



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

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CERTIFICATE OF ANALYSIS

Date of Certificate: 25-10-06 Certificate No: QF0156

Description of Product: **Gastrointestinal Cancer Antigen (CA 19-9)**
Liquid (Aseptically Filtered) in 50 mM PBS, pH 7.2 – 7.6 and 0.15 % Sodium Azide

Batch No.: FGI0009 Product Code: FGI Grade: Partially Pure

Origin: Human Fluids Manufacturing: Oct'06 Expiry: Sep'10

Sr. No.	Test	Test Method	Acceptance Criteria	Observation
01	Identification	ELISA	Positive	Passes
02	CA 19-9 Content	Roche Elecsys	>10 Ku/ml	957.2 kU/ml
03	Purity Ratio	Activity/ml/OD280nm	As observed	141 kU/ml/OD
04	Co product 125	Roche Elecsys	< 25%	< 1%
05	Co product 15-3	Roche Elecsys	< 25%%	< 1%
06	Co product 72-4	Roche Elecsys	< 25%%	< 1%
07	Co product AFP	Roche Elecsys	< 25%	< 1%
08	Co product Ferritin	Roche Elecsys	< 25%	< 1%
09	Co product CEA	Roche Elecsys	< 25%	< 1%
10	Bio-burden	Plate Count	< 10 CFU/ml	Passes
11	Viral Marker Test For HBsAg, Anti-HCV Anti- HIV _{I & II}	ELISA (US-FDA Approved BIORAD/Ortho clinical Diagnostics)	Negative	Passes
12	Absence of Viral DNA /RNA for (HBV, HIV _I and HCV)	PCR	Negative	Passes*

Opinion: The lot **FGI0009** conforms to the release specifications for Gastrointestinal Cancer Antigen (Code: FGI). (* 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)

•TEL 91- 22 - 2768 6226 / 6285 /1949 • FAX: 91- 22 - 2768 6087



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CERTIFICATE OF ANALYSIS

Date of Certificate: 27-03-07 Certificate No: QF0177

Description of Product: **Gastrointestinal Cancer Antigen (CA 19-9)**
Liquid (Aseptically Filtered) in 50 mM PBS (pH 7.2 – 7.6)
and 0.09 % w/v Sodium Azide

Batch No.: FGI0010 Product Code: FGIhp Grade: High Pure

Origin: Human Fluids Manufacturing: Mar-07 Expiry: Feb 11

Sr. No.	Test	Test Method	Acceptance Criteria	Observation
01	Identification	ELISA (Calbiotech)	Positive for CA 19-9	Passes
02	CA 19-9 Content	Roche Elecsys 2010	>10 Ku/ml	121.4 Ku/ml
03	Purity Ratio	Activity/ml/OD _{280nm}	As observed	2.6 X 10 ⁶ Ku/ml/OD
04	Co product 125	Roche Elecsys 2010	0 - 1%	< 0.013 %
05	Co product 15-3	Roche Elecsys 2010	0 - 1%	< 0.002 %
06	Co product 72-4	Roche Elecsys 2010	0 - 1%	< 0.005 %
07	Co product Ferritin	Roche Elecsys 2010	0 - 1%	Not Detected
08	CEA	Roche Elecsys 2010	0 - 1%	< 0.003%
09	AFP	Roche Elecsys 2010	0 - 1%	Not Detected
10	Bio-burden	Plate Count	< 10 CFU/ml	Passes
11	Viral Marker Test For HBsAg, Anti-HCV Anti- HIV _{I & II}	ELISA (US-FDA Approved BIORAD/Ortho clinical Diagnostics)	Negative	Passes
12	Absence of Viral DNA /RNA for (HBV, HIV _I and HCV)	PCR	Negative	Passes*

Opinion: The batch **FGI0010** conforms to the release specifications for Gastrointestinal Cancer Antigen CA 19-9, High Pure (Code: FGIhp). (* Soft copy available on request)

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

Recommended Storage: 2-8° C
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