# GALACTOSE

## Enzymatic UV determination of galactose in urine

### TEST SUMMARY
The galactose eventually present in the sample, reacts with galactose dehydrogenase and with $NAD^+$ 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 thermostatation. 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 title 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 |
| 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

(ΔA sample/ΔA 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 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
IVD Only for IVD use
LOT Lot of manufacturing
REF Code number
Storage temperature interval
Expiration date
Warning, read enclosed documents
Read the directions
Biological risk

Mod. 01.06 (ver. 1.2 - 04/03/2006)

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