**TECO DIAGNOSTICS**
1268 N. Lakeview Ave.
Anaheim, CA 92807
1-800-222-9880

# BUN TEST
# U.V. METHOD
# TC MATRIX-240/480

## INTENDED USE
For the quantitative determination of urea concentration in serum or plasma on TC Matrix analyzer. For in vitro diagnostic use only.

## SUMMARY AND EXPLANATION OF THE TEST
Urea is the end-product of the nitrogen generated during the breakdown of protein. Urea is produced in the liver. It constitutes the majority of the NPN (non-protein nitrogen) fraction of the blood and is normally excreted by the kidney in urine. Blood Urea Nitrogen (BUN) levels are therefore related to protein metabolism (intake and catabolism) and to liver and kidney function.
Urea is hydrolyzed by urease to produce ammonia. The ammonia is then coupled with α-ketoglutarate and NADH to produce glutamate and $NAD^+$. The rate of absorbance decrease is directly proportional to the amount of urea present in the sample.
The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the concentration of urea in the sample and is used by the TC Matrix System to calculate and express the urea concentration.

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

$$NH_3 + \text{NADH} + H^+ + \alpha\text{-ketoglutarate} \xrightarrow{\text{Glutamate dehydrogenase}} \text{Glutamate} + NAD^+ + H_2O$$

## REAGENT PREPARATION
No preparation is required.

## REAGENT COMPOSITION
α-Ketoglutarate: 2.9 mmol/L
Urease: >24000 IU/L
Glutamate dehydrogenase: >1300 IU/L
NADH: 0.35mmol/L
Also contains non-reactive chemicals for optimal system performance.

## REAGENT STORAGE AND STABILITY
Urea reagent stored unopened at 2ºC to 8ºC is stable until the expiration date shown on the bottle label. Once opened, Urea Reagent is stable for 14 days, or until the expiration date on the bottle label whichever occurs first.
DO NOT FREEZE.

## SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum or plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and is allowed to clot. The serum is then separated from the clot. A maximum limit of two hours from the time of collection is recommended.
2. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.
3. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum and plasma should be stored at 2ºC to 8ºC. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15ºC to -20ºC. Samples are stable for at least 2 months when frozen. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

## CALIBRATION
Calibration stability is 30 days. Calibration stability depends on the application characteristics and cooling capacity of the autoanalyzer used.

At least two level controls must be run once in every 24 hours. Each laboratory should determine its own quality control scheme and procedures. If quality control results are not within acceptable limits, calibration is required

**Note:** Refer to the TC Matrix manual for further instructions on calibrating the instrument

## MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
Arcal Auto Calibrator
At least two levels of control material.

## LIMITATIONS
1. The anticoagulant Sodium Citrate was found to be incompatible with this method.
2. The anticoagulants Ammonium Heparin, EDTA, Lithium Heparin, Potassium Oxalate, Sodium Fluoride and Sodium Heparin were found to be compatible with this method.

## INTERFERENCES
1. Fluoride is a known inhibitor of urease activity and will decrease the reaction rate of this reagent.
2. The presence of ammonium ions in anticoagulants may produce falsely elevated results.
3. Lipemic samples >3+ should be ultra-centrifuged and the analysis performed on the infranate.
4. On this method, refer to the work of Young for comprehensive list of drugs and substances which affect on urea concentration.

## EXPECTED VALUE
7 - 18 mg/dL or 2.5 to 6.4 mmol/L

## PROCEDURE
**Settings for TC-Matrix 240/480**

| | | | |
|---|---|---|---|
| Test Name: | BUN | R1: | 160 |
| Full Name: | BUN | R2: | 37 |
| Pri. Wave: | 340 nm | Sample volume: | 2.0 |
| Sec. Wave: | 700 nm | Calibration Type: | 2 point linear |
| Assay/ Point: | Fixed-time | K Value: | / |
| Start - End: | 19 - 25 | Point: | 2 |
| Decimal place: | 1 | Blank Type: | Water |
| Unit: | mg/dL | Point 0 (Blank) Con.: | 0.0 |
| Linearity Range: | 3.0000 - 300.0000 | Point 1 (STD) Con.: | Standard/ |
| Correlation Factor: | 1.0000 - 0.0000 | | Calibrator |

**PERFORMANCE CHARACTERISTICS**

**B549-TC2/TC4: 05/2024**

**Analytical Range:** 3- 300 mg/dL
For Urea analyte by Urea Reagent on TC Matrix System, this method has been demonstrated to be linear from 3-300 mg/dL.

**Accuracy:** Comparison study was performed between TC Matrix System and Beckman Coulter Synchron® using Urea Reagent and 40 samples. The results of this study in yield a correlation coefficient of 0.99 with a regression equation of y=0.99X +0.53.

**Precision:** Within Run precision for Urea Reagent Set was determined following a modification of NCCLS EP5-A. Two commercial human serum samples were assayed on TC Matrix System for 25 times.

| Sample | Sample 1 | Sample 2 |
|---|---|---|
| N | 25 | 25 |
| Mean (mg/dl) | 17 | 52 |
| Standard Deviation (mg/dl) | 0.5 | 2.2 |
| Coefficient of Variation (%) | 3.4 | 4.4 |

Run-to-Run precision for Urea Reagent was determined following a modification of NCCLS EP5-A. Two commercial human serum samples were assayed on TC Matrix Systems five times per day for five days for a total of 25 values.

| Sample | Sample 1 | Sample 2 |
|---|---|---|
| N | 25 | 25 |
| Mean (mg/dl) | 17 | 52 |
| Standard Deviation (mg/dl) | 0.6 | 2.1 |
| Coefficient of Variation (%) | 3.1 | 4.1 |

**PRECAUTIONS**

1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory should perform quality control testing to assure the results are reliable before testing the specimens.

**REFERENCES**


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TECO DIAGNOSTICS
1268 N. LAKEVIEW AVE.
ANAHEIM, CA 92807
U.S.A.