



Galactose Assay for Cedex[®] Bio & Bio HT Analyzers

Reliable and convenient automated determination

In cell cultures, the galactose concentration in the growth medium has an influence on the glycosylation of recombinant proteins (e.g., therapeutic antibodies), therefore the quality of glycosylated products can be controlled by continuous monitoring of the galactose concentration. Furthermore, galactose can be used instead of glucose as feed for the cells. Defined concentrations of galactose can regulate the mitochondrial metabolism, for example, to reduce the accumulation of lactate.

In yeast fermentation (e.g. *S. cerevisiae*), galactose can be a transcription promoter for vectors used in recombinant protein production, and at the same time galactose serves as source of carbon and energy. Addition of galactose to the culture in absence of glucose results in efficient transcription induction. Due to the rapid consumption, the transcription stops once galactose depletes under the limit for induction. Therefore a continuous monitoring of the galactose concentration is necessary to control the optimal feed.

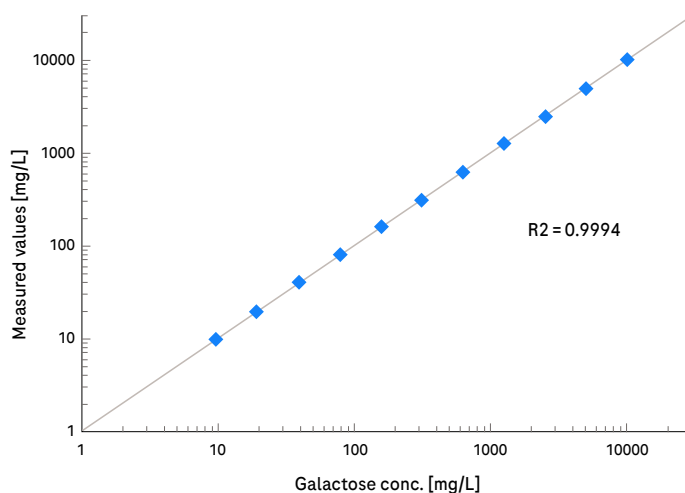
Automated testing on Cedex Analyzers enables fast and easy galactose monitoring, for perfect process control achieving optimal yield.

Process control based on fast and reliable analytics

- High accuracy, results are consistent to HPLC
- No sample filtration or other pretreatment required
- Wide measuring range, option for on-board dilution
- Barcoded reagents, ready-to-use
- Calibration required only once per lot

Wide test range, low sample volume, high accuracy

Protocol	Galactose range	Sample vol.
GAL 2B low range	0.055 – 27.8 mmol/L, 9.9 – 5000 mg/L	5 µL
GAL 2D high range	0.55 – 278 mmol/L, 99 – 50000 mg/L, up to max, solubility with auto-dilution	20 µL

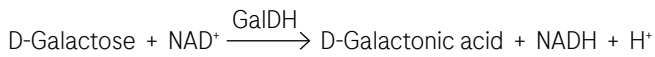


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The recovery of D-galactose standard solutions on a Cedex Bio HT Analyzer shows a perfect linearity over the test range and a high accuracy of the results.. (Roche evaluation data)

Assay principle

In the Cedex assay, D-Galactose is oxidized by nicotinamide adenine dinucleotide (NAD) in presence of β -galactose dehydrogenase (GalDH). The amount of NADH formed in this reaction is measured photometrically at 340 nm and is directly proportional to the amount of D-Galactose in the sample.



High specificity

The galactose assay shows no crossreactivity with other carbohydrates in the shown list, except of L-arabinose and 2-deoxy-D-galactose, which are chemically very similar to D-galactose. However, these substances are not common in culture media for mammalian cells or E. coli, therefore, there is no risk of an interference.

Positive signal in the galactose test:

- | | |
|------------------------|--------------------------|
| • D-Galactose, | relative recovery = 1.00 |
| • L-Arabinose, | relative recovery = 0.47 |
| • 2-Deoxy-D-galactose, | relative recovery = 0.27 |

No reaction in the galactose test:


- | | |
|-----------------------------|-------------|
| • D - Arabinose | • Maltose |
| • L - Fucose | • Melibiose |
| • D - Fructose | • Raffinose |
| • L - Galactose | • D-Ribose |
| • D - Galactose-6-Phosphate | • Stachyose |
| • D - Galacturonic acid | • Sucrose |
| • D - Glucose | • Trehalose |
| • D - Glucuronic acid | • D-Xylose |
| • D - Lactose | |

Ordering information

Product	Pack size	Catalog number
Galactose/Arabinose Bio	4 x 50 tests	08 391 599 001
Galactose/Arabinose Bio HT	200 tests	08 391 629 001
Calibrator D Bio	6 x 1 mL	07 368 321 001
Control D Level 1 Bio	6 x 1 mL	07 368 178 001
Control D Level 2 Bio	6 x 1 mL	07 368 186 001
Control D Level 3 Bio	6 x 1 mL	07 368 194 001

Regulatory Disclaimer
For use in quality control/manufacturing process only.

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Published by
Roche Diagnostics GmbH
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