

CERTIFICATE OF ANALYSIS

Complement Technology, Inc.
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Product: **Factor H-Dpl**
Catalog # **A337** Lot #
Exp. Date:

Description: Factor H-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥35 mg/mL employing an extinction coefficient of E1%/280nm = 10	65 mg/ml
FILL VOLUME	1.0 – 1.2 mL	1.1 mL
PHYSICAL APPEARANCE	Clear, straw colored	Clear, straw colored
BUFFER	Phosphate Buffered Saline pH 7.2	Conforms
PRESERVATIVE	None, filtered through a 0.22 µm pore size filter.	None, filtered through a 0.22 µm pore size filter.

CH50 FUNCTIONAL ACTIVITY*

CH50/mL NHS Std	≥ 75 CH50 Units/mL	163 CH50 U/mL
CH50/mL Factor H-Dpl reconstituted with 500 µg Factor H/mL	≥ 75 CH50 Units/mL	196 CH50 U/mL
Ratio: $\frac{\text{CH50/mL Factor H-Dpl} + \text{H}}{\text{CH50/mL NHS Std}}$	≥ 0.50	1.2
Percent Classical Pathway Activity of H-Dpl + H		≥100 %

ALTERNATIVE PATHWAY (AP) ACTIVITY **

APH50/mL NHS Standard	≥ 70 APH50 Units/mL	190 APH50 U/mL
APH50/mL Factor H-Dpl reconstituted with 500 µg Factor H/mL	≥ 70 APH50 Units/mL	190 APH50 U/mL
Ratio: $\frac{\text{APH50/mL Factor H-Dpl} + \text{H}}{\text{APH50/mL NHS Std}}$	> 0.60	1.00
Percent Alternative Pathway Activity of H-Dpl + H		≥100 %

IMMUNOCHEMICAL ANALYSIS

Ouchterlony (Immunodiffusion)	No Factor H antigen detectable using various dilutions of anti-Human Factor H antiserum	Conforms
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Complement Factor H-Depleted Human Serum, Lot # 11a (Continued)

STARTING MATERIAL: HUMAN SERUM/PLASMA

HBsAg 3.0	Negative	Negative
Anti-HIV 1 and 2 Plus O	Negative	Negative
Anti-HCV 3.0	Negative	Negative
HIV-1/HCV/HBV by NAT	Negative	Negative
West Nile Virus (WNV) by NAT	Negative	Negative
Anti-Syphilis	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 CH50 unit is defined as the input of NHS Complement Standard or of a mixture of H-Dpl reconstituted with purified Factor H @ 500 µg/ml in undiluted serum (for example, for ½ diluted serum: 100 µL H-Dpl + 50 µL Factor H (1 mg/ml) + 50 µL GVB^o) 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 NHS Complement Standard or of H-Dpl reconstituted with purified Factor H @ 500 µg/ml in undiluted serum (for example, for ½ diluted serum: 100 µL H-Dpl + 50 µL Factor H (1 mg/ml) + 50 µL GVB^o) yielding 50% lysis of 1.5×10^7 Er when incubated for 30 minutes at 37°C in a total reaction volume of 100 µL GVB^o containing a final concentration of 5mM MgEGTA.

WARNING

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

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