

# CERTIFICATE OF ANALYSIS

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## Complement Technology, Inc.

4801 Troup Hwy, Suite 701

Tyler, Texas 75703, USA

Product: **Factor I-Dpl**

Catalog # **A338** Lot #

Exp. Date:

### Description: Factor I-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	$\geq 35$ mg/mL employing an extinction coefficient of $E1\%/280\text{nm} = 10$	61 mg/ml
FILL VOLUME	1.0 – 1.2 mL	1.05 mL
PHYSICAL APPEARANCE	Clear, straw colored	Clear, straw colored
BUFFER	Phosphate Buffered Saline pH 7.2	Conforms
PRESERVATIVE	None, filtered through a 0.22 $\mu\text{m}$ pore size filter.	None, filtered through a 0.22 $\mu\text{m}$ pore size filter.

### CH50 FUNCTIONAL ACTIVITY\*

CH50/mL NHS Std	$\geq 75$ CH50 Units/mL	179 CH50 U/mL
CH50/mL Factor I-Dpl reconstituted with 35 $\mu\text{g}$ Factor I/mL	$\geq 75$ CH50 Units/mL	179 CH50 U/mL
Ratio: $\frac{\text{CH50/mL Factor I-Dpl} + \text{I}}{\text{CH50/mL NHS Std}}$	$\geq 0.50$	1.0
Percent Classical Pathway Activity of I-Dpl + I		100 %

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

APH50/mL NHS Standard	$\geq 70$ APH50 Units/mL	154 APH50 U/mL
APH50/mL Factor I-Dpl reconstituted with 35 $\mu\text{g}$ Factor I/mL	$\geq 70$ APH50 Units/mL	154 APH50 U/mL
Ratio: $\frac{\text{APH50/mL Factor I-Dpl} + \text{I}}{\text{APH50/mL NHS Std}}$	$> 0.60$	1.0
Percent Alternative Pathway Activity of I-Dpl + I		100 %

### IMMUNOCHEMICAL ANALYSIS

Ouchterlony (Immunodiffusion)	No Factor I antigen detectable using various dilutions of anti-Human Factor I antiserum	Conforms
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Complement Factor I-Depleted Human Serum, Lot # 2a (Continued)

STARTING MATERIAL: HUMAN SERUM/PLASMA

HBsAg	Negative	Negative
Anti-HIV 1/2 Plus O	Negative	Negative
Anti-HCV	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-HTLV-I/II	Negative	Negative
Anti-HBc	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 NHS Complement Standard or of a mixture of I-Dpl reconstituted with purified Factor I @ 35 µg/ml in undiluted serum (for example, for ½ diluted serum: 100 µL I-Dpl + 3.5 µL Factor I (1 mg/ml) + 96.5 µL GVB<sup>++</sup>) 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<sup>++</sup>.

\*\* One unit of alternative pathway activity (APH50) is defined as the input of NHS Complement Standard or of I-Dpl reconstituted with purified Factor I @ 35 µg/ml in undiluted serum (for example, for ½ diluted serum: 100 µL I-Dpl + 3.5 µL Factor I (1 mg/ml) + 96.5 µL GVB<sup>o</sup>) yielding 50% lysis of  $1.5 \times 10^7$  Er when incubated for 30 minutes at 37°C in a total reaction volume of 100 µL GVB<sup>o</sup> containing a final concentration of 5 mM MgEGTA.

**WARNING**

Factor I depleted serum will activate  
Spontaneously upon addition of metal ions  
Unless factor I or a similar controlling agent is  
Added prior to addition of metals. The lack of  
factor I allows uncontrolled activation of the  
Alternative pathway with consumption of all of  
The factor B and some of the C3.

**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