

Reflotron[®] BUN



REF 11200704 209

15 tests

English

Intended use

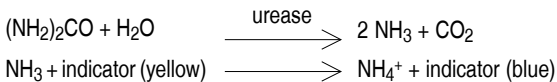
Test for the quantitative determination of urea nitrogen (BUN) in blood, serum or plasma with Reflotron.

Clinical aspects

The determination of urea nitrogen plays an important role in the evaluation of renal function. The test is often used together with the determination of creatinine for differentiation between prerenal and postrenal azotaemia on the basis of the urea nitrogen / creatinine ratio. Other indications for the determination of urea nitrogen are end-stage renal failure and determination in dialysis patients as the urea nitrogen concentration is representative for protein breakdown and provides information on the metabolic status.

Test principle¹

After application to the test strip, the sample flows into the reaction zone, in the case of blood after separation of the erythrocytes from the plasma. The urea nitrogen contained in the sample is hydrolyzed to ammonium carbonate from which ammonia is expelled due to the alkaline buffering. This leads to the partial colour change of a buffered indicator to green/blue, the intensity of which is proportional to the urea nitrogen concentration of the sample:



At a temperature of 37 °C the depth of colour formed is measured at 642 nm and the urea nitrogen concentration displayed after about 190 seconds in mg/dL or mmol/L depending on how the instrument has been set.

Components per test: urease (jackbean) > 4.7 U; 3,3',5,5'-tetrachlorophenol-3,4,5,6- tetrabromosulphophthalein (indicator) 20.4 µg; buffer.

Precautions and warnings

For in vitro diagnostic use. Please observe the usual precautions for handling laboratory reagents.

Storage and shelf-life

Store at 2-30 °C. Under these conditions the tests can be used up to the expiry date printed on the pack or container. After removing a test strip, be sure to restopper the container immediately otherwise exposure to dust, humidity etc. may render the test strips unusable.

Sample collection and treatment^{2,3}

Capillary blood; whole blood collected in standard sample collection tubes, as well as serum prepared from this; heparinized or EDTA-blood or heparinized or EDTA-plasma. Use **fresh capillary or venous blood** immediately after collection.

Heparinized or EDTA blood kept in closed containers should be used within 8 hours. After precipitation of the cellular components the supernatant plasma may be used if care is taken not to shake the specimen. If coated single-use containers or capillary pipettes are used, please observe the stability data given by the manufacturer.

Serum and EDTA- or heparinized plasma kept in closed containers is stable for 7 days at 4-25 °C.

Testing procedure

Additional materials required (not supplied): Reflotron instrument; Reflotron Pipette and pipette tips or capillary pipette, controls, usual laboratory equipment for collecting blood.

Before carrying out a test, please read the Reflotron manual and be sure that you are familiar with the instrument's operation.

Switch on the instrument.

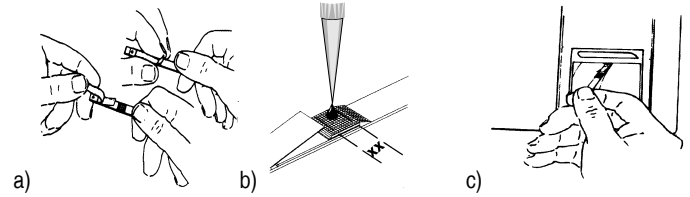
When the display shows "READY", remove a test strip from the container.

Replace the desiccant stopper on the container immediately.

Unwrap the strip (a), taking care not to bend it.

Using the Reflotron Pipette, for example, draw sample material into to the pipette (avoiding bubbles) and apply as a drop to the centre of the red application zone (xx) – being careful not to touch the application zone with the pipette tip (b); required volume of specimen for application: 30 µl (see illustration).

With the sliding cover or flap open, place the test strip on to the guide within 15 sec and slide forward horizontally until it locks into place (c). Close the sliding cover or flap.



