



CERTIFIED REFERENCE MATERIAL BCR[®] – 613

CERTIFICATE OF ANALYSIS

PROSTATE SPECIFIC ANTIGEN (PSA)		
	Mass in reconstituted material ¹⁾	
	Certified value ³⁾ [µg]	Uncertainty ⁴⁾ [µg]
PSA ²⁾	71	7
<p>1) When the material is reconstituted according to the specified procedure (see instructions for use).</p> <p>2) Carbohydrate mass of the molecule not included.</p> <p>3) This value is the unweighted mean of means of 5 accepted data sets, independently obtained by 5 laboratories. Each value was calculated from the amino acid pattern. The certified value is therefore traceable to the amino acid composition of the material and to the amino acids used as calibrants.</p> <p>4) Estimated expanded uncertainty U with a coverage factor $k = 2$, corresponding to a level of confidence of about 95 %, as defined in the Guide to the Expression of Uncertainty in Measurement (GUM).</p>		

This certificate is valid for one year after purchase.

Sales date:

The entire contents of the ampoule must be reconstituted as prescribed under instructions for use.
The reconstituted material can be assumed to be a pure, homogenous solution.
The minimum sample intake is 10 µL.

DESCRIPTION OF THE SAMPLE

Each sample is in lyophilised form and contains purified PSA without additives. The material is kept under argon gas in sealed glass ampoules.

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: May 2007

Signed: _____

Prof. Dr. Hendrik Emons
Unit for Reference Materials
EC-JRC-IRMM
Retieseweg 111
2440 Geel, Belgium

ANALYTICAL METHOD USED FOR CERTIFICATION

Quantitative amino acid analysis

PARTICIPANTS

- BPGP France sarl, Dammartine en Goele (FR)
- Endocrine Services, Bidford on Avon (GB)
- N.C.S.R. Demokritos, Athens (EL)
- Seratec GmbH, Göttingen (DE)
- Universiteit Gent, Gent (BE)
- Université d'Aix Marseille II, Marseille (FR)

SAFETY INFORMATION

The seminal fluid used to produce the purified PSA material has been tested for the presence of HIV1/HIV2, Hepatitis B surface antigen and HCV and found negative (see sections 3.1. and 3.2. of the certification report). However the material is of human origin and should be handled with adequate care. It is intended for *in vitro* analysis only.

INSTRUCTIONS FOR 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.

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

1. Allow ampoule to equilibrate for 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 distilled water 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 use immediately or cover the ampoule contents with an airtight seal and store for no longer than 24 hours at 4 °C prior to use.

Freezing and thawing should be avoided.

STORAGE

Upon arrival the material shall be stored at – 20 °C or lower temperatures 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

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NOTE

A technical report on the production of BCR-613 is available on the internet (<http://www.irmm.jrc.be>). A paper copy can be obtained from IRMM on request.