

CERTIFICATE OF ANALYSIS

Page 1 of 2

Complement Technology, Inc.

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

Product: **C1q/FD-Dpl**

Catalog # **A399** Lot #

Exp. Date:

Description: Complement C1q and Factor D (FD)-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥ 40 mg/mL employing an extinction coefficient of $E1\%/280\text{nm} = 10.0$	67 mg/mL
FILL VOLUME	1.0 – 1.2 mL	1.1 mL
PHYSICAL APPEARANCE	Clear, straw colored	Conforms
BUFFER	Phosphate buffered saline, pH 7.3	Conforms
PRESERVATIVE	None, filtered through a 0.22 μm pore size filter.	Conforms

Classical pathway (CP) ACTIVITY *

NHS Std	≥ 75 CH50/mL	233 CH50/mL
Un-reconstituted C1q/FD-Dpl	≤ 10 CH50/mL	< 1.0 CH50/mL
Un-reconstituted % Activity (Compared to NHS) $\frac{\text{CH50/mL C1q/FD-Dpl} \times 100}{\text{CH50/mL NHS Std}}$	$\leq 5\%$	< 1%
Reconstituted C1q/FD-Dpl (+ 70ug C1q and 1.4ug FD /mL)	≥ 40 CH50/mL	303 CH50/mL
Reconstituted % Activity (Compared to NHS) $\frac{\text{CH50/mL C1q/FD-Dpl} + \text{C1q} + \text{FD} \times 100}{\text{CH50/mL NHS Std}}$	$\geq 50\%$	130%

Alternative Pathway (AP) ACTIVITY **

NHS Std	≥ 60 AP50/mL	214 AP50/mL
Un-reconstituted C1q/FD-Dpl	≤ 10 AP50/mL	< 1 AP50/mL
Un-reconstituted % Activity (Compared to NHS) $\frac{\text{AP50/mL C1q/FD-Dpl} \times 100}{\text{AP50/mL NHS Std}}$	$\leq 5\%$	< 1%
Reconstituted C1q/FD-Dpl (+ 70ug C1q and 1.4ug FD /mL)	≥ 50 AP50/mL	214 AP50/mL
Reconstituted % Activity (Compared to NHS) $\frac{\text{AP50/mL C1q/FD-Dpl} + \text{C1q} + \text{FD} \times 100}{\text{AP50/mL NHS Std}}$	$\geq 50\%$	100%

CERTIFICATE OF ANALYSIS

Page 2 of 2

Complement C1q/FD-Depleted Human Serum, Lot 2a (Continued)

IMMUNOCHEMICAL ANALYSIS

Ouchterlony	No C1q or Factor D antigen detectable using various dilutions of anti-Human C1q and anti-Human Factor D antiserum	Conforms
-------------	---	----------

STARTING MATERIAL: HUMAN SERUM/PLASMA

HBsAg	Negative	Negative
Anti-HIV-1/2 plus O	Negative	Negative
Anti-HCV 3.0	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
Anti-HBc	Negative	Negative
Anti-HTLV – I/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 unit of classical pathway activity (CH50) is defined as the input of C1q/FD-Dpl or C1q/FD-Dpl reconstituted with purified C1q & Factor D, 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 alternative pathway activity (APH50) is defined as the input of C1q/FD-Dpl or C1q/FD-Dpl reconstituted with purified C1q & Factor D 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 µL GVB^o 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