CERTIFICATE OF ANALYSIS

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

Product: **C8-Dpl**
Catalog # **A325 Lot #**
Exp. Date:

Description: Complement C8-Depleted Human Serum

Specifications	**Limits**	**Results**
PROTEIN CONCENTRATION	≥40 mg/mL employing an extinction coefficient of E1%/280nm = 10	60 mg/ml
FILL VOLUME	1.0 – 1.2 mL	1.1 mL
PHYSICAL APPEARANCE	Clear, straw colored	Clear, straw colored
BUFFER	Phosphate Buffered Saline, pH 7.3	Conforms
PRESERVATIVE	None, filtered through a 0.22 µm pore size filter.	None, filtered through a 0.22 µm pore size filter.
CLASSICAL PATHWAY (CP) ACTIVITY*		
Recommended volume of C8-Dpl serum per assay	≤ 40 µL	20 µL
C8H50 units/mg purified C8 at the recommended input of C8-Dpl	≥ 70,000 Units/mg	609,000 Units/mg
Input of purified C8 to yield 1 C8H50	≤ 14 ng	1.6 ng
C8H50/mL NHS Complement Std at the recommended input of C8-Dpl	≥ 5,400 Units/mL	26,000 Units/mL
Input of C8 in NHS Complement Std to yield 1 C8H50	≤ 8 ng	2.1 ng
CP Ratio: $\frac{\text{C8H50/mg PurifiedC8}}{\text{C8H50/mg C8 in NHS Std}}$	≥ 0.60	1.27
Background A_{412} EA blank reading at the recommended input of C8-Dpl	≤ 0.100	0.030
CH50 FUNCTIONAL ACTIVITY UPON RECONSTITUTION**		
CH50/mL NHS Std	≥ 75 CH50/mL	145 CH50/mL
CH50/mL C8-Dpl reconstituted with 100 µg C8/mL	≥ 50 CH50/mL	145 CH50/mL
Ratio: $\frac{\text{CH50/mL C8-Dpl + C8}}{\text{CH50/mL NHS Std}}$	≥ 0.60	1.00

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Complement C8-Depleted Human Serum, Lot # 8 (Continued)

ALTERNATIVE PATHWAY (AP) ACTIVITY ***

APH50/mL NHS Std.	≥ 50 APH50/mL	167 APH50/mL
Input NHS Std to yield 1 APH50	≤ 20 µL	6 µL
APH50/mL C8-Dpl + C8	≥ 30 APH50/mL	160 APH50/mL
Input C8-Dpl + C8 to yield 1 APH50	≤ 33 µL	6.3 µL
AP Ratio: $\frac{\text{APH50/mL C8-Dpl + C8}}{\text{APH50/mL NHS Std}}$	> 0.60	0.96
IMMUNOCHEMISTRY		
Ouchterlony	No C8 antigen detectable using various dilutions of goat anti-C8	Conforms

STARTING MATERIAL: HUMAN SERUM/PLASMA		
HBsAg	Negative	Negative
Anti-HBc	Negative	Negative
Anti-HIV 1 and 2 Plus O	Negative	Negative
Anti-HCV	Negative	Negative
Anti-Syphilis	Negative	Negative
HCV by NAT	Negative	Negative
HIV by NAT	Negative	Negative
HTLV 1 and 2	Negative	Negative
West Nile Virus	Negative	Negative
HBV by NAT	Negative	Negative

SAFETY PRECAUTIONS: This product is derived from human blood and although it tested negative for HIV antibodies and Hepatitis B and C it should be handled with appropriate precautions including wearing of gloves and safety glasses.

* One C8H50 unit measured by classical pathway activation is defined as the amount of C8 required to yield 50% lysis of 3 x 10^7 EA when incubated in the presence of the recommended volume of C8-Dpl serum for 30 minutes at 37°C in a total reaction volume of 500 uL GVB^{++}.

** One CH50 unit is defined as the input of C8-Dpl, reconstituted with C8, or NHS Complement Std. yielding 50% lysis of 1 x 10^8 EA when incubated for 60 minutes at 37°C in a total reaction volume of 1.5 mL GVB^{++}.

*** One unit of alternative pathway activity (APH50) is defined as the input of C8-Dpl, reconstituted with 100ug/ml purified C8, or NHS Complement Standard yielding 50% lysis of 1.5 x 10^7 rabbit erythrocytes (Er) when incubated for 30 minutes at 37°C in a total reaction volume of 100 µL GVB^o containing a final MgEGTA concentration of 5 mM.

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

FOR RESEARCH USE ONLY. NOT FOR HUMAN OR DRUG USE.

Signature of Analyst _____ Date of Analysis _____

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