JOINT RESEARCH CENTRE
Directorate F – Health, Consumers and Reference Materials

CERTIFICATE OF ANALYSIS

ERM®- DA483/IFCC

HUMAN SERUM		
	Mass Concentration	
	Certified value [2] [mg/L]	Uncertainty [3] [mg/L]
IgG PR3 ANCA[1]	270	29

1) Immunoglobulin G proteinase 3 anti-neutrophil cytoplasmic antibodies as measured by immunoassays.

2) Unweighted mean value of the means of 10 accepted data sets each set obtained in a different laboratory and/or with a different method of determination. The certified mass concentration and its uncertainty are traceable to the stated value of the mass concentration in United States National Reference Preparation (USNRP) 12-0575C (Reimer et al., Am. J. Clin. Pathol. 77 (1982) 12-19).

3) The uncertainty is the expanded uncertainty of the certified value with a coverage factor $k = 2$ corresponding to a level of confidence of about 95 % estimated in accordance with ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement (GUM:1995), ISO, 2008.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used after reconstitution is 5 µL.

NOTE

European Reference Material ERM®-DA483/IFCC was produced and certified under the responsibility of the European Commission's Joint Research Centre according to the principles laid down in the technical guidelines of the European Reference Materials® co-operation agreement between BAM-JRC-LGC. Information on these guidelines is available on the internet (http://www.erm-crm.org).

Accepted as an ERM®, Geel, February 2017

Signed: D. Flo

Dr Doris Florian
European Commission, Joint Research Centre
Directorate F – Health, Consumers and Reference Materials
Retieseweg 111
B-2440 Geel, Belgium

DESCRIPTION OF THE MATERIAL

Each sample is the lyophilised form of a 1.0 mL portion of serum with additives (4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid (HEPES), sodium azide, benzamidine hydrochloride monohydrate, sodium chloride and aprotinin). The material is kept under argon gas in threaded glass bottles with rubber stoppers and polypropylene screw caps. The lyophilised powder has to be reconstituted with (1.00 ± 0.01) g of milli Q water.

ANALYTICAL METHODS USED FOR CERTIFICATION

1. Enzyme-linked immunosorbent assay (ELISA)
2. Chemiluminescent immunoassay
3. Fluorescence immunoassay

PARTICIPANTS

AESKU Diagnostics GmbH & Co., Wendelsheim, DE

Bio-Rad Laboratories INC., California, US

EUROIMMUN Medizinische Labordiagnostika AG, Dassow, DE

EuroDiagnostica AB Malmö, SE

IMMCO Diagnostics, Buffalo, US

INOVA Diagnostics, INC., San Diego, US

Lund University, Lund, SE

ORGENTEC Diagnostika GmbH, Mainz, DE

Phadia / Thermo Fisher Scientific, Freiburg, DE

Roche Diagnostics GmbH, Penzberg, DE

Siemens Healthcare Diagnostics Products GmbH, Marburg, DE

SAFETY INFORMATION

The usual laboratory safety precautions apply. Do not discharge the waste into the drain. Each portion of donated blood used in the production of the material has been tested and found negative for Hepatitis B surface antigen, HIV 1&2 antibodies, HIV antigen and Hepatitis C antibodies. However, the product must be handled with care as any material of human origin. It is intended for *in vitro* analysis only.

INSTRUCTIONS FOR USE AND INTENDED USE

The material is primarily intended to be used for the calibration of immunoassay-based *in vitro* diagnostic devices. As for any calibrator it should be verified that it is commutable. The ERM-DA483/IFCC is expected to be commutable for the majority of IgG PR3 ANCA methods. However, if another method is used other than those included in the report accompanying the material, the commutability should be verified.

The entire content of the vial must be reconstituted one day prior to an analysis.

Reconstitution of the material

The material must be reconstituted according to the following procedure:

- Remove the vial from the freezer and place it in the room where the balance is located one hour before reconstitution.
- Prior to reconstitution, tap the bottom of the vial gently on the surface of the table. Make sure that all the material has settled down on the bottom of the vial. Remove the screw cap.
- Weigh the vial together with the rubber stopper. Note the mass or press the “TARE” button on the balance. Lift carefully the rubber stopper until the groove.
- Add 1.00 mL of milli Q water through the groove, and press the rubber stopper back into place. Weigh the vial and note the mass. If you have used the “TARE” function, the value can be used directly for the mass m. Otherwise the first mass must be subtracted from the second to obtain m.
- The concentration of a particular protein in the solution, corrected for the reconstitution mass, can be obtained by multiplying the certified value for that protein with $m_{intended}$ / m, with $m_{intended}$ the mass intended to be added (1.0000 g).
- Leave the vial at room temperature for one hour, then gently mix by inversion at least five times (do not shake it) during the next hour.
- Leave the vial at room temperature overnight. The following day, gently mix by inversion five times in a period of one hour, prior to starting the analysis.

STORAGE

Unopened vials should be stored at either - 20 °C or - 70 °C, as it has been shown that the material is stable at both temperatures for up to a year. If microbial contamination has been excluded during the reconstitution procedure, the solution of ERM-DA483/IFCC can be used for one week. It is advisable to cover the vial with the original seal after use and to store it at 2 to 8 °C.

Please note that the European Commission cannot be held responsible for changes that happen during storage of the material at the customer's premises.

LEGAL NOTICE

Neither the European Commission, its contractors nor any person acting on their behalf:

(a) make any warranty or representation, express or implied, that the use of any information, material, apparatus, method or process disclosed in this document does not infringe any privately owned intellectual property rights; or

(b) assume any liability with respect to, or for damages resulting from, the use of any information, material, apparatus, method or process disclosed in this document save for loss or damage arising solely and directly from the negligence of the European Commission's Joint Research Centre.

NOTE

A detailed technical report is available on https://crm.jrc.ec.europa.eu/. A paper copy can be obtained from the Joint Research Centre, Directorate F – Health, Consumers and Reference Materials on request.

European Commission – Joint Research Centre
Directorate F – Health, Consumers and Reference Materials
Retieseweg 111, B - 2440 Geel (Belgium)
Telephone: +32-(0)14-571.705 - Fax: +32-(0)14-590.406