

AN ITALIAN COMPANY THAT RESEARCHES, DEVELOPS AND PRODUCES READY TO USE KITS USING CHROMATOGRAPHIC TECHNIQUES FOR CLINICAL LABORATORIES

CONTROL LYOPHIL. IN URINE FOR BIOGENIC AMINES - LEVELS 1 and 2 (Noradrenaline, Adrenaline, Dopamine, VMA, HVA, 5-HIAA, Metanephrine, Normetanephrine, 3-Methoxytyramine, Hydroxyproline)

Cod. Z10559

OBJECTIVE

These controls in urine are used for internal quality control and serve to keep under control the accuracy and precision of the analytical procedures dedicated to the quantitative determination of the analytes contained therein. These controls are lyophilized in human matrix and are available in two different concentration range.

RECONSTITUTION

Remove the metal seal and rubber stopper from the vial. Add exactly 5 ml of HPLC grade H₂O in the vial. Replace the rubber stopper, shake and let stand for 5 to 10 minutes. Before use, mix by inverting the vial to dissolve the material until a homogeneous clear solution.

STORAGE AND STABILITY

The controls are stable for 36 months from the date of preparation if stored at 2-8 $^{\circ}$ C. After reconstitution are stable 7 days at 2-8 $^{\circ}$ C and 3 months at -20 $^{\circ}$ C (except VMA, 5-HIAA, stable 1 month at -20 $^{\circ}$ C). Do not use after the expiry date.

PRECAUTIONS

These controls in human matrix should be treated with care and treated as potentially infectious.

LOT		M	\square	
041		Sept	Sept	
		2023	2026	

PACKAGING AVAILABLE:

- Z10559 CONTROL IN URINE FOR BIOGENIC AMINES - LEVELS 1 and 2 2 x 5 x 5 ml

Release N° 002	July 2019
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CONCENTRATIONS CODE Z10559



ANALYTE	MEASUREMENT UNIT	MEDIUM VALUE L1	RANGE L1	MEDIUM VALUE L2	RANGE L2
NORADRENALINE	μg/l	68,0	47,6 - 88,5	389,0	272,3 - 505,7
ADRENALINE	μg/l	16,0	11,2 – 20,8	84,7	59,3 – 110,1
DOPAMINE	μg/l	135,1	94,6 – 175,7	781,0	546,7 - 1.015,2
VMA	mg/l	1,6	1,1 – 2,1	15,7	11,0 – 20,4
HVA	mg/l	1,0	0,7 – 1,4	11,6	8,1 – 15,1
5-HIAA	mg/l	1,3	0,9 – 1,7	16,4	11,5 – 21,3
METANEPHRINE	µg/l	35,7	25,0 - 46,5	544,5	381,2 – 707,9
NORMETANEPHRINE	μg/l	62,6	43,8 - 81,4	923,5	646,5 – 1.200,6
3-METHOXYTYRAMINE	μg/l	25,4	17,8 – 33,0	318,1	222,7 – 413,6
HYDROXYPROLINE	mg/l	9,9	6,9 – 12,8	45,2	31,6 – 58,8

This product fulfills all the requirements of Directive 98/79/EC of 27/10/1998 on in vitro diagnostic medical devices (IVD). The declaration of conformity is available upon request.

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FOR IN VITRO DIAGNOSTIC USE ONLY

produced by

COMPANY WITH
MANAGEMENT SYSTEM
CERTIFIED BY DNV
= ISO 9001=
= ISO 13485 =



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