# UREA COLOR FL

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|---|---|
| UC F400 CH | 4 x 100 ml |
| UC 100F CH | 4 x 250 ml |

## INTENDED USE

Reagent for quantitative in vitro determination of urea in biological fluids.

## SUMMARY OF TEST

Urea is the major nitrogen-containing metabolic product of protein catabolism in humans. The biosynthesis of urea from amino nitrogen-derived ammonia is carried out exclusively by hepatic enzymes of the urea cycle. More than 90% of urea is excreted through the kidneys, with losses through the gastrointestinal tract and skin accounting for most of the remaining minor fraction. Urea is neither actively reabsorbed nor secreted by the tubules but is filtered freely by the glomeruli. More importantly, urea production is too dependent on several nonrenal variables such as diet and hepatic synthesis to make it useful as a measure of GFR.

## PRINCIPLE OF THE METHOD

Urease hydrolizes urea in the sample to release ammonium ions and $CO_2$. Ammonium ions react with hypochlorite and salycilate yielding a green product. Absorbance increase is proportinal to the amount of urea in the sample, and is measured at 600 nm.

## KIT COMPONENTS

**For in vitro diagnostic use only.**
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

**UREA-C R1A** **F400: 2 x 100 ml (liquid) blue cap**
**100F: 2 x 250 ml (liquid) blue cap**

**UREA-C R1B** **F400: 1 x 2 ml (liquid) blue cap**
**100F: 1 x 5 ml (liquid) blue cap**

**UREA-C R2** **F400: 2 x 100 ml (liquid) red cap**
**100F: 2 x 250 ml (liquid) red cap**

Composition in the final mixture: Phosphate buffer 15 mM, Sodium salycilate > 10 mM, Sodium nitroprussiate > 1 mM, Sodium Hypochlorite > 0,1%, Urease > 1 KU/l, stabilizers.

**Standard:** **urea 50 mg/dl - 5 ml**

Store all components at 2-8°C.

## MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

## REAGENT PREPARATION

**Preparation of Reagent R1:**
Mix 1 part of reagent R1B with 100 parts of reagent R1A.
Stability of prepared reagent R1: use preferably within 14 days at 2-8°C.

Reagent R2 is ready to use.

Stability of unmixed reagents: up to expiration date on labels at 2-8°C
Stability since first opening of vials: use preferably within 60 days at 2-8°C.

## PRECAUTIONS

**UREA-C R1A:** It is not classified as hazardous.

**UREA-C R1B:** It is not classified as hazardous.

**UREA-C R2: Warning.** Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

**Standard:** It is not classified as hazardous.

## SPECIMEN

Serum, plasma (avoid ammonium heparinate). Urine.
Urea is stable 3 days at 2-8°C.
Dilute urine sample 1:100 with deionized water.

## TEST PROCEDURE

Wavelenght: 600 nm
Lightpath: 1 cm
Temperature: 37°C

| dispense: | blank | standard | sample |
|---|---|---|---|
| reagent R1 | 1 ml | 1 ml | 1 ml |
| water | 10 µl | - | - |
| standard | - | 10 µl | - |
| sample | - | - | 10 µl |
| incubate at 37°C for 5 minutes | | | |
| reagent R2 | 1 ml | 1 ml | 1 ml |

Mix, incubate 5 minutes at 37°C.
Read against reagent blank the absorbance of standard (As) and sample (Ax).

## RESULTS CALCULATION

Serum/plasma:

$$\text{urea mg/dl} = \frac{Ax}{Ac} \times 50 \text{ (standard value)}$$

Random urine sample:

$$\text{urea mg/dl} = \frac{Ax}{Ac} \times 50 \times 100$$

(standard value and dilution factor)

## EXPECTED VALUES

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|---|---|---|
| Adults: | 10 - 50 mg/dl | (1.7 - 8.3 mmol/l) |
| Urine: | 20 - 35 g/24h | (332 - 580 mmol/24h) |

Each laboratory should establish appropriate reference intervals related to its population.

## QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
**QUANTINORM CHEMA**
with normal or close to normal control values
**QUANTIPATH CHEMA**
with pathological control values.
If required, a multiparametric, human based calibrator is available:
**AUTOCAL H**

Please contact Customer Care for further information.

## TEST PERFORMANCE

**Linearity**
the method is linear up to 300 mg/dl.
If the value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

**Sensitivity/limit of detection (LOD)**
The limit of detection is 3 mg/dl.

**Interferences**
No interference was observed by the presence of:

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| hemoglobin | ≤ 500 mg/dl |
| bilirubin | ≤ 35 mg/dl |
| lipids | ≤ 1000 mg/dl |

**Precision**

| intra-assay (n=10) | mean (mg/dl) | SD (mg/dl) | CV% |
|---|---|---|---|
| sample 1 | 42.51 | 1.18 | 2.77 |
| sample 2 | 155.58 | 1.13 | 0.73 |

| inter-assay (n=20) | mean (mg/dl) | SD (mg/dl) | CV% |
|---|---|---|---|
| sample 1 | 42.59 | 1.29 | 3.02 |
| sample 2 | 156.91 | 3.22 | 2.05 |

**Methods comparison**
A comparison between UREA COLOR and UREA UV CHEMA gave the following results:

Urea Color = y
Urea UV = x
n = 104

$y = 0.95 x + 4.70$ mg/dl $r^2 = 0.99$

## WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

## REFERENCES


Clin. Chem. 1966, 12(3), 151-7
Tietz Textbook of Clinical Chemistry, fourth Edition, Burtis-Ashwood (2006).
HU Bergmeyer - Methods of enzymatic analysis, (1987).


## MANUFACTURER


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## SYMBOLS

| | |
|---|---|
| IVD | *in vitro* diagnostic medical device |
| LOT | batch code |
| REF | catalogue number |
| | temperature limit |
| | use by date |
| | caution |
| | consult instructions for use |