

CERTIFICATE OF ANALYSIS

Complement Technology, Inc.
4801 Troup Hwy, Suite 701
Tyler, Texas 75703, USA

Product: C1s-Dpl
Catalog # A304 Lot #
Exp. Date:

Description: C1s-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥ 40 mg/ml using an extinction coefficient of $E^{1\%}_{/280\text{ nm}} = 10$	60 mg/mL
FILL VOLUME	0.50 – 0.55 mL	0.55 mL
PHYSICAL APPEARANCE	Clear, straw colored	Clear, straw colored
BUFFER	Phosphate Buffered Saline, pH 7.4	Conforms
PRESERVATIVE	None, filtered through a 0.22 μm pore size filter	None, filtered through a 0.22 μm pore size filter

CH50 FUNCTIONAL ACTIVITY UPON RECONSTITUTION*

CH50/mL NHS Standard	≥ 75 CH50/mL	167 CH50/mL
CH50/mL C1s-Dpl reconstituted with 31 μg C1s proenzyme/mL	≥ 40 CH50/mL	147 CH50/mL
Ratio: $\frac{\text{CH50/mL C1s-Dpl} + \text{C1s proenzyme}}{\text{CH50/mL NHS Std}}$	≥ 0.50	0.88
Percent Classical Pathway activity of C1s-Dpl + C1s proenzyme		88 %

ALTERNATIVE PATHWAY (AP) ACTIVITY**

APH50/mL NHS Standard	≥ 50 APH50/mL	161 APH50/mL
Input NHS Std to yield 1 APH50	≤ 20 μL	6.2 μL
APH50/mL C1s-Dpl	≥ 50 APH50/mL	161 APH50/mL
Input C1s-Dpl to yield 1 APH50	≤ 20 μL	6.2 μL
AP Ratio $\frac{\text{APH50/mL C1s-Dpl}}{\text{APH50/mL NHS Std}}$	≥ 0.50	1.0

IMMUNOCHEMICAL ANALYSIS

Ouchterlony	No C1s antigen detectable using various dilutions of goat anti-human C1s antiserum	Conforms
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Product: **C1s-Dpl # 2 (continued)**

HUMAN SERUM/PLASMA STARTING MATERIAL

HBsAg		Negative	Negative
Anti-HIV-I/2 plus O	antibodies	Negative	Negative
WNV-RNA		Negative	Negative
Anti-HCV		Negative	Negative
HCV by NAT		Negative	Negative
HIV by NAT		Negative	Negative
HBV by NAT		Negative	Negative
West Nile Virus (WNV) by NAT		Negative	Negative
Anti-Syphilis		Negative	Negative
Anti-HBc		Negative	Negative
Anti-HTLV-I/II		Negative	Negative

* One CH50 unit is defined as the input of C1s-Dpl, reconstituted with C1s proenzyme, or NHS Complement Standard yielding 50% lysis of 1×10^8 EA when incubated for 60 minutes at 37 °C in a total reaction volume of 1.5 mL GVB⁺⁺.

** One unit of whole alternative pathway activity (APH50) is defined as the input of C1s-Dpl or NHS Complement Standard yielding 50% lysis of 1.5×10^7 rabbit erythrocytes (Er) when incubated for 30 minutes at 37 °C in a total reaction volume of 100 μ L GVB^o containing a final Mg-EGTA concentration of 5 mM.

STORE AT -70°C or BELOW. Avoid Repeated Freeze/Thaw
Thaw quickly at 37°C, mix, and put in an ice+water bath to cool.

FOR RESEARCH USE ONLY NOT FOR HUMAN OR DRUG USE

Signature of Analyst

Date of Analysis