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UriSet 24

24 h Urine Collection Set – Evaluation Study



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University Hospital Großhadern
Munich/Germany



Pre-analytics

The innovative concept of the **UriSet 24 NFT** is based on findings determined in a series of numerous tests and in co-operation with Institute of Clinical Chemistry, University Hospital Großhadern, Munich/Germany.

Apart from other fields of applications, this urine collection set is particularly intended for the collection of 24 h urines and analysis of

Epinephrine
Norepinephrine
Dopamine

Metanephrine
Normetanephrine

Vanillylmandelic acid
Homovanillic acid
Hydroxyindoleacetic acid

The analysis results outlined below answer the most important questions raised by physicians and laboratories:

1. Which acid concentration and quantity is required for optimum long term stabilization of the above-mentioned marker molecules in 24 h urines?
2. Which capacity must a urine container have to hold most 24 h urines?
3. Which are the most suitable storage conditions for the urine sample between collection and analysis?

1. Acid Concentration

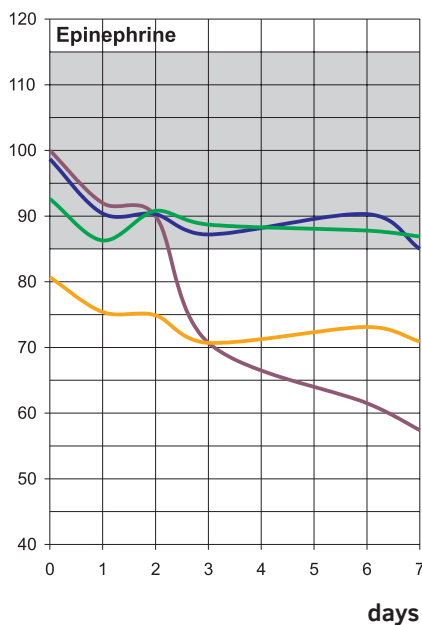
Pooled urines were spiked and aliquots adjusted to show different pH values (in 13 steps of 0.5 pH units from pH = 0.5 to pH = 6.5). The test was established to determine if the samples remained stable when stored in a dark place at room temperature.

Values ranging within the limits of methodical measuring accuracy (illustrated by grey sections in the diagrams) were considered an optimal pH range.

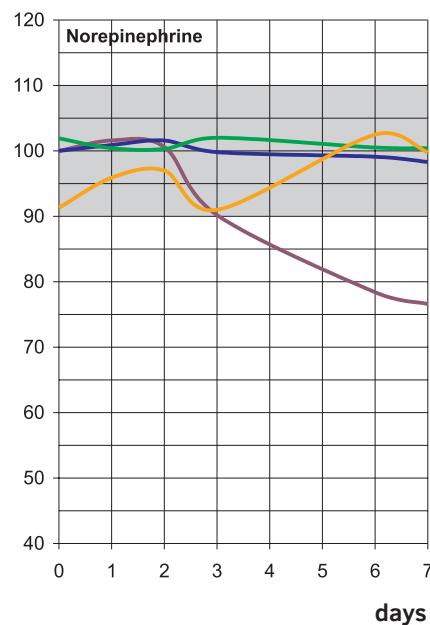
To simplify the graphics, the following diagrams on the chronological development (7 days) of percentage recovery show only four of the 13 pH steps measured, i.e. pH values **0.5 (orange)**, **2.5 (green)**, **5.0 (blue)** and **6.5 (violet)**.

Recovery of analytes (shown in per cent) over 7 days
Urines of pH steps: ---0.5 ---2.5 ---5.0 and --- 6.5

