

CERTIFICATE OF ANALYSIS

Page 1 of 2

Complement Technology, Inc.
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Tyler, Texas 75703, USA

Product: **C3-Dpl (Immuno Dpl)**
Catalog # **A314 Lot #**
Exp. Date:

Description: Complement C3-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 $E_{1\%/280\text{nm}} = 10$	63 mg/ml
FILL VOLUME	1.0 – 1.2 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 C3-Dpl serum per assay	≤ 30 μL	6 μL
C3H50 units/mg purified C3 at the recommended input of C3-Dpl	$\geq 2,000$ Units/mg	10,950 Units/mg
Input of purified C3 to yield 1 C3H50	≤ 500 ng	91 ng
C3H50 in NHS Complement Std. at the recommended input of C3-Dpl	$\geq 2,500$ Units/ml, $\geq 2,000$ Units/mg C3	16,400 Units/ml 13,100 Units/mg C3
Input of C3 in NHS Complement Std. to yield 1 C3H50	≤ 500 ng	76 ng
CP Ratio: $\frac{\text{C3H50/mg Purified C3}}{\text{C3H50/mg C3 in NHS Std}}$	≥ 0.60	0.84
Background A_{412} EA blank reading at the recommended input of C3-Dpl	≤ 0.300	0.239
<u>CH50 FUNCTIONAL ACTIVITY UPON RECONSTITUTION**</u>		
CH50/mL NHS Std	≥ 80 CH50/mL	145 CH50/mL
CH50/mL C3-Dpl reconstituted with 1.2 mg C3/mL	≥ 60 CH50/mL	189 CH50/mL
Ratio: $\frac{\text{CH50/mL C3-Dpl} + \text{C3}}{\text{CH50/mL NHS Std}}$	≥ 0.60	1.30

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Complement C3-Immuno Depleted Human Serum, Lot # 5b (Continued)

ALTERNATIVE PATHWAY (AP) ACTIVITY ***

APH50/mL NHS Std.	≥ 50 APH50/mL	113 APH50/mL
Input NHS Std to yield 1 APH50	≤ 20 μ L	8.8 μ L
APH50/mL C3-Dpl + C3 (1.2 mg C3/mL C3-Dpl)	≥ 50 APH50/mL	158 APH50/mL
Input C3-Dpl + C3 to yield 1 APH50	≤ 20 μ L	6.3 μ L
AP Ratio: $\frac{\text{APH50/mL C3-Dpl + C3}}{\text{APH50/mL NHS Std}}$	> 0.60	1.40

IMMUNOCHEMISTRY

Ouchterlony	No C3 antigen detectable using various dilutions of Goat anti-C3	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 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 C3H50 unit measured by classical pathway activation is defined as the amount of C3 required to yield 50% lysis of 3×10^7 EA when incubated in the presence of the recommended volume of C3-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 C3-Dpl, reconstituted with C3, 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 C3-Dpl, reconstituted with purified C3 or C3 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.
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