

✓ **REFERENCE**



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|--|--------------------------------------|------------------------------------|---------------|
| Miroalbumin high level calibrator (400) | MARE5-001 MARE5-005 | 1 x 1 ml 1 x 5 ml | 2-8 °C |
| Human albumin in synthetic urine standardized from a secondary preparation of human albumin and ERM-DA470k/IFCC, sodium azide (< 1g/l) | | | |
| Batch number : | 21G16 | | |
| Expiry date : | 01/2023 | | |
| Control date : | 17/08/21 | | |
| Quality control report : | DGM-QAC-REP-21190 | | |
| Document prepared and signed by : | L.Ginneberge | | |

may react with lead or copper plumbing to form highly explosive metal azides.

✓ **ANALYTICAL PERFORMANCES**

See the corresponding reagents technical sheet.

✓ **PREPARATION AND REAGENTS STABILITY**

The calibrator is ready for use; once opened, it is stable until expiry date if stored stoppered in appropriate temperature conditions and without any contamination (avoid pipetting and decantation).

✓ **METHOD OF ANALYSIS AND CALCULATION**

See the corresponding reagents technical sheet

✓ **QUALITY CONTROL**

Accuracy and reproducibility: analytical performances can be checked with the internal quality control serum of the laboratory or with the Liquichek™ (BIORAD) Control urines (see the values range obtained with Diagam reagents and indicated on the accompanying BIO-RAD sheet).

Calibration: calibration curve and stability of calibration curve can be validated with the Diagam calibration control (**MACON-002**). In case of analytical performances modification, calibrate the method again and contact the manufacturer if modifications are subsisting.

✓ **BIBLIOGRAPHY**

(1) Certification of proteins in the human serum. Certified Referenced Material ERM® -DA470k/IFCC. I. Zegers et al.

<http://irmm.jrc.ec.europa.eu/>

(2) Miller, W.G. et al. Current issues in measurement and reporting of urinary albumin excretion. Clin. Chem. (2009); 55:1: 24-38.

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

The microalbumin high level calibrator is a synthetic urine containing human albumin at fixed value diluted in HEPES pH 7.4 buffer containing stabilizers and sodium azide (<1g/l) as preservative.

✓ **PRINCIPLE OF TEST**

The human albumin reacts upon a specific antibody for human albumin and the turbidity induced by the formation of immune complexes is recorded at 340 nm. The turbidity measured is directly proportional to the albumin concentration of the calibrator which can be used for the quantitative determination of microalbumin in immunoturbidimetry.

✓ **PRECAUTIONS**

For in vitro single diagnostic use. To be handled by entitled Personnel. Products from human source were tested and found free from HBsAg and antibodies to HCV and HIV but this material should be treated just as carefully as potentially infective.

Products containing sodium azide have to be handled with care; avoid ingestion and contact with skin and mucous membranes. Sodium azide

























MARE5 21G16 IFU EN v03 23/08/21


| | | |
|---------------------|----------------|-----------|
| Microalbumin | CAL H | |
| | mg/l | |
| | certified val. | U* |
| | 400 | 20 |

U*: The certified uncertainty is the half-width of the 95% confidence interval of the mean.
Values assigned from the reference ERM-DA470k/IFCC.

Symbols

The following symbols may appear on the packaging and labelling:

| | | | |
|---|--|---|--|
|  | <i>Batch code</i> |  | <i>Buffer</i> |
|  | <i>Use by</i> |  | <i>Calibrator</i> |
|  | <i>Manufacturer</i> |  | <i>High</i> |
|  | <i>In Vitro Diagnostics Medical Device</i> |  | <i>Medium</i> |
|  | <i>Temperature limitation (store at)</i> |  | <i>Low</i> |
|  | <i>Catalogue number</i> |  | <i>4 Levels</i> |
|  | <i>Consult instructions for use</i> |  | <i>5 Levels</i> |
|  | <i>Reagent</i> |  | <i>6 Levels</i> |
|  | <i>Kit</i> |  | <i>Control</i> |
|  | <i>Contents</i> |  | <i>This product meets the requirements of European Directive 98/79 CE concerning diagnostic medical devices in vitro</i> |
|  | <i>Antibody or Antiserum</i> |  | <i>Track version changes</i> |

| | |
|---|--|
|  | <i>Diagam Belgium: Rue du Parc Industriel 40, 7822 Ghislenghien, Belgium</i> |
| <i>DiAgam Headquarters</i> | <i>Avenue Louis Lepoutre 70, 1050 Bruxelles, Belgique</i> |
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