

CERTIFICATE OF ANALYSIS

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Complement Technology, Inc.

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Tyler, Texas 75703, USA

Product: **C7-Dpl**

Catalog # **A324** Lot #

Exp. Date:

Description: Complement C7-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥ 40 mg/mL employing an extinction coefficient of $E1\%/280\text{nm} = 10$	65 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 7.2 – 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 C7-Dpl serum per assay	≤ 40 μL	20 μL
C7H50 units/mg purified C7 at the recommended input of C7-Dpl	$\geq 100,000$ C7H50 Units/mg	606,000 Units/mg
Input of purified C7 to yield 1 C7H50	≤ 10 ng	1.65 ng
C7H50/mL NHS Complement Std at the recommended input of C7-Dpl	$\geq 4,600$ C7H50 Units/mL	15,900 Units/mL
Input of C7 in NHS Complement Std to yield 1 C7H50	≤ 6 ng	3.51 ng
CP Ratio: $\frac{\text{C7H50/mg purified C7}}{\text{C7H50/mg C7 in NHS Std}}$	≥ 0.60	2.13
Background A ₄₁₂ EA blank reading at the recommended input of C7-Dpl	≤ 0.100	0.021

CH50 FUNCTIONAL ACTIVITY UPON RECONSTITUTION**

CH50/mL NHS Std	≥ 75 CH50/mL	147 CH50/mL
CH50/mL C7-Dpl reconstituted with 60 μg C7/mL	≥ 50 CH50/mL	158 CH50/mL
Ratio: $\frac{\text{CH50/mL C7-Dpl} + \text{C7}}{\text{CH50/mL NHS Std}}$	≥ 0.60	1.07

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Complement C7-Depleted Human Serum, Lot # 4 (Continued)

ALTERNATIVE PATHWAY (AP) ACTIVITY ***

APH50/mL NHS Standard	≥ 50 APH50/mL	182 APH50/mL
Input NHS Std to yield 1 APH50	≤ 20 μ L	5.5 μ L
APH50/mL C7-Dpl + C7	≥ 30 APH50/mL	208 APH50/mL
Input C7-Dpl + C7 to yield 1 APH50	≤ 33 μ L	4.8 μ L
AP Ratio: $\frac{\text{APH50/mL C7-Dpl + C7}}{\text{APH50/mL NHS Std}}$	> 0.60	1.14

IMMUNOCHEMISTRY ANALYSIS Ouchterlony	No C7 antigen detectable using various dilutions of goat anti-human C7 antiserum	Conforms
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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
HIV-1/HCV/HBV by NAT	Negative	Negative
West Nile Virus (WNV) by NAT	Negative	Negative
HTLV 1 and 2	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 C7H50 unit measured by classical pathway activation is defined as the amount of C7 required to yield 50% lysis of 3×10^7 EA when incubated in the presence of the recommended volume of C7-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 C7-Dpl, reconstituted with C7, 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 1.5mL GVB⁺⁺.

*** One unit of alternative pathway activity (APH50) is defined as the input of C7-Dpl, reconstituted with purified C7 or C7 in 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.

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