

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 systems. Moreover we offer a comprehensive test menu which 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 a 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.

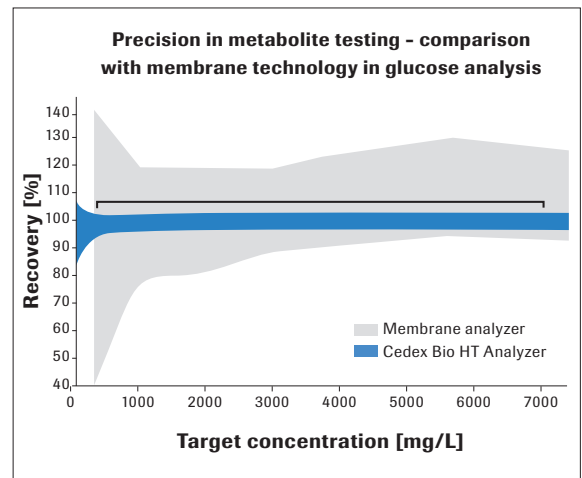


Figure 1: Recovery of glucose concentration was determined in parallel using the Cedex Bio HT Analyzer and a membrane analyzer. (Roche evaluation data)

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.

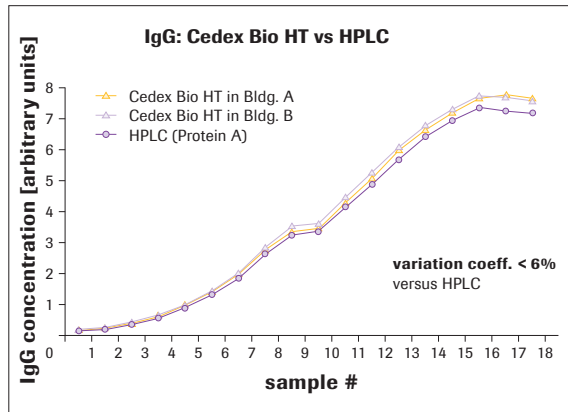


Figure 2: Results comparable to HPLC. The IgG titer in the culture medium was monitored over a production period of 18 days. Samples were analyzed in parallel using HPLC (Protein A) and two Cedex Bio HT Analyzers in separate locations (bldg A/B). The consistent results represent the perfect precision 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

Cedex Bio and Cedex Bio HT Assays

Find answers you need, with a comprehensive testing 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.



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



Cedex Bio Analyzer

Cedex Bio HT Analyzer

Throughput	
60 – 80 tests per hour	260 – 400 tests per hour
Sample capacity	
up to 8 samples at once (continuous loading)	up to 96 + 30 samples at once (continuous loading)
Test kit capacity	
13	32
Daily maintenance	
semi automated, <15 – 20 minutes hands on	automated
Automated on-board sample dilution	
selectable dilution	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 Analyzers has been proven for all assays.

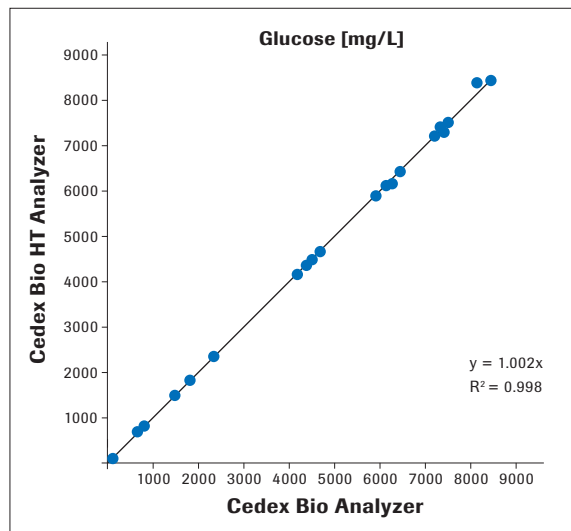


Figure 3: Comparison of the Cedex Bio and Cedex Bio HT Analyzer showing the same recovery of glucose. (Roche evaluation data)

Cedex Bio Analyzer

Small footprint, big impact



 weight 38.6 kg

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 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 tests in 35 min)
 - Designed for manual or robotic loading of 96-well plates
- **Long-term operation:** Long time on-board stability of reagents and long assay calibration intervals
- **Flexible dilution:** Automated sample dilution capabilities save time and ensure high accuracy
- **Full automation:** Online integration with automated systems to optimize measurement points and timelines

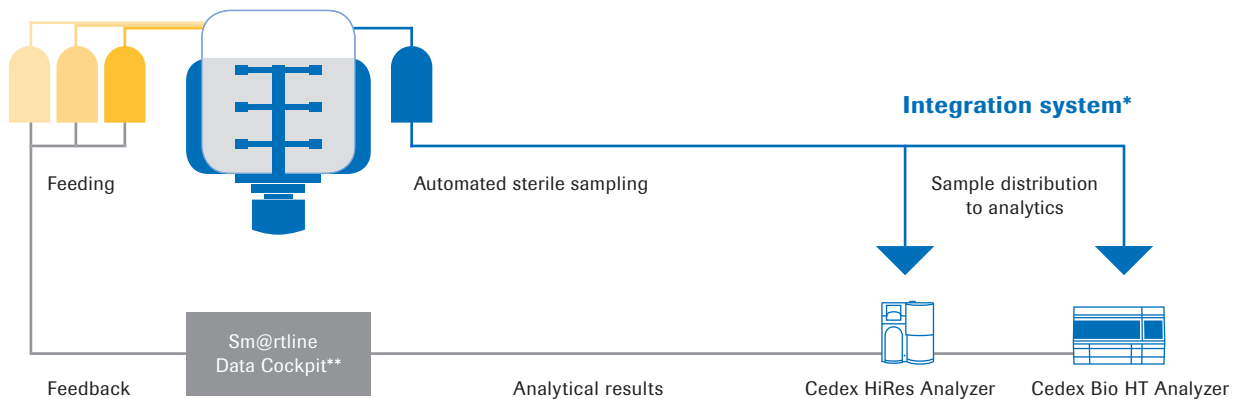


Figure 4: Process integration and automation capabilities with Cedex Bio HT and Cedex HiRes Analyzer
 *Various integration systems are available. **Sm@rtline Data Cockpit is provided by AGU, Leverkusen, Germany

Ordering information

Product

Cedex Bio Analyzer

Cedex Bio HT Analyzer

Kit 96-well plate Cedex

Rack 96-well plate Cedex

Catalog number

06 395 554 001

06 608 116 001

09 181 687 001

09 241 400 001

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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