

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
α - Fetoprotein	20ng/mL by IMx	1.3 ng/mL
β - 2 - Microglobulin	100 μ g/L by IMx	<5 μ g/L
CEA	1.5ng/mL by IMx	0.3 ng/mL
Cortisol	4 μ g/dL by TDx	0.0 μ g/dL
Estradiol	100pg/mL by RIA	17 pg/mL
β - hCG	10mIU/mL by IMx	0.6 mIU/mL
hCG	10mIU/mL by IMx	0.6 mIU/mL
Prolactin	5ng/mL by IMx	0.0 ng/dL
PSA	1ng/mL by IMx	0.0 ng/dL
Insulin	8 μ IU/mL by IMx	<0.2 μ IU/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	140 μ g/dL by Dimension	91 μ g/dL
Ammonia	<300 μ mol/L by SMAC	150 μ mol/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.