

CERTIFICATE OF ANALYSIS

Complement Technology, Inc.
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Tyler, Texas 75703, USA

Product: **C9-Dpl**
Catalog # **A326** Lot #
Exp. Date:

Description: Complement C9-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥ 40 mg/mL employing an extinction coefficient of $E_{1\%/280\text{nm}} = 10$	67 mg/ml
FILL VOLUME	1.0 to 1.1 mL	1.05 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.

CLASSICAL PATHWAY (CP) ACTIVITY*

Recommended volume of C9-Dpl serum per assay	≤ 25 μL	2.8 μL
C9H50 units/mg purified C9 at the recommended input of C9-Dpl	$\geq 100,000$ Units/mg	253,000 Units/mg
Input of purified C9 to yield 1 C9H50	≤ 13.3 ng	4.0 ng
C9H50/mL NHS Complement Std at the recommended input of C9-Dpl	$\geq 4,500$ Units/mL	185,000 Units/mL
Input of C9 in NHS Complement Std to yield 1 C9H50	≤ 13.3 ng	5.4 ng
CP Ratio: $\frac{\text{C9H50/mg Purified C9}}{\text{C9H50/mg C9 in NHS Std}}$	≥ 0.60	> 1.0
Background A_{412} EA blank reading at the recommended input of C9-Dpl	≤ 0.250	0.02

CH50 FUNCTIONAL ACTIVITY UPON RECONSTITUTION**

CH50/mL NHS Std	≥ 75 CH50/mL	185 CH50/mL
CH50/mL C9-Dpl reconstituted with 100 μg C9/mL	≥ 45 CH50/mL	233 CH50/mL
Ratio: $\frac{\text{CH50/mL C9-Dpl + C9}}{\text{CH50/mL NHS Std}}$	≥ 0.60	> 1.0

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Complement C9-Depleted Human Serum, Lot # 8a (Continued)

ALTERNATIVE PATHWAY (AP) ACTIVITY ***

APH50/mL NHS std	≥ 50 APH50/mL	143 APH50/mL
Input NHS Std to yield 1 APH50	≤ 20 μ L	7 μ L
APH50/mL C9-Dpl + C9	≥ 50 APH50/mL	182 APH50/mL
Input C9-Dpl + C9 to yield 1 APH50	≤ 20 μ L	5.5 μ L
AP Ratio: $\frac{\text{APH50/mL C9-Dpl + C9}}{\text{APH50/mL NHS Std}}$	> 0.50	> 1.0

IMMUNOCHEMISTRY

Ouchterlony	No C9 antigen detectable using various dilutions of goat anti-C9	Conforms
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STARTING MATERIAL: HUMAN SERUM/PLASMA

HBsAg 3.0	Negative	Negative
Anti-HIV 1 and 2 Plus O	Negative	Negative
Anti-HCV 3.0	Negative	Negative
HIV-1/HCV/HBV by NAT	Negative	Negative
West Nile Virus (WNV) by NAT	Negative	Negative
Anti-Syphilis	Negative	Negative
Anti-HTLV I/II	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 C9H50 unit measured by classical pathway activation is defined as the amount of C9 required to yield 50% lysis of 3×10^7 EA when incubated in the presence of the recommended volume of C9-Dpl serum for 30 minutes at 37°C in a total reaction volume of 500 μ L GVB⁺⁺.

** One CH50 unit is defined as the input of C9-Dpl, reconstituted with C9, or NHS Complement Std 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 alternative pathway activity (APH50) is defined as the input of C9-Dpl, reconstituted with purified C9 (@100 μ g C9/mL) or C9 in NHS Complement Std 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.
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