Human Serum Reference Standard

Cat. No. HS-7H **Lot. No.** (See product label)

SPECIFICATION

Product Overview	Each sample is the lyophilized form of a 1.0 mL portion of serum with additives (4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid (HEPES), sodium azide, benzamidine hydrochloride, sodium chloride and aprotinin). The material is kept under nitrogen gas in threaded glass bottles with rubber stoppers and polypropylene screw caps. The water mass fraction of the sample is (4.3±0.6) mg/g. The lyophilised powder has to be reconstituted with (1.00±0.01) g of distilled water.
Species	Human
Usage	The material is primarily inteded to be used for the calibration of immunoassay-based in-vitro diagnostic devices or control products for the protens certified. As for any calibrator it should be verified that it is commutable. The material ia produced in a similar manner as ERM-DA470, the use of which has led to a significant reduction in the between-method and between-laboratory variation for the proteins certified. It was verified during the value assignment procedure that there were no significant matrix effects, and that different methods produced consistent results. However, when the material is used as a calibrator, the commutability should be verified for the particular assay concerned.The entire content of the vial must be reconstituted.
Quality Control Test	1. Turbidimetry2. Nephelometry3. Visual spectrometry
Notes	Avoid swallowing as well as contact with skin. Do not discharge the waste into the drain. Each portion of donated blood used in the production of the material has been tested for the presence of HBs antigen, HCV, HIV1/HIV2, and HTLV1 antibodies and

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	found to be negative. However, the product must be handled with adequate care as any material of human origin. It is intended for "in vitro" analysis only.
Storage	Unopened ampoules should be stored at -(20±2) °C. Under the condition that any microbial contamination during the reconstitution procedure has been excluded, the solution of ERM-DA470k/IFCC can be used for one week. It is advisable t°C over the vial with the original seal after use and to store it at 2 to 8 °C.However, the European Commission cannot be held responsible for changes that happen during storage of the material at the customer's premises, especially of opened samples.
Concentration	α2 macroglobulin (A2M): 1.43 g/Lα1 acid glycoprotein (AAG): 0.617 g/Lα1 antitrypsin (AAT): 1.12 g/Lalbumin (ALB): 37.2 g/Lcomplement 3c (C3c): 1.00 g/Lcomplement 4 (C4): 0.162 g/Lhaptoglobin (HPT): 0.889 g/Limmunoglobulin A (lgA): 1.80 g/Limmunoglobulin G (lgG): 9.17 g/Limmunoglobulin M (lgM): 0.723 g/Ltransferrin (TRF): 2.36 g/Ltransthyretin (TTR): 0.220 g/L
Reconstitution	Reconstitution of the matericalTo make it ready for use, the material has to be reconstituted according to the following procedure:Remove the vial from the freezer during the afternoon of the day before use and place the vial for 1 hour in the room where the balance is located.After 1 hour tap the bottom of the vial gently on the surface of the table. Make sure that all the meterial has settled down on the bottom of the vial. Remove the screw cap.Weigh the vial together with the rubber stopper. Document the mass or press the "TARE" button on the balance. Lift the rubber stopper with care until air is allowed to enter the vial and the groove in the rubber stopper becomes accessible.Add 1.00 mL of water through the groove, and press the rubber stopper back into place. Weigh the vial and document 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 cystatin C in the solution, corrected for the reconstitution mass, can be obtained by multiplying the certified value for that protein with mintended/m, with mintened the

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	mass intended to be added (1.000 g).Leave the vial at room temperature for one hour, then invert it carefully at least five times (do not shake it) during the next hour.Leave the vial at room temperature overnight. On the day of use invert the vial carefully five times during one hour.

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