

Advance the potential of your cell culture
Discover in-process control solutions



We are CustomBiotech from Roche

*In your operations, behind your decisions,
powering your products*

You are driving a paradigm shift. Scientific and technological advances emerging from creative companies across the globe are transforming the way we look at disease and breaking down boundaries for treatment. The untapped potential in these innovations is accompanied by many challenges. How do you secure a supply chain in a global landscape? How do you ensure compliance in a demanding regulatory environment? How do you remain competitive in a fast-paced market? Now more than ever, business success hinges on finding suppliers, collaborators, and other partners who understand your needs and allow you to focus on what matters.

What if all of those partners were one single ally — a market leader with decades of experience in biotechnology and *in vitro* diagnostics standing shoulder to shoulder with your team?

Welcome to Roche CustomBiotech.





Innovation

Count on great ideas that work. From research and development to manufacturing and logistics, our experts and facilities cover an unparalleled spectrum of skills and technologies to explore any idea.



Customization

Invest time and resources into what you do best. For everything else, rely on us. With customized development, manufacturing, labeling, packaging and filling of components, we streamline the path of your product to market.



Service

Tackle problems with a smart ally. From business and regulatory issues to production troubleshooting, we help safeguard your operations and market standing with fast answers to problems, anytime and anywhere.



Security

Set your mind at ease. Our global reach, stringent standards and state-of-the-art manufacturing mean a secured supply of products and services to drive your business forward, when and where needed.





Knowledge is the power

Complete solutions for reliable in-process control

Discover more, so you can do more

Maintaining optimal cell culture conditions throughout the cell culture and fermentation process is vital to producing high yields of top-quality biopharmaceuticals. Accurate monitoring of complete culture physiology inside bioreactors is simple and fast with Cedex Analyzers. This family of instruments performs precise measurements and can detect subtle changes in nutrients, metabolites, or cell morphology and growth, enabling informed decisions and fast time response.

Featuring a broad and continuously growing test portfolio, the Cedex Analyzer Family combines the functionalities of multiple instruments to deliver powerful testing capabilities with reduced workflow complexity. These robust platforms were designed for diagnostic applications and then adapted to withstand continuous operation in pharmaceutical process development and industrial production. Furthermore, they have been rigorously tested in our own manufacturing. Cedex Analyzers support the Quality by Design (QbD) approach and complete process automation, allowing high level of success for cell culture and fermentation both in development and in GMP manufacturing environments.

Cedex Analyzer family provides:

- Detailed understanding of the bioprocess and influencing factors
- Comprehensive testing capabilities that increase productivity and quality
- Peace of mind that the instruments function reliably
- Process safety instead of security and compliance with the strict regulatory requirements



Reliable in-process control for all stages of bioprocess development and production

Instruments	Test capabilities	Sample capacity	Technology	Benefits in your process
Cedex Bio Analyzer	26 different assays for mammalian and microbial cultures, including IgG and LDH, continuously expanding menu	8	Photometric analyzer, Ion selective electrodes	<p>Early process research</p> <ul style="list-style-type: none"> Develop a full understanding of the fermentation process and all critical influences <p>Bioprocess development</p> <ul style="list-style-type: none"> Develop tight control of bioprocess Generate accurate process models Meet Quality by Design (QbD) and Design of Experiment (DoE) requirements Obtain comparable data from both the Cedex Bio and Bio HT. Easily transfer technology to a manufacturing environment anytime and at any stage. <p>Bioprocess manufacturing</p> <ul style="list-style-type: none"> Maintain reliable control of your bioprocess
Cedex Bio HT Analyzer		96 + 30		
Cedex HiRes Analyzer	Cell density, viability, aggregation rate, and morphological parameters, such as cell diameter and cell compactness	20	High resolution scanner imaging, Trypan blue exclusion method	



Cedex HiRes Analyzer



Cedex Bio Analyzer



Cedex Bio HT Analyzer

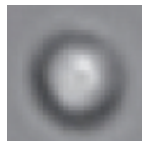
Take control of your bioprocess

Cedex Analyzer Family

Gain tight control

With **high precision and data integrity**, measurements with Cedex Analyzers are accurate time after time. The **Quality by Design** approach is supported to monitor your bioprocess.

- Reliable time-course profiles can be translated into **predictive models of the bioprocess** to detect and to resolve problems as early as possible by implementing real-time measures.
- Accurate and reliable analytics allow full characterization of influencing factors.
- Well-informed decisions can be made to safeguard **optimal culture conditions**, resulting in consistently **high product quality** and yield.



Accuracy in cell analysis with high-resolution imaging

Figure 1: Image of living cell (Cedex HiRes Analyzer image).