The instrument displays BUN to confirm that it has correctly read in the test-specific magnetic code. The display shows the number of seconds left before the result is displayed. The urea nitrogen concentration is calculated automatically from the readings taken using a function and conversion factors that are entered in the instrument via the magnetic strip on the underside of each test strip. The urea nitrogen concentration is displayed in mg/dL or mmol/L depending on whether the instrument has been set to conventional or SI units. Remove the used test strip from the Reflotron and dispose of it according to your laboratory's procedure.

Calibration

The function curve for Reflotron BUN, for converting reflectance values into concentrations, is defined for each lot of Reflotron BUN, using the Urea/Urea-N method (kinetic UV test) of Roche Diagnostics. The data are automatically programmed into the instrument during testing.

Quality control

For quality control use Reflotron Precinorm U or Reflotron Check to meet individual laboratory requirements or to comply with regulations. The results must be within the prescribed ranges. Each laboratory must specify corrective measures to be applied in the event of values being out of range.

Notes; limitations of the procedure - interferences^{1,2,4}

Do not use ammonium heparinate.

Ammonia and other volatile components which can occur particularly in the blood of patients with kidney disease are detected but do not affect the result of the test on account of the very low concentrations.

The following had no influence on the results in the concentration ranges tested (criterion: recovery ± 10 % of baseline): haematocrit up to 55 %, haemolysis up to 1 %, lipaemia, bilirubin and 50 drugs tested.

Measuring range and dilution²

Measuring range: 9.0 – 140 mg/dL or 3.21 – 50.0 mmol/L.

If the measured urea nitrogen value is above the measuring range for Reflotron BUN (indicated by > in front of the displayed result), the **serum** or **plasma** may be diluted 1 + 1 with physiological saline. The true urea nitrogen concentration C can be calculated from the measured urea nitrogen concentration C_{dil} using the following formula: C = 2 C_{dil}.

Reference ranges^{5*}

Blood, serum, plasma.

Adults	< 65 years	< 23.4 mg/dL	< 8.3 mmol/L
	> 65 years	< 33.2 mg/dL	< 11.9 mmol/L

*Used conversion factor (mg/dl) urea / urea nitrogen 2.14

Used conversion factor: mg/dL x 0.357 = mmol/L

It is up to each laboratory to check that the reference ranges are appropriate to its patient groups, and to establish its own reference ranges if necessary. For diagnostic purposes the urea nitrogen results should always be evaluated in combination with the history, the clinical examination and the results of other examinations and tests carried out.

Performance characteristics²

The data for Reflotron UREA/BUN were determined in series of tests. The majority of the data for the test were within the given ranges.

Repeatability (within-series imprecision):

CV (coefficient of variation) 3.0 % in the normal range, 2.3 % in the pathological range; sample material: serum.

Reproducibility (day-to-day imprecision):

CV 3.0 % in the normal range, 3.5 % in the pathological range;

sample material: control sera.








Accuracy (methods comparisons; mmol/L; regression equations, n samples, correlation coefficient r):

$y = 0.978 x + 0.35$ and $1.029 x + 0.02$, respectively, (n= 40-110; r=0.995; sample materials: serum, EDTA blood, EDTA plasma; reference method x: urease method, Roche Diagnostics).

References

1. Price CP, Koller PU. J Clin Chem Clin Biochem 1988; 26: 233-250
2. Daten der Evaluierung; Roche Diagnostics GmbH
3. Guder WG et al. Lab med 1989; 13: 299-402
4. Koller PU et al. Lab med 1989; 399-402
5. Heil W et al. Reference Ranges for Adults and Children, 2000; Roche Diagnostics GmbH

Symbol table

	Catalogue number
	Batch code
	In vitro diagnostic medical device
	Manufacturer
	Use by
	Temperature limitation
	This product fulfills the requirements of the European Directive 98/79 EC for in vitro diagnostic medical devices

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Significant additions or changes are indicated by a change bar in the margin.

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