EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements

CERTIFIED REFERENCE MATERIAL
BCR® – 486

CERTIFICATE OF ANALYSIS

ALFAFOETOPROTEIN (AFP)		
	Mass in the reconstituted material[1)]	
	Certified value [3)] [µg]	Uncertainty [4)] [µg]
AFP mass per ampoule[2)]	100	9

1) When the material is reconstituted according to the specified procedure (see instructions for use).
2) Carbohydrate mass of the molecule not included.
3) This value is the unweighted mean of means of 3 accepted datasets, independently obtained by 3 laboratories. Each value was calculated from the amino acid pattern and from the determination of the molar absorption coefficient. The certified value is therefore traceable to the amino acid composition of the material and to the amino acids used as calibrants.
4) Expanded uncertainty with a coverage factor k = 2, corresponding to a level of confidence of about 95 %, according to the Guide to the Expression of Uncertainty in Measurement (GUM).

This certificate is valid for one year after purchase.

Sales date:

The entire content of the ampoule must be reconstituted, i.e. subsampling of the dried powder is not recommended. The reconstituted material can be assumed to be a pure, homogenous solution. The minimum sample intake is 10 µL.

NOTE

This material has been certified by BCR (Community Bureau of Reference, the former reference materials programme of the European Commission). The certificate has been revised under the responsibility of IRMM.

Brussels, October 1998
Revision: March 2007

Signed:

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DESCRIPTION OF THE SAMPLE

Each sample is in lyophilised form and consists of purified AFP without additives. The material is kept under nitrogen gas in sealed glass ampoules.

ANALYTICAL METHOD USED FOR CERTIFICATION

A combination of UV absorbency measurements and amino acid analysis

PARTICIPANTS

- Birmingham and Midland Hospital for Women, Birmingham (GB)
- Max Planck Institut für Biophysikalische Chemie, Göttingen (DE)
- Statens Seruminstitut, København (DK)

SAFETY INFORMATION

The Hep G2 cell line used to produce the purified AFP material has been tested for the presence of Hepatitis B surface antigen and found negative. However, the material is of human origin and must be handled with adequate care. It is intended for *in vitro* analysis only.

INTENDED USE

The material is intended to be used as a pure calibrant to establish traceability of serum-based reference materials which in turn will be employed in routine laboratory assays. If the material is used for calibration of *in vitro* diagnostic devices the commutability has to be assessed by the user.

INSTRUCTIONS FOR USE

To make the material ready for use, it has to be reconstituted according to the following procedure:

Reconstitution buffer
Phosphate Buffer Saline (PBS): 50 mmol/L phosphate buffer, pH = 7.4, NaCl 0.8 g/L

Reconstitution procedure

1. Allow ampoule to equilibrate for at least 1 hour at room temperature prior to opening.
2. After ensuring that the contents are entirely in the body of the ampoule, break the snap top.
3. Slowly add 1.0 mL of the reconstitution buffer to the ampoule using a calibrated dilutor. The accuracy of the dispenser is required to be better than ± 0.5 % as assessed by multiple weighings of water.
4. Swirl the ampoule gently and intermittently for five minutes to ensure complete dissolution of the contents.

Following reconstitution, cover the ampoule with an airtight seal and store for no longer than 24 hours at 4 °C prior to its use.

For dilution of the material the addition of a carrier protein is recommended.

STORAGE

Upon arrival, the material shall be stored at - 20 °C for not more than 12 months until use. 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.

LEGAL NOTICE

NOTE

A technical report on the production of BCR-486 is available on the internet (http://www.irmm.jrc.be). A paper copy can be obtained from IRMM on request.

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