

Universal Negative Human Serum

Catalog Number: UNI000

Lot Number: <Lot Specific>

Storage:	-20 °C	Expiration Date:	<Lot Specific>
Filtration:	0.22 µm	Country of Origin:	USA/EU
Preservative:	None	Source:	Human Plasma
Manufacture Date:	<Lot Specific>		

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	131 – 151	mmol/L	ISE
Potassium	3.5 – 5.5	mmol/L	ISE
Chloride	95 – 108	mmol/L	ISE
Calcium	7.0 – 10.0	mg/dL	Arsenazo III
Phosphorus	2.0 – 4.0	mg/dL	Phosphomolybdate
Uric Acid	4.0 – 6.0	mg/dL	Uricase/Trinder
Total Protein	5.0 – 6.0	g/dL	Biuret
Cholesterol	As Found	mg/dL	Enzymatic
Triglycerides	As Found	mg/dL	GPO
Bioburden	≤100	CFU/mL	USP/BAM
pH	7.0 – 7.5	Not Applicable	pH Meter
IgG	<100	mg/dL	Immunologic
IgM	<10	mg/dL	Immunoturbidimetric

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), and HCV (NAT), by FDA approved methods. Material has been tested for Syphilis according to section 610.40 of the CFR.

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.



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