Boost productivity

Along with proven technology and ease of use, the Cedex Analyzers allow for bioprocess **workflow optimization** from start to finish.

- **Data reproducibility and consistency** is obtained, independent of the instrument, the process stage, site, or department.
- **One analyzer family** to measure key nutrients, metabolite concentrations, as well as cell density, viability and morphology.
- Cedex Bio and Bio HT Analyzers run a **highly versatile menu of tests** in mammalian cell, bacterial, or yeast cultures.
- **Streamlined sample management** with easy-to-use, barcoded reagents and consumables and front-loading, tailored to each analyzer.

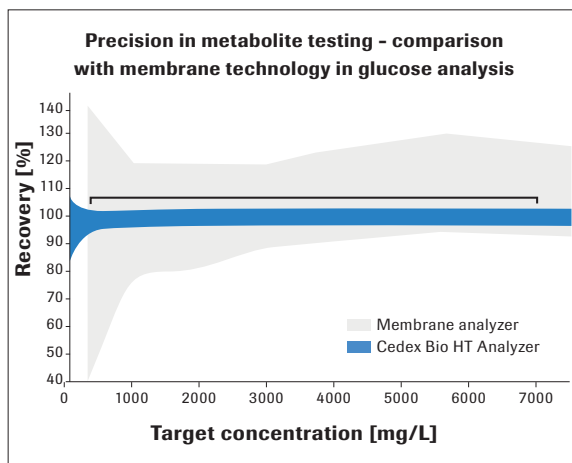


Figure 2: Recovery of glucose concentration was determined in parallel using the Cedex Bio HT Analyzer and a membrane analyzer. Reference: Evaluation data of Roche Diagnostics



Count on quality technology

The Cedex Analyzer family was developed using industry-proven diagnostic technology and to meet GMP requirements (Good Manufacturing Practice). These platforms were adapted and adjusted to **support process development and industrial production at Roche Pharmaceuticals**.

Cedex Analyzers:

- are **robust** instruments tolerating **continuous operation** and rigorous use.
- require minimal user handling, **preventing manual errors** which provides **adding process safety instead of security** and accuracy.
- have **easy maintenance** procedures.
- **minimize costs and add convenience** since no backup instrument is needed.

Improve workflow efficiency

Online integration of the analyzers used in biomanufacturing is a mandatory requirement in today's state-of-the-art bioprocesses. The Cedex Analyzers can be readily incorporated into closed loop systems for **automated in-process control**.

- **Validated integration** with the Sm@artline Data Cockpit middleware enables the virtual consolidation of samplers, analyzers, and sensors.
- **Around-the-clock monitoring** of cell culture conditions with immediate response.
- Results are sent **securely to LIMS or MES** systems.
- **Complete traceability** and compliance is ensured.

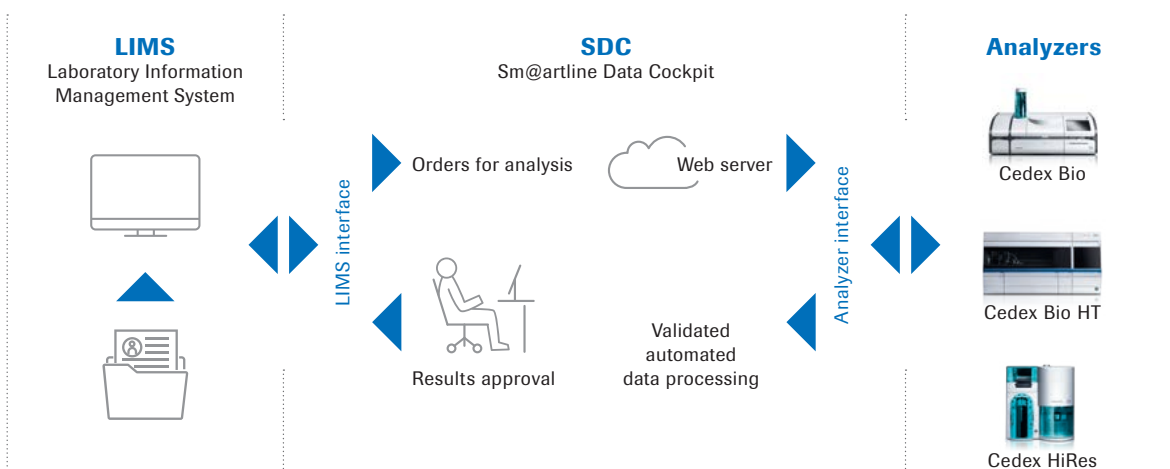


Figure 3: Sm@rtLine Data Cockpit (SDC) is a middleware provided by AGU, Leverkusen, Germany.

Regulatory disclaimer

For use in quality control/manufacturing process only.

Trademark

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