

# CERTIFICATE OF ANALYSIS

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**Complement Technology, Inc.**  
4801 Troup Hwy, Suite 701  
Tyler, Texas 75703, USA

Product: **C3/FB-Dpl**  
Catalog # **A345 Lot #**  
Exp. Date:

Description: Complement C3 and Factor B (FB)-Depleted Human Serum made by immunoaffinity chromatography

<b><u>Specifications</u></b>	<b><u>Limits</u></b>	<b><u>Results</u></b>
PROTEIN CONCENTRATION	≥40 mg/mL employing an extinction coefficient of E1%/280nm = 10.0	58 mg/mL
FILL VOLUME	0.50 – 0.55 mL	0.53 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) FUNCTIONAL ACTIVITY (CH50) \***

NHS Std	≥ 75 CH50/mL	165 CH50/mL
Un-reconstituted C3/FB-Dpl	≤ 10 CH50/mL	< 1.0 CH50/mL
Un-reconstituted % Activity compared to NHS $\frac{\text{CH50/mL C3/FB-Dpl} \times 100}{\text{CH50/mL NHS Std}}$	≤ 10%	< 1%
Reconstituted C3/FB-Dpl (+ 1.2mg C3/mL)	≥ 60 CH50/mL	185 CH50/mL
Reconstituted % Activity compared to NHS $\frac{\text{CH50/mL C3/FB-Dpl} + \text{C3} \times 100}{\text{CH50/mL NHS Std}}$	≥ 60%	112%

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

NHS Std	≥ 50 AP50/mL	190 AP50/mL
Input NHS Std to yield 1 APH50	≤ 20 µL	5.3 µL
Un-reconstituted C3/FB-Dpl	≤ 10 AP50/mL	< 1 AP50/mL
Un-reconstituted % Activity compared to NHS $\frac{\text{AP50/mL C3/FB-Dpl} \times 100}{\text{AP50/mL NHS Std}}$	≤ 10%	< 1%

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

Reconstituted C3/FB-Dpl with C3 (+ 1.2mg C3/mL)	≤ 10 AP50/mL	< 1 AP50
Reconstituted % Activity with C3 compared to NHS $\frac{\text{AP50/mL C3/FB-Dpl} + \text{C3}}{\text{AP50/mL NHS Std}} \times 100$	≤ 10%	< 1 %
Reconstituted C3/FB-Dpl with C3 & FB (+ 1.2mg C3 and 0.2mg FB/mL)	≥ 50 AP50/mL	194 AP50/mL
Input C3/FB-Dpl + C3 & FB to yield 1 AP50	≤ 20 µL	5.2 µL
Reconstituted % Activity with C3 & FB compared to NHS $\frac{\text{AP50/mL C3/FB-Dpl} + \text{C3 and FB}}{\text{AP50/mL NHS Std}} \times 100$	≥ 60%	102%

### IMMUNOCHEMICAL ANALYSIS

Ouchterlony	No C3 or Factor B antigen detectable using various dilutions of anti-Human C3 & anti-Human Factor B antiserum	Conforms
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### STARTING MATERIAL: HUMAN SERUM/PLASMA

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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 unit of classical pathway activity (CH50) is defined as the input of C3/FB-Dpl or C3/FB-Dpl reconstituted with purified C3 & Factor B, or NHS Complement Standard yielding 50% lysis of  $1 \times 10^8$  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/FB-Dpl or C3/FB-Dpl reconstituted with purified C3 & Factor B or NHS Complement Standard yielding 50% lysis of  $1.5 \times 10^7$  rabbit erythrocytes (Er) when incubated for 30 minutes at 37°C in a total reaction volume of 100 µL GVB<sup>o</sup> 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

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