

# CERTIFICATE OF ANALYSIS

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

Product: **C6-Dpl**  
Catalog # **A323** Lot #  
Exp. Date:

Description: Complement C6-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	$\geq 40$ mg/mL employing an extinction coefficient of $E_{1\%/280\text{nm}} = 10$	65 mg/ml
FILL VOLUME	1.0 – 1.2 mL	1.05 mL
PHYSICAL APPEARANCE	Clear, straw colored	Clear, straw colored
BUFFER	50 mM sodium phosphate, 150 mM sodium chloride, pH 7.4	Conforms
PRESERVATIVE	None, filtered through a 0.22 $\mu\text{m}$ pore size filter.	None, filtered through a 0.22 $\mu\text{m}$ pore size filter.

## CLASSICAL PATHWAY (CP) ACTIVITY\*

Recommended volume of C6-Dpl serum per assay	$\leq 40$ $\mu\text{L}$	25 $\mu\text{L}$
C6H50 units/mg purified C6 at the recommended input of C6-Dpl	$\geq 100,000$ Units/mg	3,461,000 Units/mg
Input of purified C6 to yield 1 C6H50	$\leq 10$ ng	0.29 ng
C6H50/mL NHS Complement Std at the recommended input of C6-Dpl	$\geq 7400$ Units/mL	131,000 Units/mL
Input of C6 in NHS Complement Std to yield 1 C6H50	$\leq 6$ ng	0.49 ng
CP Ratio: $\frac{\text{C6H50/mg Purified C6}}{\text{C6H50/mg C6 in NHS Std}}$	$\geq 0.60$	$>1.0$
Background $A_{412}$ EA blank reading at the recommended input of C6-Dpl	$\leq 0.100$	0.003

## CH50 FUNCTIONAL ACTIVITY UPON RECONSTITUTION\*\*

CH50/mL NHS Std	$\geq 75$ CH50/mL	167 CH50/mL
CH50/mL C6-Dpl reconstituted with 65 $\mu\text{g}$ C6/mL	$\geq 50$ CH50/mL	233 CH50/mL
Ratio: $\frac{\text{CH50/mL C6-Dpl} + \text{C6}}{\text{CH50/mL NHS Std}}$	$\geq 0.60$	1.4

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## Complement C6-Depleted Human Serum, Lot # 5 (Continued)

### ALTERNATIVE PATHWAY (AP) ACTIVITY \*\*\*

APH50/mL NHS Std.	$\geq 50$ APH50/mL	182 APH50/mL
Input NHS Std to yield 1 APH50	$\leq 20$ $\mu$ L	5.5 $\mu$ L
APH50/mL C6-Dpl + C6	$\geq 30$ APH50/mL	206 APH50/mL
Input C6-Dpl + C6 to yield 1 APH50	$\leq 33$ $\mu$ L	4.9 $\mu$ L
AP Ratio: $\frac{\text{APH50/mL C6-Dpl + C6}}{\text{APH50/mL NHS Std}}$	$> 0.60$	1.13

### IMMUNOCHEMISTRY

Ouchterlony	No C6 antigen detectable using various dilutions of goat anti-C6	Conforms
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### STARTING MATERIAL: HUMAN SERUM/PLASMA

HBsAg	Negative	Negative
ANTI-HIV 1/2	Negative	Negative
ANTI-HCV	Negative	Negative
HCV by NAT	Negative	Negative
HIV by NAT	Negative	Negative
HBV by NAT	Negative	Negative
WNV by NAT	Negative	Negative
ANTI-Syphilis	Negative	Negative
ANTI-HBc	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 C6H50 unit measured by classical pathway activation is defined as the amount of C6 required to yield 50% lysis of  $3 \times 10^7$  EA when incubated in the presence of the recommended volume of C6-Dpl serum for 30 minutes at 37°C in a total reaction volume of 500  $\mu$ L GVB<sup>++</sup>.

\*\* One CH50 unit is defined as the input of C6-Dpl, reconstituted with C6, or NHS Complement Std. yielding 50% lysis of  $1 \times 10^8$  EA when incubated for 60 minutes at 37°C in a total reaction volume of 1.5 mL GVB<sup>++</sup>.

\*\*\* One unit of alternative pathway activity (APH50) is defined as the input of C6-Dpl, reconstituted with purified C6 or C6 in NHS Complement Std yielding 50% lysis of  $1.5 \times 10^7$  rabbit erythrocytes (Er) when incubated for 30 minutes at 37°C in a total reaction volume of 75  $\mu$ L GVB<sup>o</sup> containing a final Mg-EGTA concentration of 13.3 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**

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Signature of Analyst

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Date of Analysis