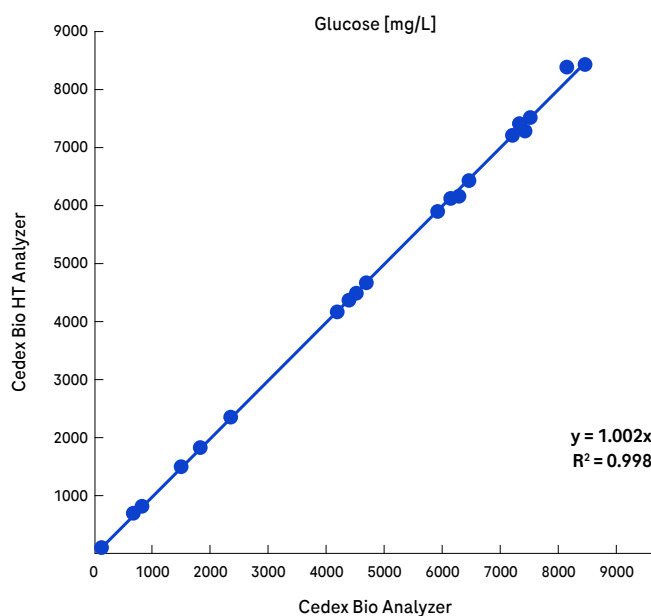
150 – 300 tests per hour

up to 96 + 30 samples at once  
(continuous loading)

32

automated

freely programmable



#### 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. Both systems can be connected to LIMS through middleware solutions with complete traceability and regulatory compliance.

03

Comparison of the Cedex Bio and Cedex Bio HT Analyzer showing the same recovery of glucose (Roche evaluation data).

# Cedex<sup>®</sup> Bio Analyzer

Small footprint, big impact. A reliable, high-quality instrument for small sample throughput.

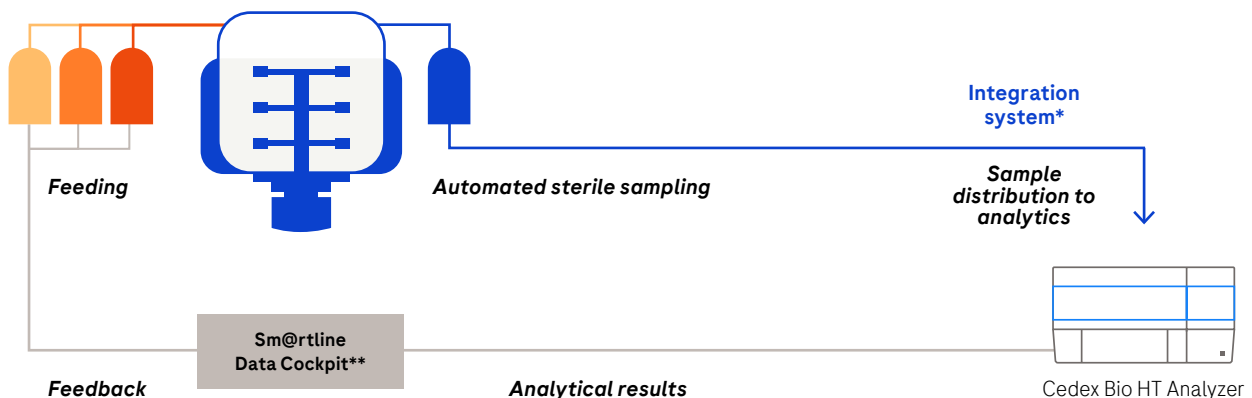
<b>Size</b>	55 cm/21.7 in X 60 cm/23.6 in X 48 cm/18,9 in
<b>Weight</b>	33.0 kg
<b>Benefits</b>	<ul style="list-style-type: none"><li>• <b>Small size:</b> Benchtop system suitable for any space</li><li>• <b>Easy handling:</b> Sophisticated and intuitive operating software</li><li>• <b>Integrated processing unit:</b> Built-in touchscreen reduces qualification effort</li><li>• <b>Reliable answers:</b> Robust and proven technology</li><li>• <b>Efficiency:</b> Low maintenance effort and frequency save time and money</li></ul>



# 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 multiwell upgrade:**
  - Use 24-/48-/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 mins)
  - Designed for manual or robotic loading of multiwell plates
- **Long-term operation:** Long time on-board stability of reagents and assay calibrators
- **Flexible dilution:** Automated sample dilution capabilities save time and accuracy
- **Full automation:** Online integration with automated systems to optimize measurement points and timelines





## Ordering information

Product	Catalog Number
Cedex® Bio Analyzer	06 395 554 001
Cedex® Bio HT Analyzer	06 608 116 001
Kit Labels Multiwell Rack	10 409 347 001
Rack Multiwell Plate Cedex	10 420 618 001

### Regulatory Disclaimer

For use in quality control/manufacturing process only.

### Trademarks

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Scan for ordering  
information of all Cedex  
Bio Analyzer and Cedex  
Bio HT Analyzer assays

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