

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 security 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 Analyzers are based on enzymatic assays, enabling high robustness and sensitivity, adapted to the unique 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 support you with reliable instrument engineering and a continuously expanding test menu, so you can monitor multiple parameters in the bioprocess without having to develop a new assay or purchase a new instrument.

Act on predictability and accuracy

Ultimately, taking control of a bioprocess 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 comes from precise and accurate data that reflect actual conditions in a bioreactor, even at low analyte concentrations. Compared to membrane-based analyzers, the Cedex Bio Analyzers have significantly higher repeatability, accuracy and precision (Figure 1). You can rely on measurements to indicate, for example, the right time points for substrate bolus shots.

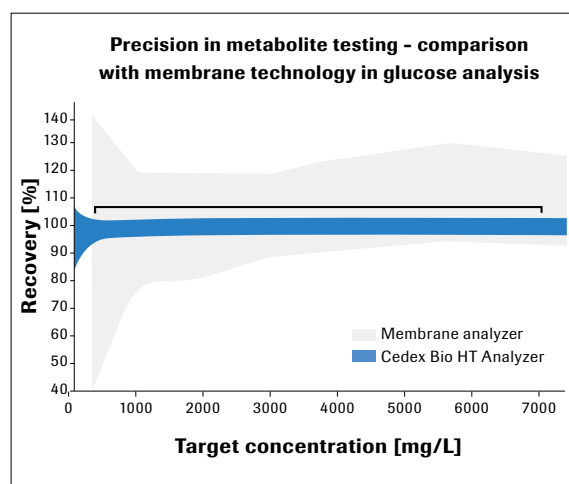


Figure 1: Recovery of glucose concentration was determined in parallel using the Cedex Bio HT Analyzer and a membrane analyzer. Reference: Evaluation data of Roche Diagnostics

See relevant information in time

Insights into the conditions of a cell culture must come early to allow for timely corrective action that can safeguard manufacturing outcome. Thus, the Cedex Bio Analyzers offer an assortment of assays, some designed specifically to measure product yield and quality throughout the fermentation process or in a cell culture. 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 measure of cell viability. A rising LDH level is an early indicator of cell lysis, which is combined with the release of intracellular proteases, glucosidases and other degrading proteins into the matrix, producing a considerable risk for the integrity of the valuable product.

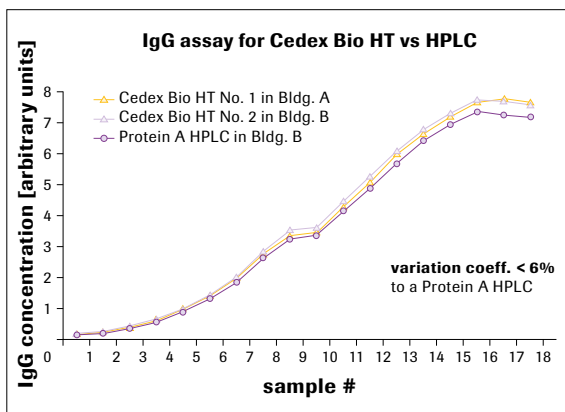


Figure 2: Results comparable to HPLC. IgG concentration in the medium was monitored by the Cedex Bio HT Analyzer and compared to HPLC data over the production period of 18 days. IgG measurements using two different Cedex Bio HT Analyzers in separate locations (Bldg A and B) resulted in highly comparable data between instruments and to HPLC.

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 of daily bioprocess needs with high robustness and low need for manual interaction.

