

CERTIFICATE OF ANALYSIS

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Complement Technology, Inc.
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Tyler, Texas 75703, USA

Product: **C2-Dpl**
Catalog # **A312** Lot #
Exp. Date:

Description: Complement C2-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥ 40 mg/mL employing an extinction coefficient of $E1\%/280\text{nm} = 10$	58 mg/mL
FILL VOLUME	1.0 - 1.1 mL	1.1 mL
PHYSICAL APPEARANCE	Clear, straw colored	Clear, straw colored
BUFFER	Phosphate Buffered Saline, pH7.2	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 C2-Dpl serum per assay	$\leq 40 \mu\text{L}$	18 μL
C2H50 units/mg purified C2 at the recommended input of C2-Dpl	$\geq 143,000$ Units/mg	7,257,000 Units/mg
Input of purified C2 to yield 1 C2H50	≤ 7 ng	0.14 ng
C2H50/mL NHS Complement Std at the recommended input of C2-Dpl	$\geq 3,600$ Units/mL	151,000 Units/mL
Input of C2 in NHS Complement Std to yield 1 C2H50	≤ 5 ng	0.13 ng
CP Ratio: $\frac{\text{C2H50/mg Purified C2}}{\text{C2H50/mg C2 in NHS Std}}$	≥ 0.60	0.96
Background A_{412} EA blank reading at the recommended input of C2-Dpl	≤ 0.200	0.106

CH50 FUNCTIONAL ACTIVITY UPON RECONSTITUTION**

CH50/mL NHS Std	≥ 75 CH50/mL	208 CH50/mL
CH50/mL C2-Dpl reconstituted with 25 μg C2/mL	≥ 75 CH50/mL	222 CH50/mL
Ratio: $\frac{\text{CH50/mL C2-Dpl} + \text{C2}}{\text{CH50/mL NHS Std}}$	≥ 0.50	1.06

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Complement C2-Depleted Human Serum, Lot # 18b (Continued)

ALTERNATIVE PATHWAY (AP) ACTIVITY ***

APH50/mL NHS std	≥ 50 APH50/mL	181 APH50/mL
Input NHS Std to yield 1 APH50	≤ 20 μ L	5.5 μ L
APH50/mL C2-Dpl	≥ 50 APH50/mL	181 APH50/mL
Input C2-Dpl to yield 1 APH50	≤ 20 μ L	5.5 μ L
AP Ratio: $\frac{\text{APH50/mL C2-Dpl}}{\text{APH50/mL NHS Std}}$	> 0.60	1.0

IMMUNOCHEMISTRY

Ouchterlony	No C2 antigen detectable using various dilutions of goat anti-C2	Conforms
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STARTING MATERIAL: HUMAN SERUM/PLASMA

HBsAg	Negative	Negative
Anti-HBc	Negative	Negative
Anti-HCV 3.0	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 1I and 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 C2H50 unit measured by classical pathway activation is defined as the amount of C2 required to yield 50% lysis of 3×10^7 EA when incubated in the presence of the recommended volume of C2-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 C2-Dpl, reconstituted with C2, 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 C2-Dpl or 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 and NOT FOR HUMAN OR DRUG USE

Signature of Analyst

Date of Analysis