Alpha-1-microglobulin Control (A1M)

✓ ***REFERENCE***

A1M Control	A1CON-002	1 x 2 ml	2-8 °C
Alpha 1 Microglobulin control is a pooled human serum standardized from a secondary reference material.			
Batch number :		**21F15**	
Expiry date :		**09/2021**	
Control date :		**15/06/21**	
Control report number :		DGM-QAC-REP-**21141**	
Document prepared and signed by :		**L.Ginneberge**	

✓ ***SAMPLES AND REFERENCE VALUES***
See the corresponding reagents technical sheet.

✓ ***COMPOSITION***
The A1M control is a synthetic biological liquid containing A1M of human origin in known concentration diluted in a buffer solution containing stabilizers and sodium azide at <1g / l as a preservative.

✓ ***PRINCIPLE OF TEST***
The latex particles in colloidal form are stabilized with anti-A1M antibodies directed specifically against A1M. The reaction of these particles with A1M, present in a biological sample, causes the specific agglutination of the latex particles. This agglutination is directly proportional to the A1M concentration of the sample.

✓ ***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.

✓ ***ANALYTICAL PERFORMANCES***
See the corresponding reagents technical sheet.

✓ ***PREPARATION AND REAGENTS STABILITY***
The control 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.

✓ ***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.

CE

A1CON 21F15 IFU EN v03 15/06/21

	CONTROL mg/l	
	Target	**Range**
Alpha-1-microglobulin	**24,70**	**19,76 – 29,64**

Values assigned from a secondary reference material.

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Symbols

The following symbols may appear on the packaging and labelling :

LOT	*Batch code*	BUF	*Buffer*
	*Use by*	CAL	*Calibrator*
	*Manufacturer*	H	*High*
IVD	*In Vitro Diagnostics Medical Device*	M	*Medium*
	*Temperature limitation (store at)*	L	*Low*
REF	*Catalogue number*	4 LEV	*4 levels*
	*Consult instructions for use*	5 LEV	*5 levels*
REAG	*Reagent*	6 LEV	*6 levels*
KIT	*Kit*	CONTROL	*Control*
CONT	*Contents*	CE	*This product meets the requirements of European Directive 98/79 CE concerning diagnostic medical devices in vitro*
Ab	*Antibody or Antiserum*		
			Track version changes

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