100 North Pointe Drive Lake Forest, California 92630 USA Phone: 949-951-2665 Ex208 Fax: 949-951-3539

## **Certificate of Analysis**

Product:	Human Serum Specialty– Double Charcoal Stripped and Delipidated	
Lot#:	199CM-01A09	
Bulk:	900 Liters	
Filled in:	3.5 Liters/Bottle	
pH:	7.45 (pH meter)	
Preservative:	None	
Filtration:	Filtered through a 0.22micron absolute membrane filter prior to bottling	
Storage:	-20°C	
D.O.M.:	01-12-2009	
Expiration date:	01-2014	
Bleed testing:	All units were tested at the donor level by FDA approved tests found negative to antibodies HIV-I/II, HCV, HTLV-1, HBsAg and Syphilis.	

Analyte	Specification and methodology	Result
Aldosterone	7.5ng/dL by RIA	<0.5 ng/dL
$\alpha$ - Fetoprotein	20ng/mL by IMx	1.3 ng/mL
ß – 2 – Microglobulin	100µg/L by IMx	<5 µg/L
CEA	1.5ng/mL by IMx	0.3 ng/mL
Cortisol	4µg/dL by TDx	0.0 µg/dL
Estradiol	100pg/mL by RIA	17 pg/mL
Ռ – hCG	10mIU/mL by IMx	0.6 mIU/mL
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Prolactin	5ng/mL by IMx	0.0 ng/dL
PSA	1ng/mL by IMx	0.0 ng/dL
Insulin	8µIU/mL by IMx	<0.2 µIU/mL
PAP	2ng/mL by IMx	<0.5 ng/mL
Thyroglobulin	10ng/mL by RIA	<1.0 g/dL
ACTH	22pg/mL by RIA	<5.0 pg/mL
CA 125	6U/mL by RIA	0.2 U/mL
CA 15-3	11U/mL by IRMA	6.7 U/mL
CA 19-9	15U/mL by IMx	<2.0 U/mL
CA 72-4	1.2U/mL by IRMA	0.0 U/mL
Neuron-Specific Enolase	3.0ng/dL by Elecsys	<0.1 ng/dL
CYFRA 21-1	3.0ng/dL by Elecsys	<1.0 ng/dL
Calcitonin	15pg/mL by RIA	0.0 pg/mL
Gastrin	15pg/mL by RIA	<2.5 pg/mL
Iron	140µg/dL by Dimension	91 µg/dL
Ammonia	<300µmol/L by SMAC	150 µmol/L
Total Protein	>3.0g/dL by SMAC	4.5 g/dL

**Caution:** Not for use in products subject to license under section 351 of the public health safety acts. For use in research or manufacturing into non-injectable products only.

