

CERTIFICATE OF ANALYSIS

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Complement Technology, Inc.
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Tyler, Texas 75703, USA

Product: **C5-Dpl**
Catalog # **A320** Lot #
Exp. Date:

Description: Complement C5-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥ 40 mg/mL employing an extinction coefficient of $E_{1\%/280\text{nm}} = 10$	65 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.

CLASSICAL PATHWAY (CP) ACTIVITY*

Recommended volume of C5-Dpl serum per assay	≤ 40 μL	30 μL
C5H50 units/mg purified C5 at the recommended input of C5-Dpl	$\geq 100,000$ Units/mg	415,000 Units/mg
Input of purified C5 to yield 1 C5H50	≤ 15 ng	2.4 ng
C5H50/mL NHS Complement Std at the recommended input of C5-Dpl	$\geq 10,000$ Units/mL	37,000 Units/mL
Input of C5 in NHS Complement Std to yield 1 C5H50	≤ 7.5 ng	2.0 ng
CP Ratio: $\frac{\text{C5H50/mg Purified C5}}{\text{C5H50/mg C5 in NHS Std}}$	≥ 0.60	0.85
Background A_{412} EA blank reading at the recommended input of C5-Dpl	≤ 0.100	0.018

CH50 FUNCTIONAL ACTIVITY UPON RECONSTITUTION**

CH50/mL NHS Std	≥ 75 CH50/mL	166 CH50/mL
CH50/mL C5-Dpl reconstituted with 100 μg C5/mL	≥ 50 CH50/mL	208 CH50/mL
Ratio: $\frac{\text{CH50/mL C5-Dpl} + \text{C5}}{\text{CH50/mL NHS Std}}$	≥ 0.60	1.3

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Complement C5-Depleted Human Serum, Lot # 19 (Continued)

ALTERNATIVE PATHWAY (AP) ACTIVITY ***

APH50/mL NHS Std.	≥ 50 APH50/mL	182 APH50/mL
Input NHS Std to yield 1 APH50	≤ 20 μ L	5 μ L
APH50/mL C5-Dpl + C5	≥ 30 APH50/mL	190 APH50/mL
Input C5-Dpl + C5 to yield 1 APH50	≤ 33 μ L	5.5 μ L
AP Ratio: $\frac{\text{APH50/mL C5-Dpl + C5}}{\text{APH50/mL NHS Std}}$	> 0.60	1.0

IMMUNOCHEMISTRY

Ouchterlony	No C5 antigen detectable using various dilutions of goat anti-C5	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

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 C5H50 unit measured by classical pathway activation is defined as the amount of C5 required to yield 50% lysis of 3×10^7 EA when incubated in the presence of the recommended volume of C5-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 C5-Dpl, reconstituted with 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 1.5mL GVB⁺⁺.

*** One unit of alternative pathway activity (APH50) is defined as the input of C5-Dpl, reconstituted with 100ug/ml purified C5 or NHS Complement Standard 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 MgEGTA 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