

# GALACTOSE

## Enzymatic UV determination of galactose in urine

### TEST SUMMARY

The galactose eventually present in the sample, reacts with galactose dehydrogenase and with NAD<sup>+</sup> forming NADH. The increase of absorbance is directly proportional to the concentration of galactose in the sample.

### SAMPLE

Urine. Stability 7 days at -20°C.

### REAGENTS

Reagent A	Tris buffer stabilizers and preservatives
Reagent B	NAD stabilizers and preservatives
Reagent C	Suspension of galactose dehydrogenase
Standard:	Galactose 20 mg/dl (1,11 mM) stabilizers and preservatives.

### MATERIAL REQUIRED BUT NOT SUPPLIED

Normal laboratory equipment. Spectrophotometer UV/VIS with thermostatisation. Automatic Micropipette. Cuvette in optical glass or monouse in optical polystyrene. Physiologic solution.

### PRECAUTIONS

Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

### REAGENTS PREPARATION

Reagents are supplied in liquid form and ready to use. Reagents are stored at 2-8°C until expiration date on label away from direct light source or 60 days after first opening.

### SAMPLE PREPARATION

If the sample would be particularly turbid, centrifuge it. If suspect in galactose, a titre superior to the test linearity, dilute the test with physiological 1:5 (1 ml of urine + 4 ml of physiologic solution) multiply the result obtained by 5.

### PROCEDURE

Kind of analysis:	End point
Reading time:	30 minutes
Wavelength:	340-365-335 nm
Temperature:	R.T. 37°C
Lightpath:	1 cm
Zero:	Reagent Blank

Reagents	Blank	Standard	Sample
Distilled water	50 µl	--	--
Standard	--	50 µl	--
Sample	--	--	50 µl
Reagent A	500 µl	500 µl	500 µl
Reagent B	500 µl	500 µl	500 µl

Read the absorbances (A1)

Reagent C	20 µl	20 µl	20 µl
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Read the absorbance (A2) after 30 minutes and calculate the delta absorbance. Subtract the blank delta absorbance to the value of sample and standard.

### CALCULATION

Urine galactose mg/24h

( $\Delta A$  sample/ $\Delta A$  standard) x 20 x dl urine 24 h

### EXPECTED VALUES

Urine  
≅ 14 mg/24h

Every laboratory should establish own reference intervals in accordance with own population.

### NOTES

- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
- Only for IVD use.

### CALIBRATION/ QUALITY CONTROL

It is suggested to perform an internal quality control. For that aim on request, are available the following control kits:

**CC03830** 4 x 1 ml  
Galactose Control Set (2 levels)

### TEST PERFORMANCE

#### Precision

Intra-assay (n = 10)	Mean (mg/dl)	SD (mg/dl)	CV%
Sample 1	10.349	0.241	2.34
Sample 2	43.282	0.610	1.41

Inter-assay (n = 10)	Media (mg/dl)	SD (mg/dl)	CV%
Sample 1	10.409	0.299	2.88
Sample 2	43.346	1.534	3.54

#### Sensibility/limit of detention

The method is able to discriminate up to 0.5 mg/dl.

#### Linearity

The method is linear up to 50 mg/dl. If the value is exceed, is suggested to dilute the sample 1+4 with physiological solution and re-perform the test multiply the result by 5.

#### Methods comparison

A comparison with a commercial available product gave the following results in a comparison on 25 samples:

Galactose LTA = x  
Galactose competitor = y  
n = 25

$y = 1,03296x - 0,32323 \text{ mg/dl}$   $r = 0,99771$

#### WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

#### PACKAGING

**CODE CC03800 (40 TESTS)**

Reagent A 1 x 20 ml  
Reagent B 1 x 20 ml  
Reagent C 1 x 900 µl  
Standard 1 x 5 ml

#### REFERENCES

Kurtz, G. & Wallenfels, K. (1974) in Methoden der enzymatischen Analyse, (Bergmeyer, H.U., Hrsg) 3. Aufl., Bd. 2, S. 1225-1229 and S. 1324-1327, Verlag Chemie, Weinheim.  
F.Pasquinelli, Diagnostica e tecniche di laboratorio (2001) Vol.1 parte 2°, pag.491-495.

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### SYMBOLS

- Only for IVD use
- Lot of manufacturing
- Code number
- Storage temperature interval
- Expiration date
- Warning, read enclosed documents
- Read the directions
- Biological risk

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