

Galactose Assay (2nd gen.) for Cedex Bio and Bio HT Analyzers

Improved reagent stability for optimal reliability and convenience

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 nutrient for the cells. Defined concentrations of galactose can regulate the mitochondrial metabolism, for example, the accumulation of lactate can be reduced.

In yeast fermentation (e.g. with *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. The 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 falls under the limit. Therefore a continuous monitoring of the galactose concentration is necessary to enable optimal feeding.

Assay improvements in new generation V2

The new test generation V2 for galactose uses the same reaction principle and results are equal to the former generation. The long-term stability of the reagent formulation has been improved, therefore the on-board time and the calibration interval could be extended, and the test precision is enhanced.

Compared features of the assay generations:

	1 st generation	2 nd gen. V2
Kit formulation	extra enzyme sol.	ready for use
On-board stability	4 weeks	4 / 16 weeks (Bio / HT)
Calibration interval	4 weeks	16 weeks
Measuring range	10 – 7000 mg/L / 0.06 – 39 mmol/L,	10 – 5000 mg/L / 0.06 – 28 mmol/L, up to maximal solubility with auto-dilution

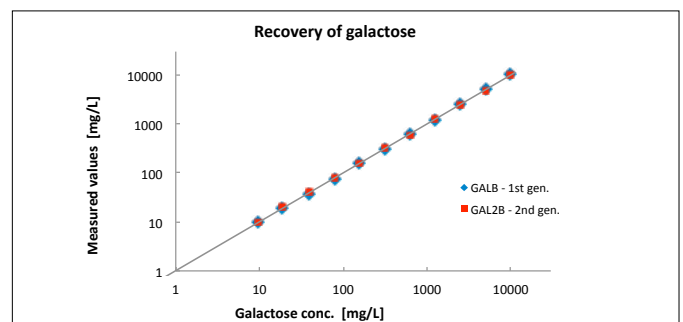


Figure 1: Comparison of the galactose recovery using the 1st and 2nd generation of the galactose assay on a Cedex Bio HT Analyzer. The results show a perfect equivalence of the test generations and an optimal linearity over the test range.

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 has no crossreactivity with other carbohydrates in the list below, except of L-arabinose and 2-deoxy-D-galactose, which are not common in cell culture applications.

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

Precision data

	Level 1	Level 2	Level 3
Mean	126 mg/L / 0.7 mmol/L	1260 mg/L / 7 mmol/L	3780 mg/L / 21 mmol/L
CV in-run	0.8%	1.2%	0.7 %
CV inter-run	3.6%	2.8%	3.5%

Representative performance data for the Cedex Bio HT Analyzers are shown. Results obtained in individual laboratories may differ. Coefficients of variation (CV) were calculated for in-run precision (n=21) and inter-run precision (on 10 days).

Ordering information

Product	Pack size	Catalog no.
Galactose V2 Bio	4 x 50 tests	08 391 599 001
Galactose V2 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

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Published by

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