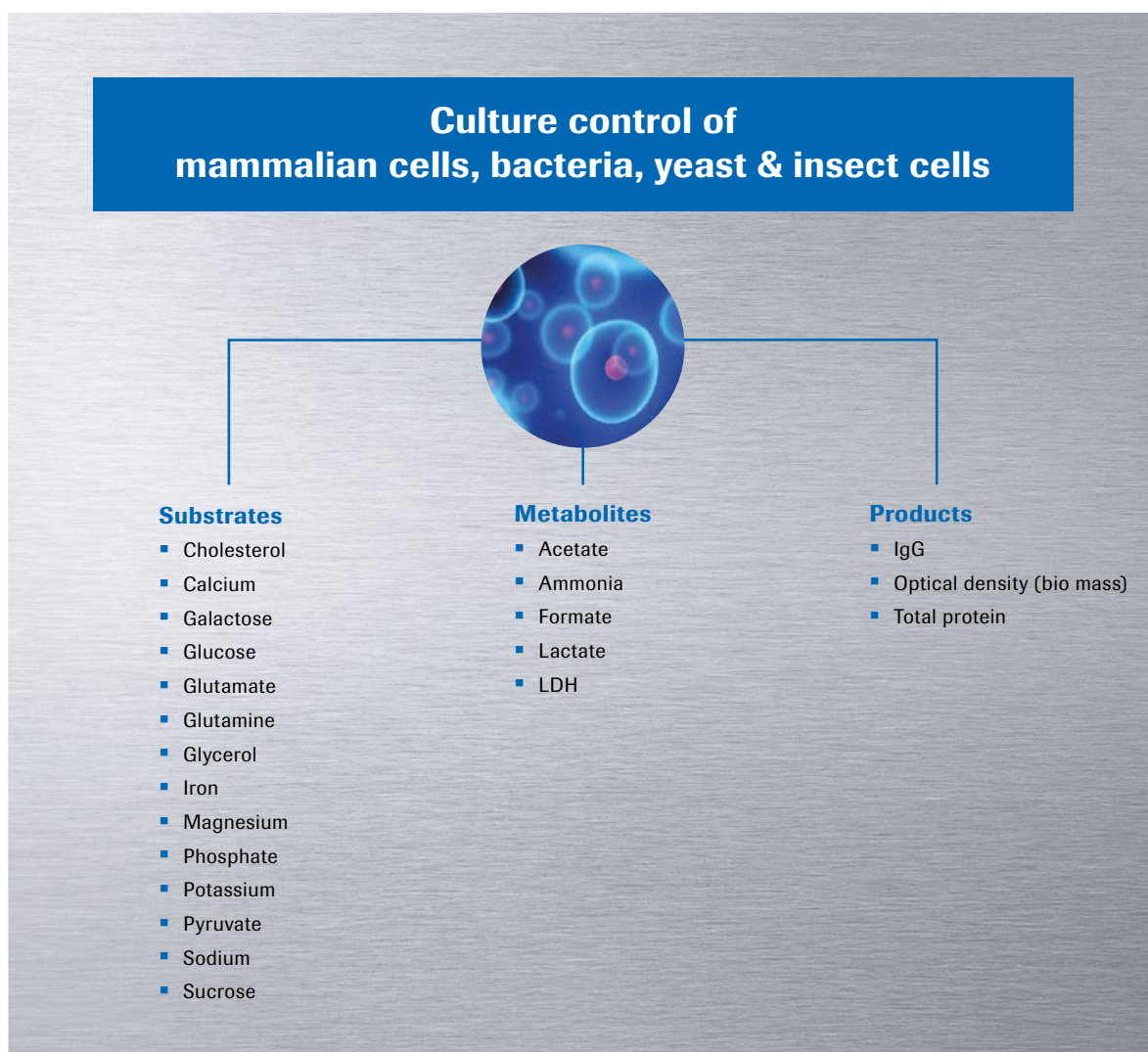
The flexible capabilities for automated sample predilution, the long on-board stabilities of the reagents and of the assay calibrations, the dedicated multi-analyte calibrators and controls, and the identification of reagents and samples via barcodes, make Cedex Bio Analyzers a perfect match for highly efficient processing.

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 strict control of biopharmaceutical manufacturing, and new assays are continually added to the menu based on industry knowledge and requests from customers. Thus, with a single platform, you have ever 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, yet 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 90 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 Analyzer 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.

