

# CERTIFICATE OF ANALYSIS

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

**Product: Factor H&D-Dpl**  
**Catalog # A437 Lot # 3**  
**Exp. Date**

Description: Factor H&D-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	$\geq 35$ mg/mL employing an extinction coefficient of $E_{1\%/280\text{nm}} = 10$	65 mg/ml
FILL VOLUME	1.0 – 1.2 mL	1.03 mL
PHYSICAL APPEARANCE	Clear, straw colored	Clear, straw colored
BUFFER	Phosphate Buffer Saline, + 0.4mM EDTA pH 7.2	Conforms
PRESERVATIVE	0.02% Azide, filtered through a 0.22 $\mu$ m pore size filter.	0.02% Azide, filtered through a 0.22 $\mu$ m pore size filter.

ALTERNATIVE PATHWAY (AP) ACTIVITY \*\*

APH50/mL Factor H&D-Dpl Not reconstituted with Factor H or D	< 1 APH50 Units/mL	< 0.1 APH50 U/mL
APH50/mL NHS Standard	$\geq 70$ APH50 Units/mL	166 APH50 U/mL
APH50/mL Factor H&D-Dpl reconstituted with Factor D (2 $\mu$ g Factor D/mL) with Factor H (500ug Factor H/mL)	$\geq 70$ APH50 Units/mL	204 APH50 U/mL
% Alternative Pathway activity of Factor H&D-Dpl reconstituted with H and D relative to NHS standard	> 60%	123%

CH50 FUNCTIONAL ACTIVITY\*\*\*

CH50/mL Factor H&D-Dpl Not reconstituted with Factor H or D	$\geq 75$ CH50 Units/mL	229 CH50 U/mL
CH50/mL NHS Std	$\geq 75$ CH50 Units/mL	172 CH50 U/mL
CH50/mL Factor H&D-Dpl reconstituted with Factor D (2 $\mu$ g Factor D/mL) with Factor H (500ug Factor H/mL)	$\geq 75$ CH50 Units/mL	196 CH50 U/mL
% Classical Pathway activity of Factor H&D-Dpl reconstituted with H and D relative to NHS standard	> 80%	114%

# CERTIFICATE OF ANALYSIS

## Complement Factor H&D-Depleted Human Serum, Lot # 3 (Continued)

% Classical Pathway activity of Factor H&D-Dpl Not reconstituted with H and D	> 80%	133%
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### IMMUNOCHEMICAL ANALYSIS

Ouchterlony (Immunodiffusion)	No Factor H or D antigen detectable using various dilutions of anti-Human Factor H and anti-Human Factor D antiserum	Conforms
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### STARTING MATERIAL: HUMAN SERUM/PLASMA

Anti-HBc	Negative	Negative
HBsAg	Negative	Negative
anti-HCV	Negative	Negative
Anti-HIV 1 and 2 Plus O	Negative	Negative
Anti-HTLV 1 and 2	Negative	Negative
HCV RNA by NAT	Negative	Negative
HIV RNA by NAT	Negative	Negative
HBV DNA by NAT	Negative	Negative
Anti-Syphilis	Negative	Negative
WNV RNA by NAT	Negative	Negative
Chagas	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 alternative pathway activity (APH50) is defined as the input of H&D-Dpl or H&D-Dpl reconstituted with purified Factor H and Factor D or NHS Complement Standard 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° containing a final MgEGTA concentration of 5 mM.

\*\*\* One unit of Classical pathway activity (CH50) is defined as the input of H&D-Dpl or H&D-Dpl reconstituted with purified Factor H and Factor D 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\*\*.

**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**

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Signature of Analyst

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Date of Analysis