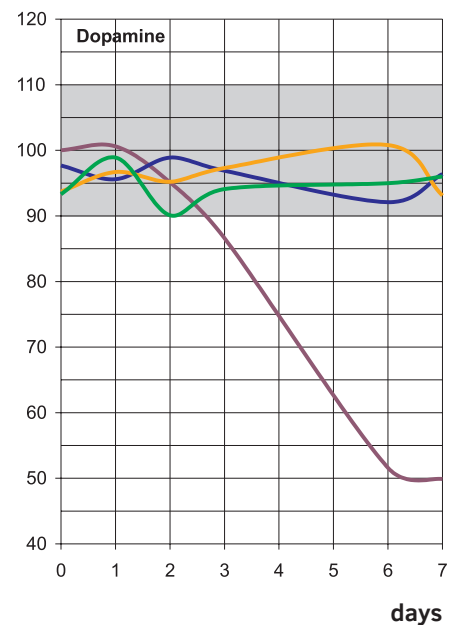
Recovery in %



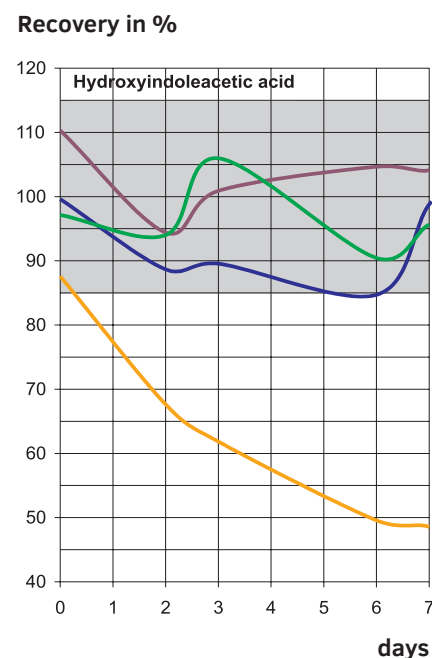
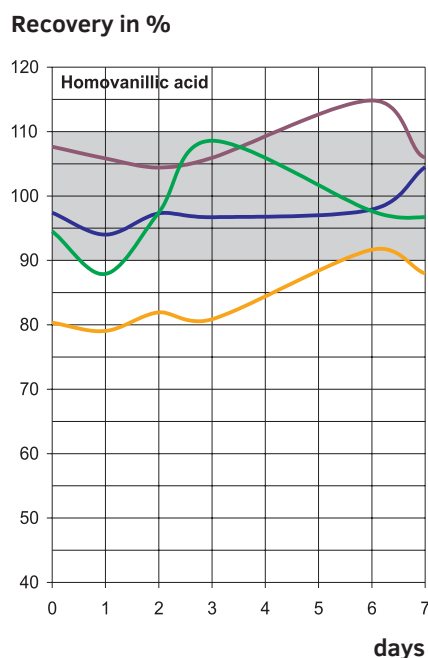
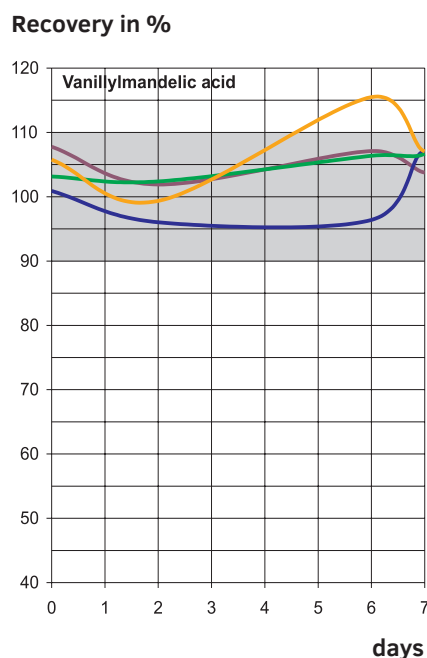
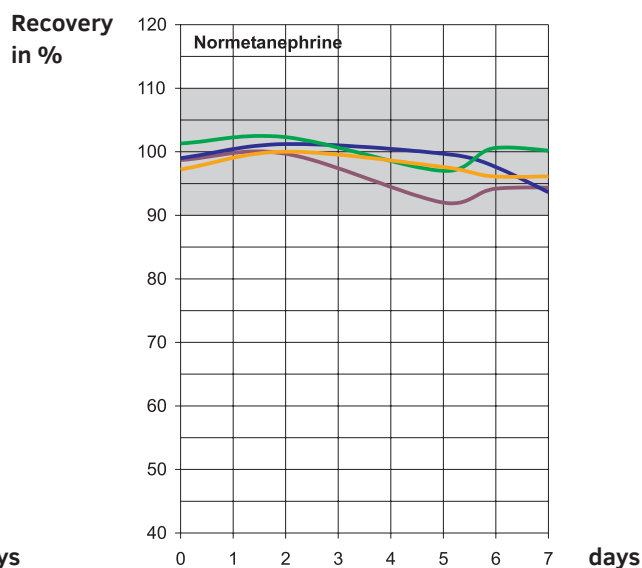
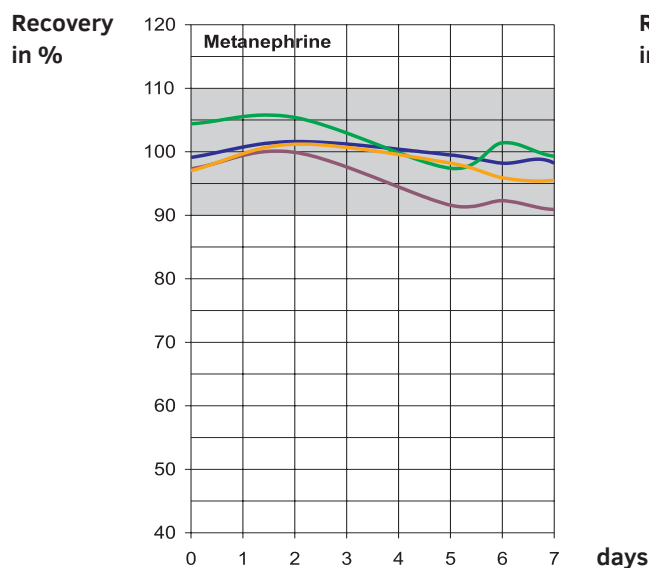
Recovery in %