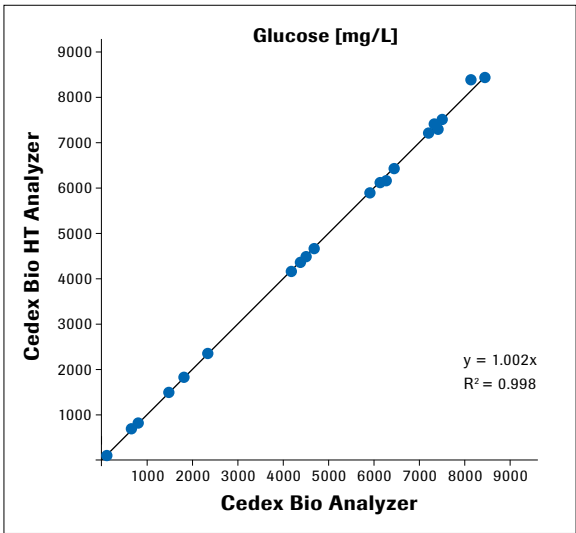
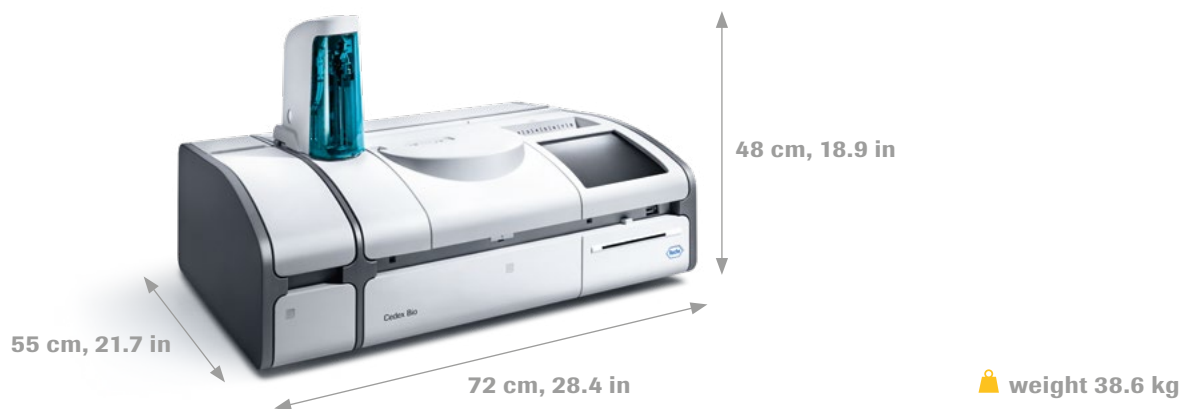


Figure 3: Comparison of the Cedex Bio and Cedex Bio HT Analyzer showing the same recovery of glucose (Roche data).

Cedex Bio Analyzer

Small footprint, big impact



A reliable, high-quality instrument for environments with 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
- **Long-term operation:** long time on-board stability of reagents and assay calibration
- **Flexible dilution:** automated sample dilution capabilities save time and accuracy
- **Full automation:** online integration with automated systems to optimize measurement points and timelines

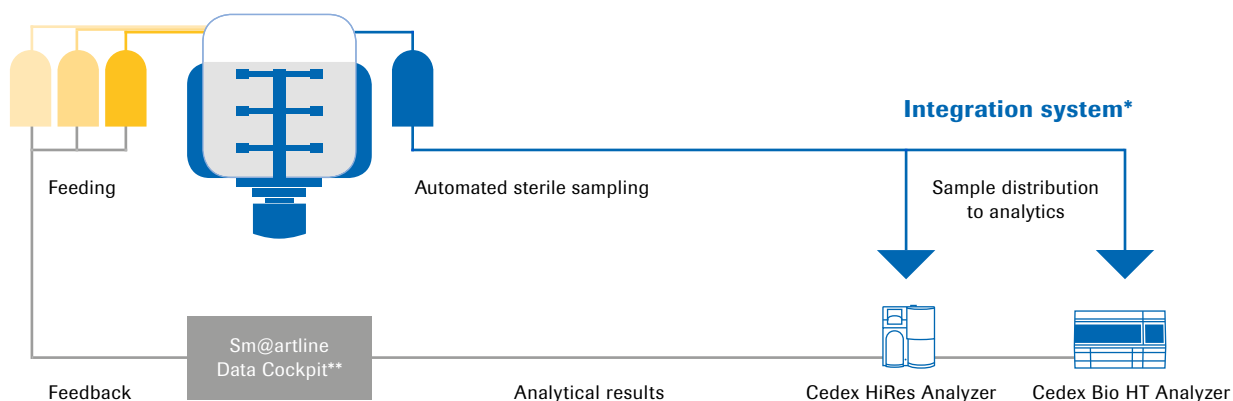


Figure 4: Process integration and automation capabilities with Cedex Bio HT and Cedex HiRes Analyzer

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

Ordering information

| Product | Catalog number |
|-----------------------|----------------|
| Cedex Bio Analyzer | 06 395 554 001 |
| Cedex Bio HT Analyzer | 06 608 116 001 |

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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