



# 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: 05-01-09 Certificate No: QF0278  
Name of the Product **Gastric Cancer Antigen** (Cancer Antigen CA 72-4)  
Liquid in Salt Buffer (50 mM Phosphate, 0.15M NaCl), (pH 7.2 – 7.6)  
Preservative 0.15% Sodium Azide  
Batch No.: FGC0010 Product Code: FGC Grade: Partially Pure  
Source: Human Fluids Manufacturing: Jan-09 Expiry: Dec –11

Sr. No.	Test	Test Method	Acceptance Criteria	Observation
01	Identification	ELISA	Positive	Passes
02	CA 72-4 Content	Roche Elecsys	≥ 10 kU/ml	16.20 kU/ml
03	Purity Ratio	Activity/ml/OD280nm	As observed	8.2 kU/ml/OD
04	Co product CA 19-9	Roche Elecsys	< 25%	< 1 %
05	Co product CA125	Roche Elecsys	< 25%	< 1 %
06	Co product CA 15-3	Roche Elecsys	< 25%	1.0 %
07	Co product AFP	Roche Elecsys	< 25 % (ng/kU)	< 1 %
08	Co product Ferritin	Roche Elecsys	< 25% (ng/kU)	< 1 %
09	Co product CEA	Roche Elecsys	< 25% (ng/kU)	1 % (97.26 ng/ml)
10	Bioburden	Plate Count	< 10	Passes
11	Viral Marker Test For HBsAg, Anti-HCV (US-FDA Approved BIORAD/Ortho clinical Diagnostics) Anti- HIV <sub>I &amp; II</sub>	ELISA	Negative	Passes
12	Absence of Viral DNA /RNA for (HBV, HIV <sub>I</sub> and HCV)	PCR	Negative	Passes*

**Opinion:** The batch **FGC0010** conforms to the release specifications for Gastric Cancer Antigen (Code: FGC).

Sanjeev Kumar Gupta, Ph.D.  
Manager -QA/RA

**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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