



# YASHRAJ BIOTECHNOLOGY LIMITED

An ISO 9001:2000 Certified Quality Assurance System

Doc. No: F/YBL/QA-01 | Issue: 01 | Rev: 00 | Date: 1-8-05

*a bio-quest for ever*

## CERTIFICATE OF ANALYSIS

Date of Certificate: 27-01-09 Certificate No: QF0286

Description of Product: **Breast Cancer Antigen (CA 15-3)**  
Liquid (Aseptically Filtered) in 50 mM PBS (pH 7.2 -7.6) and  
0.15 % w/v Sodium Azide

Batch No.: FBC0024 Product Code: FBC Grade: Partially Pure

Origin: Human Fluids Manufacturing: Jan 09 Expiry: Dec 12

Sr. No.	Test	Test Method	Acceptance Criteria	Observation
01	Identification	ELISA (Calbiotech)	Positive for CA 15-3	Passes
02	CA 15-3 Content	Roche Elecsys	> 5 Ku/ml	15.89 Ku/ml
03	Purity Ratio	Activity/ml/OD280nm	As observed	1.01 kU/ml/OD
04	Co product 19-9	Roche Elecsys	< 25%	8.37 %
05	Co product 125	Roche Elecsys	< 25%	18.25 %
06	Co product AFP	Roche Elecsys	< 25%	< 1 %
07	Co product 72-4	Roche Elecsys	< 25%	6.48 %
08	Co Product Ferritin	Roche Elecsys	< 25%	< 1 %
09	Co product CEA	Roche Elecsys	< 25% (ng/U)	22.5 %
10	Bio-burden	Plate Count	< 10 CFU/ml	Passes
11	Viral Marker Test For HBsAg, Anti- HCV (US-FDA Approved BioRad & Ortho clinical Diagnostics) Anti-HIV I & II	ELISA	Negative	Passes
12	Absence of Viral DNA /RNA for (HBV, HIV I and HCV)	PCR	Negative	Passes*

**Opinion:** The batch **FBC0024** conforms to the release specifications for Breast Cancer Antigen (Code: FBC). (\* Soft copy available on request).

Sanjeev Kumar Gupta, Ph.D.  
Manager -Quality Assurance & Regulatory Affairs

**Recommended Storage: 2-8° C**

**Caution: This product is not for human consumption. Use only in In-Vitro research or products. All bio-safety precautions must be practiced while handling.**

**Production Unit:** PLOT NO. C-232, TTC IND. AREA, MIDC, NAVI MUMBAI – 400 705 (INDIA)

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