UREA Colorimetric Method

Reagent for quantitative determination of urea in human serum and plasma or urines.

**PRINCIPLE**
Enzymatic and colorimetric method based on the specific action of urease which hydrolyses urea in ammonium ions and carbon dioxide. Ammonium ions then form with chloride and salicylate a blue-green complex. This coloration, proportional to urea concentration in the specimen, is measured at 600 nm.

**SAFETY CAUTIONS**
BIOLABO reagents are designated for professional, in vitro diagnostic use.
- Verify the integrity of the contents before use.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.
- All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

**STABILITY AND STORAGE**
Store at 2-8°C, well recap in the original vial and away from light.
- Unopened, reagents are stable until expiry date stated on the label when stored and used as described in the insert.
- Once reconstituted, working reagent (R1+R2) is stable for 1 month when free from contamination.
- Once opened, Base (vial R3) diluted ¼ is stable for 3 months when free from contamination.
- Once opened, the contents of vial R4 is stable for at least 3 months when free from contamination.
- Discard any reagent if cloudy or if absorbance of blank against water at 600 nm > 0.100.
- Don’t use working reagent or diluted contents of vial R3 after expiry date stated on the label of the kit.

**SPECIMEN COLLECTION AND HANDLING**
Unhemolysed serum or heparinised plasma. Avoid fluoride or ammonium as anticoagulant which interfere with the assay.
- Urea is stable in serum or plasma for:
  - 24 h at room temperature.
  - several days at 2-8°C.
  - at least 2-3 months frozen.
- 24h Urine: diluted (1+19) with demineralised water before assay.
- Urea is stable in urines for:
  - 4 days at 2-8°C.
- Add antibacterial agent as Thymol to improve the stability.

**INTERFERENCES**
No interference of assayed substances (ascorbic acid, bilirubin, haemoglobin, triglycerides) with the test.
For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

**SPECIFICATIONS**
- Instrumentation: Bioelectronic enzyme analyzer or photometer.
- Method: Colorimetric method based on the specific action of urease which hydrolyses urea in ammonium ions and carbon dioxide.
- Principle: Enzymatic and colorimetric method.
- Measurement of plasma or serum urea concentration is widely used.
- Regulation: In accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

**REAGENTS PREPARATION**
Add contents of vial R2 (Urease) into vial R1 (Salicylate). Mix gently by inversion.

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**MATERIAL REQUIRED BUT NOT PROVIDED**
1. Basic medical analysis laboratory equipment.
2. Normal and pathological control sera
CALIBRATION
- Standard enclosed in the kit (vial R4) or BIOLABO Multicalibrator REF 95015 traceable to SRM 909b.
- Or any calibrator traceable to a reference method or material.

The calibration frequency depends on proper instrument functions and on the preservation of reagent.

It is recommended to calibrate in the following cases:
1. When changing batch of reagent.
2. After maintenance operations on the instrument.
3. If control values are out of range, even after using a new vial of fresh control serum.

QUALITY CONTROL
- BIOLABO EXATROL-N Level I REF 95010.
- BIOLABO EXATROL-P Level II REF 95011.
- Other assayed control sera referring to the same method.
- External quality control program.

It is recommended to control in the following cases:
- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:
1. Repeat the test with the same control.
   If control is out of range, apply following actions:
   - When changing batch of reagent.
   - After maintenance operations on the instrument.

2. When changing vial of reagent.
   - At least once within 24 hours.
   - At least once a run.

3. If control values are out of range, even after using a new vial of fresh control serum.

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4. Other assayed control sera referring to the same method.

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