

CERTIFICATE OF ANALYSIS

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Complement Technology, Inc.

4801 Troup Hwy, Suite 701
Tyler, Texas 75703, USA

Product: **C3/C5-Dpl**

Catalog # **A342** Lot #

Exp. Date:

Description: Complement C3 and C5-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 = 10.0	63 mg/ml
FILL VOLUME	0.50 – 0.55 mL	0.53 mL
PHYSICAL APPEARANCE	Clear, straw colored	Conforms
BUFFER	10 mM sodium phosphate, 140 mM sodium chloride, pH 7.3	Conforms
PRESERVATIVE	None, filtered through a 0.22 μ m pore size filter.	Conforms

CLASSICAL PATHWAY (CP) FUNCTIONAL ACTIVITY (CH50) *

NHS Std	≥ 75 CH50/mL	175 CH50/mL
Un-reconstituted C3/C5-Dpl	≤ 10 CH50/mL	<1 CH50/ml
Un-reconstituted % Activity compared to NHS $\frac{\text{CH50/mL C3/C5-Dpl} \times 100}{\text{CH50/mL NHS Std}}$	$\leq 10\%$	<1%
Reconstituted C3/C5-Dpl (+ 1.2 mg C3 and 75 μ g C5/ml)	≥ 60 CH50/mL	175 CH50/ml
Reconstituted % Activity with C3 & C5 compared to NHS $\frac{\text{CH50/mL C3/C5-Dpl} + \text{C3} + \text{C5} \times 100}{\text{CH50/mL NHS Std}}$	$\geq 60\%$	100%

ALTERNATIVE PATHWAY (AP) FUNCTIONAL ACTIVITY (AP50) **

NHS Std	≥ 50 AP50/mL	200 AP50/mL
Input NHS Std to yield 1 APH50	≤ 20 μ L	5 μ L
Un-reconstituted C3/C5-Dpl	≤ 10 AP50/mL	<1 AP50/mL
Un-reconstituted % Activity compared to NHS $\frac{\text{AP50/mL C3/C5-Dpl} \times 100}{\text{AP50/mL NHS Std}}$	$\leq 10\%$	<1%

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Complement C3/C5-Depleted Human Serum, Lot #2 (Continued)

Reconstituted C3/C5-Dpl (+ 1.2 mg C3 and 75 µg C5/ml)	≥ 50 AP50/mL	222 AP50/mL
Input C3/C5-Dpl + C3 & C5 to yield 1 AP50	≤ 20 µL	4.5 µL
Reconstituted % Activity with C3 & C5 compared to NHS $\frac{\text{AP50/mL C3/C4-Dpl} + \text{C3} + \text{C5}}{\text{AP50/mL NHS Std}} \times 100$	$\geq 60\%$	111%

IMMUNOCHEMICAL ANALYSIS

Ouchterlony	No C3 or C5 antigen detectable using various dilutions of anti-Human C3 and anti-Human C5 antiserum	Conforms
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STARTING MATERIAL: HUMAN SERUM/PLASMA

HBsAg	Negative	Negative
anti-HIV 1/2 ANTIBODIES	Negative	Negative
anti-HCV ANTIBODIES	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
Zika RNA by NAT	Negative	Negative
anti-HBc ANTIBODIES	Negative	Negative
anti-HTLV-I/II ANTIBODIES	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 CH50 unit is defined as the input of C3/C5-Dpl, with or without reconstitution with C3 & C5, 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 C3/C5-Dpl, with or without reconstitution with C3 & C5 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 µL GVB^o 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