

CERTIFICATE OF ANALYSIS

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Complement Technology, Inc.
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Tyler, Texas 75703, USA

Product: **C4-Dpl(Immuno Dpl)**
Catalog # **A308** Lot #
Exp. Date:

Description: Complement C4-Depleted Human Serum made by immunoaffinity chromatography

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥40 mg/mL employing an extinction coefficient of E1%/280nm = 10	60 mg/ml
FILL VOLUME	1.0 – 1.1 mL	1.1 mL
PHYSICAL APPEARANCE	Clear, straw colored	Clear, straw colored
BUFFER	10 mM sodium phosphate, 145 mM sodium chloride, 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.
<u>CLASSICAL PATHWAY (CP) ACTIVITY*</u>		
Recommended volume of C4-Dpl serum per assay	≤ 40 µL	20 µL
C4H50 units/mg purified C4 at the recommended input of C4-Dpl	≥ 160,000 Units/mg	589,000 Units/mg
Input of purified C4 to yield 1 C4H50	≤ 10 ng	1.7 ng
C4H50 in NHS Complement Std. at the recommended input of C4-Dpl	≥ 40,000 Units/ml, ≥ 100,000 Units/mg C4	215,000 Units/ml 536,000 Units/mg C4
Input of C4 in NHS Complement Std. to yield 1 C4H50	≤ 5 ng	1.9 ng
CP Ratio: $\frac{\text{C4H50/mg PurifiedC4}}{\text{C4H50/mg C4 in NHS Std}}$	≥ 0.60	1.10
Background A ₄₁₂ EA blank reading at the recommended input of C4-Dpl	≤ 0.100	0.023
<u>CH50 FUNCTIONAL ACTIVITY UPON RECONSTITUTION**</u>		
CH50/mL NHS Std	≥ 80 CH50/mL	167 CH50/mL
CH50/mL C4-Dpl reconstituted with 0.4 mg C4/mL	≥ 60 CH50/mL	196 CH50/mL
Ratio: $\frac{\text{CH50/mL C4-Dpl + C4}}{\text{CH50/mL NHS Std}}$	≥ 0.60	1.17

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Complement C4-Immuno Depleted Human Serum, Lot # 3a (Continued)

ALTERNATIVE PATHWAY (AP) ACTIVITY ***

APH50/mL NHS Std.	≥ 50 APH50/mL	160 APH50/mL
Input NHS Std to yield 1 APH50	≤ 20 μ L	6.3 μ L
APH50/mL C4-Dpl + C4 (0.4 mg C4/mL C4-Dpl)	≥ 50 APH50/mL	190 APH50/mL
Input C4-Dpl + C4 to yield 1 APH50	≤ 20 μ L	5.3 μ L
AP Ratio: $\frac{\text{APH50/mL C4-Dpl + C4}}{\text{APH50/mL NHS Std}}$	> 0.60	1.19

IMMUNOCHEMISTRY

Ouchterlony	No C4 antigen detectable using various dilutions of Goat anti-C4	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
Anti-HBc	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 C4H50 unit measured by classical pathway activation is defined as the amount of C4 required to yield 50% lysis of 3×10^7 EA when incubated in the presence of the recommended volume of C4-Dpl serum for 30 minutes at 37°C in a total reaction volume of 500 μ L GVB⁺⁺. Lysis was measured @ 412 nm after a 3-fold dilution with GVBE.

** One CH50 unit is defined as the input of C4-Dpl, reconstituted with C4, 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 1.5mL GVB⁺⁺.

*** One unit of alternative pathway activity (APH50) is defined as the input of C4-Dpl, reconstituted with purified C4 or C4 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 containing a final Mg-EGTA concentration of 5 mM.

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

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

Signature of Analyst

Date of Analysis