CHROMATOGRAPHY URINE

Human Lyo Urine
for Intra-Laboratory Quality Control
in Occupational Medicine and Endocrinology

10 x 10 ml **REF 3649**

INTENDED USE

Kit for chromatographic *in vitro* control of Lyophilized Human Urine.

PRINCIPLE

Chromatography Urine is a lyophilized human urine containing components in well known concentrations and without any preservative which may interfere with the test. The product is intended for intra-laboratory quality control purposes only and is supplied with the intervals of the suggested acceptable values for each component. Chromatography urine is not to be used to prove the truth of measurements.

REAGENTS

Kit components: **REF 3649**

REAGENT 1 (lyo) **10 vials**
Lyophilized human urines
STABILITY: stored at 2-8°C, the reagent is stable up to the expiration date on the label.

PREPARATION OF THE REAGENT 1

Carefully open a vial of Reagent 1, avoiding any loss of the lyo material.
Pipette exactly 10.0 ml of distilled water into the vial. Be very careful in the reconstitution step because the concentration values for the components depend on the accuracy of this step. Close the vial and incubate for 20 minutes at room temperature. Shake gently until complete dissolution. Avoid to form any foam.
NOTE: reconstituted chromatography urine is to be treated as patient samples.
STABILITY: at least 5 days at 2-8°C.

SPECIFIC VALUES

The average values in the following table were obtained from several analysis performed in different laboratories. Tests were performed using a representative sample of this lot of chromatography urine. Intervals of the suggested reference values were calculated on inter-laboratory variability and are indicative only. The average values are specific for each lot of chromatography urine. The values listed may vary in time. Variations in time or among laboratories may be caused by differences in laboratories techniques, equipment, reagents, applied procedures. Each laboratory should define its own reference values.

LOT	91220
EXPIRY DATE	2023-12

OCCUPATIONAL MEDICINE

Component	Unit	Average	Reference range
δ-Aminolevulinic acid	mg/L	7.97	6.37-9.56
Porphobilinogen	mg/L	0.20	0.16-0.25
Coproporphyrines	µg/L	Φ	Φ
Uroporphyrines	µg/L	Φ	Φ
Total Porphyrines	µg/L	Φ	Φ

ENDOCRINOLOGY

Component	Unit	Average	Ref. range
Free Catecholamines	µg/L	---	---
Free Adrenaline	µg/L	---	---
Free Noradrenaline	µg/L	---	---
Total Catecholamines	µg/L	---	---
Serotonin (5HT+5HTP)	mg/L	12.1	9.7 – 14.5
5-Hydroxyindolacetic acid	mg/L	5.53	4.32-6.75
17-Hydroxycorticosteroides	mg/L	22.3	16.7-27.9
17-Ketosteroides	mg/L	17.4	13.9- 20.8
Metanephrines	mg/L	10.1	7.6-12.6
Vanilmandelic acid	mg/L	16.8	13.4 – 20.1

ELECTROLYTE / PROTEIN

Component	Unit	Average	Reference range
Copper Urine	µg/dL	60.2	48.1 – 72.2
Total Protein (Coomassie) manual	mg/L	9.6	7.2-12
Total Protein (Coomassie) COBAS	mg/L	ND	ND
Total Protein (RED PYROGALLOL) manual	mg/L	9.2	7.4-11.1
Total Protein (RED PYROGALLOL) COBAS	mg/L	ND	ND
Zinc manual	µg/dL	50.7	40.5 – 60.8
Zinco COBAS	µg/dL	49.6	39.7 – 59.5

NOTES

1. Chromatography urine values are considered in normal ranges for some components and in pathological ranges for others.
2. The serum of each urine donor was tested by clinical laboratory methods and resulted negative for Hepatitis B surface virus (HBsAg), antibody to anti hepatitis C (HCV) and antibody to anti HIV-1/HIV-2. No test can completely assure that products containing human source materials will be free of these or other infectious agents. According to good laboratory practice, all human source material should be considered potentially infectious for hepatitis B (HBV), hepatitis C (HCV), HIV-1, HIV-2, HTLV-I, HTLV-II and all other infectious agents; therefore, handle chromatography urine with the same precautions used with patient specimens. Refer to MSDS.
3. ♦ Data not available when printing. Please inquire for more information.
4. Φ Average and reference intervals for this assay were not defined, due to low or absent assignment participation values. Please contact FAR for more information.

IVD CE

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