

CERTIFICATE OF ANALYSIS

Complement Technology, Inc.
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Tyler, Texas 75703, USA

Product: C1q-Dpl
Catalog # **A300** Lot #
Exp. Date:

Description: C1q-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥ 40 mg/ml using an extinction coefficient of $E^{1\%}_{280\text{ nm}} = 10$	64 mg/mL
FILL VOLUME	1.0 – 1.1 mL	1.05 mL
PHYSICAL APPEARANCE	Clear, straw colored	Clear, straw colored
BUFFER	Phosphate Buffered Saline, 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 ACTIVITY*

Recommended volume of C1q-Dpl serum per assay	40 μL or less	5 μL
C1qH50 Units/mg purified C1q at the recommended input of C1q-Dpl	$\geq 12,500$ Units/mg	887,000 Units/mg
Input of purified C1q to yield 1 Unit	≤ 80 ng/Unit	1.13 ng/Unit
C1qH50 Units/ml NHS Complement Std (at 70 μg C1q/ml) at the recommended input of C1q-Dpl	$\geq 3,500$ Units/ml	77,000 Units/ml
Input of C1q in NHS Std to yield 1 Unit	≤ 20 ng/Unit	0.91 ng/Unit
Ratio: $\frac{\text{C1qH50/mg C1q}}{\text{C1qH50/mg C1q in NHS Std}}$	≥ 0.2	0.81
Background A_{412} EA blank reading at the recommended input of C1q-Dpl	≤ 0.250	0.012

CH50 FUNCTIONAL ACTIVITY UPON RECONSTITUTION**

CH50/mL NHS Standard	≥ 75 CH50/mL	222 CH50/mL
CH50/mL C1q-Dpl reconstituted with 100 μg C1q/mL	≥ 40 CH50/mL	256 CH50/mL
Ratio: $\frac{\text{CH50/mL C1q-Dpl} + \text{C1q}}{\text{CH50/mL NHS Std}}$	≥ 0.50	1.15

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Product: **C1q-Dpl # 24 (continued)**

ALTERNATIVE PATHWAY (AP) ACTIVITY***

APH50/mL NHS Standard	≥ 50 APH50/mL	250 APH50/mL
Input NHS Std to yield 1 APH50	≤ 20 μ L	4.0 μ L
APH50/mL C1q-Dpl	≥ 50 APH50/mL	328 APH50/mL
Input C1q-Dpl to yield 1 APH50	≤ 20 μ L	3.05 μ L
AP Ratio $\frac{\text{APH50/mL C1q-Dpl}}{\text{APH50/mL NHS Std}}$	≥ 0.50	1.3

IMMUNOCHEMICAL ANALYSIS

Ouchterlony	No C1q antigen detectable using various dilutions of goat anti-human C1q antiserum	Conforms
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HUMAN SERUM/PLASMA STARTING MATERIAL

HBsAg	Negative	Negative
Anti-HBc antibodies	Negative	Negative
Anti-HIV-I and 2 plus O antibodies	Negative	Negative
Anti-HCV antibodies	Negative	Negative
Anti-Syphilis antibodies	Negative	Negative
HCV by NAT	Negative	Negative
HIV by NAT	Negative	Negative
HTLV 1 and 2	Negative	Negative
West Nile Virus (WNV)	Negative	Negative

* One C1qH50 unit measured by classical pathway activation is defined as the amount of C1q required to yield 50% lysis of 3×10^7 EA when incubated in the presence of the recommended volume of C1q-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 C1q-Dpl, reconstituted with C1q, or NHS Complement Standard 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 whole alternative pathway activity (APH50) is defined as the input of C1q-Dpl 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 Mg-EGTA concentration of 10 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