

✓ **REFERENCE**



|   |                  |                          |               |
|---|------------------|--------------------------|---------------|
| <b>5 calibrators KIT</b>  | <b>A1REK-000</b> | <b>5 x 1 ml</b>          | <b>2-8 °C</b> |
| Alpha 1 Microglobulin is a pooled human serum standardized from a secondary reference material. |                  |                          |               |
| Batch number :  |                  | <b>21C04</b>             |               |
| Expiry date :   |                  | <b>09/2021</b>           |               |
| Control date :  |                  | <b>14/06/21</b>          |               |
| Quality control report :  |                  | <b>DGM-QAC-REP-21042</b> |               |
| Document prepared and signed by :   |                  | <b>L.Ginneberge</b>      |               |

✓ **ANALYTICAL PERFORMANCES**

See the corresponding reagents technical sheet.

✓ **PREPARATION AND REAGENTS STABILITY**

The calibrators are ready for use ; once opened, they are stable until expiry date if stored stoppered in appropriate temperature conditions and without any contamination.

✓ **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.

Calibration : Calibration curve and stability of calibration curve can be validated with the DiAgam calibration controls (**A1COS-002, A1CON-002**). Calibrate when the quality control results are outside acceptable range (contact the manufacturer if the deviations subsist), when the reagent lot number changes or when government regulations require.

✓ **BIBLIOGRAPHY**

Tietz Textbook of Clinical chemistry and molecular Diagnostics, fourth edition, edited by Carl A. Burtis, Edward R. Ashwood, David E. Bruns, 2006

Use of Anticoagulants in Diagnostic Laboratory Investigations & Stability of blood, plasma, and serum samples. Publication WHO/DIL/LAB/99.1 Rev. 2. Jan. 2002.

Clinical guide to laboratory tests, second edition, edited by Norbert W. Tietz, 1990

CLSI. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition. CLSI document H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2007.



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✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

Alpha-1- Microglobulin calibrators are synthetic biological fluids containing human Alpha1- Microglobulin at fixed value diluted in buffer containing stabilizers and sodium azide (<1g/l) as preservative.

✓ **PRINCIPLE OF TEST**

The human serum sample reacts upon a specific antibody for A1M coated on a latex particles. In the presence of A1M, the particles agglutinate. This aggregation and the turbidity induced by the formation of immune complexes. The turbidity measured is directly proportional to the A1M sample concentration.

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


|                              | CAL 1          |       | CAL 2          |       | CAL 3          |       | CAL 4          |       | CAL 5          |       |
|------------------------------|----------------|-------|----------------|-------|----------------|-------|----------------|-------|----------------|-------|
|                              | mg/l           |       | mg/l           |       | mg/l           |       | mg/l           |       | mg/l           |       |
|                              | certified val. | $U^*$ | certified val. | $U^*$ | certified val. | $U^*$ | certified val. | $U^*$ | certified val. | $U^*$ |
| <b>Alpha-1-microglobulin</b> | <b>5,23</b>    | 0,262 | <b>10,47</b>   | 0,524 | <b>24,94</b>   | 1,247 | <b>49,24</b>   | 2,462 | <b>99,37</b>   | 4,969 |

$U^*$  : The certified uncertainty is the half-width of the 95% confidence interval of the mean.  
Values assigned from the secondary reference.

**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>   |

|   |  |
|---|--|
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