



a bio-quest for ever

YASHRAJ BIOTECHNOLOGY LIMITED

An ISO 9001:2000 Certified Quality Assurance System

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CERTIFICATE OF ANALYSIS

Date of Certificate: 26/02/2008

Certificate No: QF0224

Description of Product: **Carcinoembryonic Antigen (CEA)**
Liquid (Aseptically Filtered) 50 mM Sod. Citrate and 150 mM NaCl (pH 7.2 – 7.6) containing 20% Glycerol and 0.15% Sod. Azide

Batch No.: FCE0008

Product Code: FCE hp

Grade: High Pure (>98%)

Origin: Human Meconium

Manufacturing: Feb-08

Expiry: Jan-10

Sr. No.	Test	Test Method	Acceptance Criteria	Observation
01	Identification	Western Blot	Positive for CEA	Passes*
02	CEA Content	ELISA (Calbiotech)	1-2 mg/ml	1.92 mg/ml
03	Total Protein	Lowry's Assay	> CEA Content	1.41mg/ml
04	Purity	CEA/TP	>98 %	Passes
05	Purity Profile	SDS-PAGE	Single Band at ~ 90 kD	Passes*
06	Bio-burden	Plate Count	< 10 CFU/ml	passes
07	Viral Marker Test for HBsAg, Anti-HCV and Anti-HIV I & II	ELISA (US-FDA Approved BioRad & Ortho clinical Diagnostics)	Negative	Passes
08	Absence of Viral DNA /RNA for (HBV, HIV I and HCV)	PCR	Negative	Passes*

Opinion: The batch **FCE0008** conforms to the release specifications for Carcinoembryonic Antigen (CEA) High Pure (Code: FCEhp). (* Soft copy available on request)

Suitability: For raising antibodies (request azide free), as primary antigen and/or preparation of controls & calibrators

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.

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