Cat. No 4-506

# DIAGNOSTIC KIT FOR DETERMINATION OF UREA CONCENTRATION

## HC – UREA

### INTRODUCTION
Urea is a product of amino acids catabolism. It is produced in liver and excreted in urine. Urea in the blood is reported as the blood urea nitrogen (BUN). Increased urea concentration in the serum, called uremia, is observed due to dehydration, renal failure, high-protein diet, increased protein catabolism caused by tissue injury or massive bleeding into the alimentary tract. The reason of reduced urea level could be overhydration, low-protein diet or starvation and severe liver disease.

### METHOD PRINCIPLE
Kinetic, enzymatic method with urease and glutamate dehydrogenase.

$$\text{urea} + 2\ H_2O \xrightarrow{\text{urease}} 2\ NH_4^+ + CO_3^{2-}$$

$$NH_4^+ + \text{2-oxoglutarate} + \text{NADH} \xrightarrow{\text{GLDH}} \text{L-glutamate} + NAD^+ + H_2O$$

The rate of absorbance changing at λ=340 nm is proportional to the urea concentration.

### REAGENTS
**Package**

| | |
|---|---|
| 1-Reagent | 6 x 74 ml |
| 2-Reagent | 6 x 19 ml |

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

**Concentrations in the test**

| | |
|---|---|
| Tris (pH 7.8) | 96 mmol/l |
| ADP | 0.6 mmol/l |
| urease | 266.7 µkat/l |
| GLDH | 16 µkat/l |
| NADH | 0.25 mmol/l |
| 2-oxoglutarate | 9 mmol/l |

**Warnings and notes**
- Product for in vitro diagnostic use only.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

### SPECIMEN
Serum, EDTA or heparinized plasma free from hemolysis, 24-hours urine.
Do not use heparine ammonium salt and fluoride as anticoagulants.
Urine preparation: before analysis urine sample should be diluted 100-fold with 0.9% NaCl, and the results multiplied by 100. Mix well probes before measurement. 24-hours urine samples should be kept at 2-8ºC preserved by maintenance of pH less than 4.
Specimen can be stored up to 7 days at 2-8ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

### PROCEDURE
The reagents are ready to use.
These reagents may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:
1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

### REFERENCE VALUES [8]

| serum / plasma | mg/dl | mmol/l |
|---|---|---|
| | < 50 | < 8.3 |
| 24-hours urine | g/24h | mmol/24h |
| | 20 – 35 | 300 – 550 |

1 mg of urea corresponds to 0.467 mg of urea nitrogen.
It is recommended for each laboratory to establish its own reference ranges for local population.

### QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) for determination in serum or CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) or LEVEL 2 (Cat. No 5-162) for determination in urine with each batch of samples.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 2 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

### PERFORMANCE CHARACTERISTICS
These metrological characteristics have been obtained using the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 1.55 mg/dl (0.26 mmol/l).
- **Linearity:** up to 300 mg/dl (50 mmol/l).
- **Specificity / Interferences**
  Haemoglobin up to 5 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.
- **Precision**

| Repeatability (run to run) n = 20 | Mean [mg/dl] | SD [mg/dl] | CV [%] |
|---|---|---|---|
| level 1 | 31.36 | 0.36 | 1.14 |
| level 2 | 98.18 | 0.60 | 0.62 |

| Reproducibility (day to day) n = 80 | Mean [mg/dl] | SD [mg/dl] | CV [%] |
|---|---|---|---|
| level 1 | 30.97 | 1.39 | 4.49 |
| level 2 | 99.36 | 2.76 | 2.78 |

- **Method comparison**

A comparison between urea values determined at Hitachi 912 (y) and at COBAS INTEGRA 400 (x) using 69 samples gave following results:
y = 1.047 x + 0.5679 mg/dl;
R = 0.9987 (R – correlation coefficient)

**WASTE MANAGEMENT**
Please refer to local legal requirements.

**LITERATURE**

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