Recovery in %



Recovery of analytes (shown in per cent) over 7 days
 Urines of pH steps: ---0.5 ---2.5 ---5.0 and ---6.5



Conclusion: All diagnostic parameters shown are stable in a pH range between 2.5 and 5.0 for a period of 7 days, stored in a dark place at room temperature.

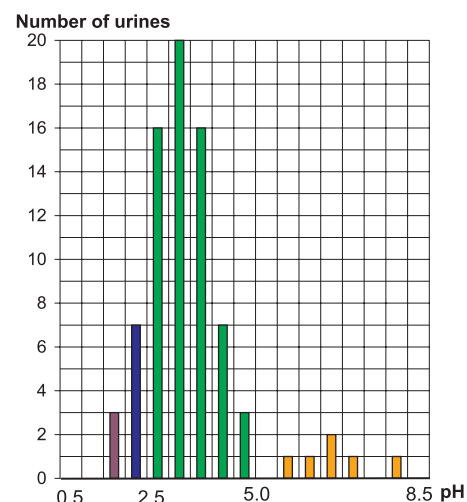
To determine the suitable acid concentration and amount, the urine volume and buffer quality from a representative group of individuals was analysed by titrating seventy-eight 24 h urines. The amount of acid required to obtain the pH range of 2.5 and 5.0 for the majority of these urines is based on these data.

The histogram on the right shows that adding 9 ml 20 % HCl shifts the pH of 62 out of the 78 urines into the target range (green bars = 79.5 %).

For the catecholamines and metanephrines, the 7 urines indicated in blue are suitable as well (88.5 %).

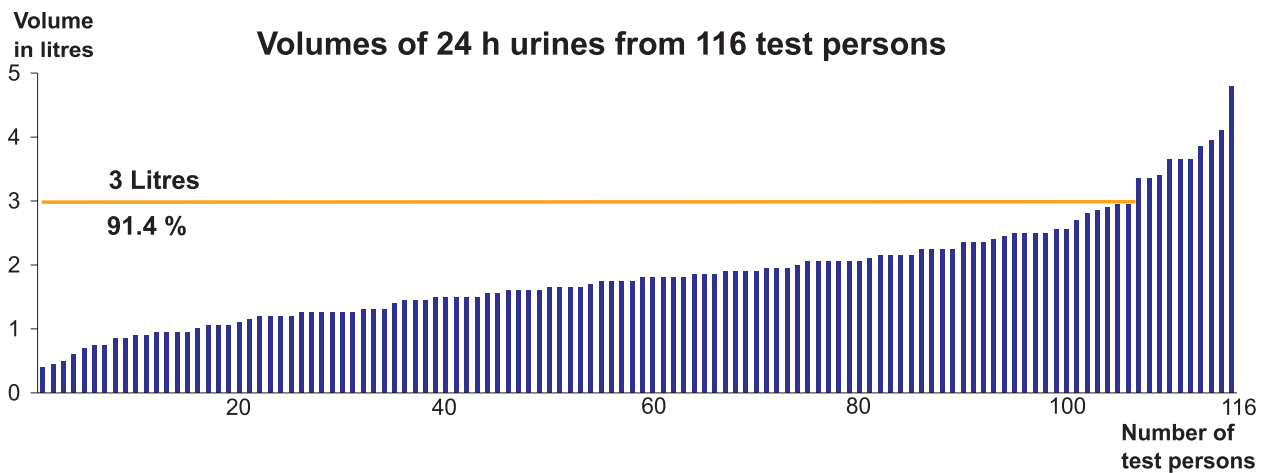
Conclusion: For the vast majority of urines, 9 ml of 20 % HCl shift the urinary pH into the required range.

