**INTENDED USE**
MEDICON UREA is a set of reagents for the quantitative determination of Urea in human serum, plasma and urine, with BECKMAN COULTER AU400/800/600/40/02/07/00/0400 and other discrete analyzers. For in vitro diagnostic use only.

**CLINICAL SIGNIFICANCE**
Urea is synthesized in the liver as the final product of protein and amino acid metabolism. Urea synthesis is therefore dependent on daily protein intake and endogenous protein metabolism. Most of the urea produced during these metabolic processes is eliminated by glomerular filtration. During diuresis a large quantity of urea is excreted in the urine and plasma urea concentration is low. During anuric disease which may occur in oliguric heart failure, excrectosis or thirst, urea redissolves in the tubules at an increased rate and plasma urea increases. Prenatal elevation of urea occurs in cardiac decompensation, increased protein catabolism, and water depletions. Urea levels may be elevated due to renal causes such as acute glomerulonephritis, chronic nephritis, polycystic kidney, tubular necrosis, and nephrotoxins. Post renal elevation of urea may be caused by obstruction of the urinary tract. In dialysis patients the urea concentration is representative of protein degradation and is also an indicator of metabolic status.

**METHOD PRINCIPLE**
The enzymatic determination of Urea is based on the following reactions:

\[
\text{Urea} + \text{H}_2\text{O} \rightarrow 2\text{NH}_2\text{CO}_2 \rightarrow 2\text{NH}_3 + \text{CO}_2 \\
2\text{NH}_2 + 2\text{α-ketoglutarate} + 2\text{NAD}^+ \rightarrow 2\text{L-glutamate} + 2\text{NADH} + 2\text{H}_2\text{O} \\
\text{GLODH: Glutamate dehydrogenase}
\]

**METHOD LIMITATIONS**
Refer to the book "Effects of Preambulatory Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Testing." The reagent is designed for in vitro diagnostic use only. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratories practices and techniques. Avoid inhalation and contact with eyes and skin.

**REAGENT COMPOSITION**
Reagent 1 (R1):
- Tris buffer (pH 7.7): 150 mM
- Urease: ≤ 30 KUL
- GLODH: ≤ 1 KUL
- ADP: 10 mM
- α-Ketoglutaric acid: 10 mM

Non reactant components and preservatives
Reagent 1 (R1):
- Tris buffer (pH 7.7): 20 mM
- NADH: 0.52 mM

Non reactant components and preservatives

**WARNINGS – PRECAUTIONS**
- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle according to the universal precautions and good laboratory practices.
- The reagent contains sodium azide (NaN₃ ≤ 0.1%). Avoid swallowing and contact with the reagent of skin and mucous membrane.
- Dispose all waste according to national laws.
- MSDS is available by MEDICON upon request.

**PREPARATION**
Reagents are ready to use and placed in the corresponding positions on the analyzers. Vials bear bar code for recognition by BECKMAN COULTER AU Series analyzers.

**REAGENT DESTRUCTION**
The reagent should not be used:
- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- After prolonged exposure to sunlight or high temperature.

**SHELF LIFE**
Unopened, reagents are stable up to the expiration date stated on the label when stored at 2 – 8 °C. Once opened, they’re stable for 40 days, if stored refrigerated on the instrument.

**SAMPLE**
Use serum or heparinized plasma as specimen. Do not use anti-coagulants, which contain ammonium or fluoride ions. Haemolysed and strongly lipemic samples should be avoided. Urea is stable in serum and plasma for 24 hours at 25 °C, several days when stored at 2 – 4 °C, and 2 – 3 months at least if frozen. Urea 24-hour collection without preservatives is recommended. Urea is stable in urine for 7 days when stored at 2 – 8 °C and for 2 days when stored at 15 – 25 °C.

For the determination of urea in urine analyzers that do not perform automatic dilution, use samples diluted 1:10 with distilled water. Samples are stable for 4 days at 2 – 8 °C.

**QUALITY CONTROL**
MEDICON suggests the MEDICON Clinical Chemistry Control Lev. 1 & 2 (1578-0961-12 & 1578-0962-012) or the BECKMAN COULTER Control Serum Lev 1 and 2, Cat. No. ODC0003, ODC0004 (MEDICON code: 4478-0964, 4478-0962) for Quality Control in serum, and the MEDITROL U 1.2 (1578-0181) or the BIORAD Liquidcheck Quantitative Urine Control Ref. 397 (Lev 1), 398 (Lev. 2) (MEDICON code: 1778-0181 and 1778-0182 respectively) for Quality Control. Control values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for Urea should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

**MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT**
Urea calibrator
Quality control material
Automated biochemistry analyzer
Common laboratory equipment

**REFERENCE INTERVALS**
- Serum: plasma - 15 – 45 mg/dL
- Plasma: 20 – 35 mg/dL or 1500 – 34200 mg/day

Each laboratory should determine its own expected values as dictated by good laboratory practice.

**WASTE DISPOSAL**
This product contains sodium azide (NaN₃), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Linearity**
The assay is linear within measuring range 0.7 – 500 mg/dL, for serum and 8.5 – 4800 mg/dL, for urine. When values exceed this range samples should be diluted accordingly.

**Sensitivity**
The lowest detectable level of Urea is estimated at 0.7 mg/dL, for serum and 8.5 mg/dL, for urine.

**METHOD PRINCIPLE**
For in vitro use

\[
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2\text{NH}_2 + 2\text{α-ketoglutarate} + 2\text{NAD}^+ \rightarrow 2\text{L-glutamate} + 2\text{NADH} + 2\text{H}_2\text{O} \\
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