

ANALYSIS CERTIFICATE

Description

Product Name	Microalbumin
Product Reference	MATUR-XXX
Kit References	- MATUR-B00, MATUR-H00, MATUR-L00, MATUR-C00, - MATUR-B00/ADV, MATUR-H00/ADV, - MATUR-B00/ALI, MATUR-H00/ALI, MATUR-L00/ALI, - MATUR-B00/ARC, MATUR-H00/ARC, MATUR-L00/ARC, - MATUR-B00/ATE, MATUR-H00/ATE, MATUR-L00/ATE, - MATUR-B00/AU, MATUR-H00/AU, MATUR-L00/AU, - MATUR-B00/COB, MATUR-H00/COB, MATUR-L00/COB, MATUR-L00/CDC, - MATUR-B00/UDA, MATUR-H00/UDA, MATUR-L00/UDA. - MATUR-L00/CGR.
Product Lot Number	22H02
Date of Manufacture	02 nd August 2022
Expiry Date	31 st July 2025
Intended Use	Single use in vitro diagnostic material.

Specifications

	Specification	QC result
Accuracy for external control (mg/L)	Included in the range	11.33 (range:9.10 – 16.90)
Accuracy for internal control (mg/L)	Included in the range	21.76 (range:20.00 – 30.00)
Repeatability, n=5 (CV in %)	≤ 7.3 %	5.22 %
Equivalence point (mg/l)	> 1500	> 2000
Product Appearance	Clear Liquid	Clear Liquid

Medium

Preservative : 0.09 % NaN₃
 Filtration : material filtrated through 0.2 µm

The human-origin products have been screened and found negative for HIV 1 and 2 antibodies and HBAg.

Storage Temperature

Since Manufacture : +2 to +8 °C
 Recommended : +2 to +8 °C

Manufacture

Manufactured in conformity with internal rigid QC standards based on International norms and Directive 98/79 EC

Signed :



Date : 26/09/22

For Quality Control

DIAGAM
RUE DU PARC INDUSTRIEL 40
7822 GHISLENGHIEN
BELGIUM
PHONE : +32(0)68.55.14.82
FAX : +32(0)68.56.89.40
VAT#: BE 0451.236.575