Number of pH values of the seventy-eight 24 h urines after adding 9 ml of a 20 % HCl solution



2. Urine Container Capacity

116 Adult test subjects were requested to collect 24 h urines without changing their drinking habits.



For 91.4 % of the test persons (106), a 3 L container was found to hold the urines collected; 10 test persons exceeded 3 L.

Recommendation: Ask the patient about his/her drinking habits and how often he/she uses the toilet, and hand out two Urine Collection Sets, as required.

3. Sample Storage

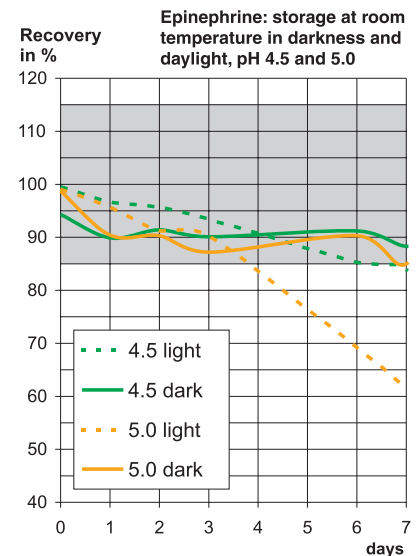
The stability of the analytes stated above is mainly determined by pH, temperature and light exposure.

Samples stored in daylight and at room temperature showed a distinctive decline in the analytes' recovery values as shown by the graph on the right, illustrating the extremely light-sensitive epinephrine and the preset pH values of 4.5 and 5.0.

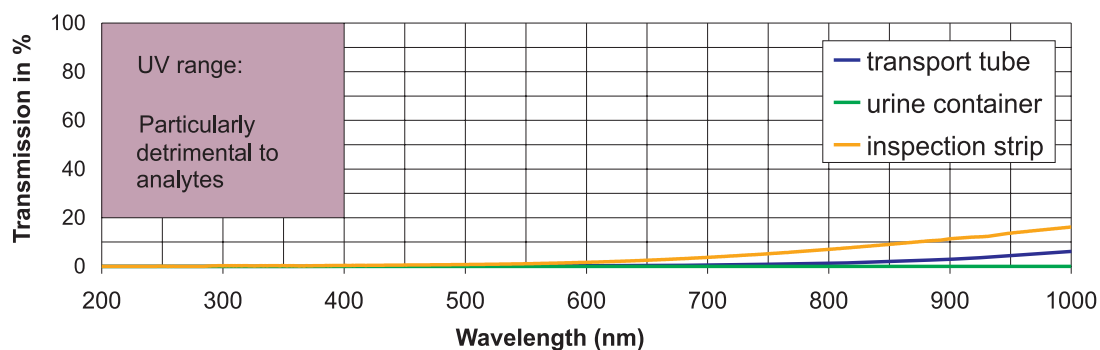
The broken lines indicate the course of epinephrine values when urine is stored in transparent tubes while the continuous lines are indicative of storage in the dark as in our urine monovettes or transport tubes with light protection.

The percentage transmission shows the amount of light that can pass through the transport tube and the urine container (i.e. through its brown coloured body and the transparent inspection strip).

In particular, the short-wave, high-energy ultraviolet light (with wavelengths below 400 nm) is detrimental to the analytes.



Transmission spectra of the plastic materials used



The materials and colouring of the collection bottle and white transport tube or Urine Monovette® were chosen so that no light can penetrate through them.