# Human Serum Double Charcoal Treated & Delipidized from Defibrinated PlasmaCatalog Number:SP1070Lot Number:

Storage:-20 °CExpiration Date:<Lot Specific>Filtration:0.22 µmCountry of Origin:USAPreservative:NoneSource:Human Defibrinated PlasmaManufacture Date: <Lot Specific>Human Defibrinated Plasma

# **Product Performance Specifications**

Test	Specifications	Unit of Measure	Methodology
Glucose	65 – 105	mg/dL	Hexokinase
B.U.N.	7 – 14	mg/dL	Berthelot
Creatinine	0.7 – 1.4	mg/dL	Jaffe
Sodium	3  –  5	mmol/L	ISE
Potassium	3.5 – 5.5	mmol/L	ISE
Chloride	85 – 108	mmol/L	ISE
Calcium	5.0 - 10.0	mg/dL	Arsenazo III
Total Protein	5.5 – 6.5	g/dL	Biuret
Cholesterol	≤10	mg/dL	Enzymatic
Triglycerides	≤10	mg/dL	GPO
Albumin	2.5 – 4.5	g/dL	BCG Dye-binding
T4	≤4	µg/dL	CLIA
TSH, 3 <sup>rd</sup> Generation	≤0.2	µIU/mL	CLIA
Progesterone	≤0.5	ng/mL	CLIA
Testosterone	≤0.2	ng/mL	CLIA
Estradiol	≤10	pg/mL	CLIA
Bioburden	≤100	CFU/mL	USP/BAM
рН	7.0 – 7.5	Not applicable	pH Meter
pH Teating	/.0 – 7.5	Not applicable	pH Meter

#### Testing

Each unit of plasma used in the preparation of this material was tested and found negative or non-reactive for HIV 1/2, HBsAg, HCV, HIV-1 (NAT), HCV (NAT), and RPR by FDA approved methods.

## Caution

In-vitro use only. Products are intended for research or manufacturing of non-injectable products only. This material was tested as stated above in the testing section. Nevertheless, products of human origin should be considered potentially infectious and handled according to universal precautions. The safe and responsible handling of the product listed above is the responsibility of the customer. We accept no liability for injury or illness resulting from the use and/or handling of the product. The customer assumes responsibility for the proper disposal of all materials in accordance with Federal and State regulations.

## Warranty

Golden West Diagnostics, LLC makes no claim or warranty that this product will perform or is suitable for use in a customer's application. It is the customer's responsibility to evaluate and qualify the product's suitability for the customer's intended use or application. Furthermore, this product is a biological material and lots may vary so it is the customer's responsibility to determine if an evaluation of each lot is warranted.

