



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: 08-10-07

Certificate No: QF0203

Description of Product: **Ovarian Cancer Antigen (CA 125)**
Liquid (Aseptically Filtered) in 50 mM Phosphate, 0.15M NaCl
(pH 7.2 – 7.6) and 0.15% Sodium Azide

Batch No.: FOC0002

Product Code: FOC

Grade: Partially Pure

Origin: Human Fluids

Manufacturing: Oct-07

Expiry: Sep-11

Sr. No.	Test	Test Method	Acceptance Criteria	Observation
01	Identification	ELISA (Calbiotech)	Positive for CA 125	Passes
02	CA 125 Content	Roche Elecsys	>10 Ku/ml	111.9 Ku/ml
03	Purity Ratio	Activity/ml/OD280nm	As observed	35.76 Ku/ml/OD
04	Co product 19-9	Roche Elecsys	< 25%	<1 %
05	Co product 15-3	Roche Elecsys	< 25%	<1 %
06	Co product 72-4	Roche Elecsys	< 25%	< 4.9 %
07	Co product AFP	Roche Elecsys	< 25 %	< 1 %
08	Co product CEA	Roche Elecsys	< 25%	< 1 %
09	Co product Ferritin	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 <small>(US-FDA Approved BioRad and Ortho clinical Diagnostics)</small>	Negative	Passes
12	Absence of Viral DNA /RNA for (HBV, HIV I and HCV)	PCR	Negative	Passes*

Opinion: The batch **FOC0002** conforms to the release specifications for Ovarian Cancer Antigen (Code: FOC). (* 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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