# Urea (BUN) Kit
# CliniQuant – FSR
## Urease – GLDH, Fixed Time

Meril Diagnostics

For *in vitro* diagnostic use
Read this pack insert thoroughly before use

| REF | Pack Size | R1 Urea Reagent | R2 Urea Reagent | R3 Urea Standard |
|---|---|---|---|---|
| UREFSR-01 | 4 x 20 / 4 x 5ml | 4 x 20ml | 4 x 5ml | 1 x 5ml |
| UREFSR-02 | 4 x 100 / 2 x 50ml | 4 x 100ml | 2 x 50ml | 2 x 5ml |

### INTENDED USE
This reagent is intended for quantitative determination of Urea (BUN) concentration level in human serum and urine.

### CLINICAL SIGNIFICANCE
Elevated serum Urea levels are observed in variety of renal diseases, liver diseases, congestive cardiac failure and diabetes.

### PRINCIPLE OF THE METHOD

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

$$NH_3 + \alpha\text{-KG} + \text{NADH} \xrightarrow{\text{GLDH}} \text{Glutamate} + \text{NAD}$$

α-KG: α-Ketoglutarate
GLDH: Glutamate dehydrogenase

### KIT COMPONENTS
Composition
R1 - Urea Reagent : Urease 10 KU/l, GLDH 2 KU/l, 2-oxoglutarate 9.78 mmol/l, Tris buffer 100 mmol/l, pH 7.9
R2 - Urea Reagent : NADH 0.32 mmol/l
R3 - Urea Standard : 50 mg/dl, Urea 0.5 g/l, Benzoic acid 0.2%

### MATERIALS REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tubes/rack, heating bath, controls, saline.

### REAGENT PREPARATION, STORAGE & STABILITY
Mix reagent 1 & reagent 2 in ratio 4:1. Keep away from direct light sources.
Stability: up to expiration date on labels at 2-8 °C.
Stability of working reagent: 30 days at 2-8 °C.

### REAGENT DETERIORATION
1. Discard the reagent if absorbance is less than 1.0 at 340 nm against distilled water.
2. Keep the Standard vial plugged after use, in order to avoid deterioration.

### WARNINGS AND PRECAUTIONS
1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

### SPECIMEN
Use unhemolysed serum, plasma. Urea is stable for 7 days at 2-8°C or 6 months at -20°C.
Dilute urine samples 1:100 with deionized water and multiply results by 100.

**Programme Parameter for MERILYZER CliniQuant**

| | |
|---|---|
| Reading Mode | Fixed Time |
| Standard Conc. | 50 (mg/dl) |
| Filter – 1 (nm) | 340 |
| Temperature | 37 °C |
| Volume (µl) | 500 |
| Delay Time (Sec) | 20 |
| Read Time (Sec) | 60 |
| Reaction Direction | Decrease |
| Reference Low | 13 |
| Reference High | 45 |
| Linearity Limit | 300 |

CE
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## TEST PROCEDURE

| Dispense | Standard | Sample |
|---|---|---|
| Working Reagent | 1000 µl | 1000 µl |
| Standard | 10 µl | - |
| Sample | - | 10 µl |
| Mix, incubate 20 seconds at 37°C, then record absorbance as A1. After exactly 60 seconds, record again absorbance as A2. | | |

## RESULT CALCULATION

Serum/plasma:

Urea mg/dl = A2-A1(sample)/A2-A1(standard) x concentration of Standard

Random urine sample:

Urea mg/dl = A2-A1(sample)/A2-A1(standard) x concentration of Standard x 100

24 hours urine sample (urea g/24h):

[A2-A1(sample)/A2-A1(standard) x concentration of Standard x 100 x urine volume] / 1000

To convert mg/dl of Urea to mg/dl of BUN divide the results by 0.467 (Urea = 2.14 x BUN)

SI conversion factor: 1 mg/dl x 0.357 = 1 mmol/l

## EXPECTED VALUES

| | | |
|---|---|---|
| Urea: 13 – 45 mg/dl | OR | 4.6 – 16 mmol/l |
| BUN: 6 – 21 mg/dl | OR | 2.1 – 7.5 mmol/l |
| Urine: 20 – 35 g/24h | OR | 332 - 580 mmol/24h |

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

## QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

Symbols used on Meril Diagnostics labels:

| | | | |
|---|---|---|---|
| REF | Catalogue No. | | Attention See Instruction for Use |
| LOT | Batch No. | IVD | *In vitro* Diagnostics |
| | Expiry Date | | Consult Instruction for Use |
| | Manufacturer | | Storage Temperature |
| | Keep Dry | | Keep Away from Sunlight |
| | Manufacturing Date | | Do not use if package is damaged |
| EC REP | Authorized European Representative in the European Community | | |

## PERFORMANCE CHARACTERISTICS

### 1. Linearity

The linearity is up to 300 mg/dl or 107 mmol/l of urea.

### 2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 1 mg/dl.

The limit of quantification is 2 mg/dl.

### 3. Interferences

No interference has been observed for the following

Hemoglobin up to 40 mg/dl

Bilirubin up to 30 mg/dl

Triglyceride up to 1000 mg/dl

### 4. Precision

Intra-assay precision

| | Mean | SD | CV |
|---|---|---|---|
| n = 20 | mg/dl | mg/dl | % |
| sample 1 | 44.39 | 0.38 | 0.87 |
| sample 2 | 160.44 | 0.53 | 0.33 |

Inter-assay precision

| | Mean | SD | CV |
|---|---|---|---|
| n = 20 | mg/dl | mg/dl | % |
| sample 1 | 41.88 | 1.8 | 4.3 |
| sample 2 | 157.4 | 6.0 | 3.8 |

### 5. Methods Comparison

Comparison was done between reference Urea Reagent and CliniQuant -FSR Urea (BUN) Reagent (test)

N = 36 $y = 1.011x - 0.136$

$r^2 = 0.995$

## LIMITATIONS

Samples with values above 300 mg/dl should be diluted with 0.9% saline, re-run and multiply results by dilution factor.

## WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

## REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 1528 - 1531.

2. Data on file: Meril Diagnostics.

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