

CERTIFICATE OF ANALYSIS

Complement Technology, Inc.
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Tyler, Texas 75703, USA

Product: **Factor D-Dpl**
Catalog # **A336** Lot #
Exp. Date:

Description: Factor D-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥ 35 mg/mL employing an extinction coefficient of $E_{1\%}^{1\text{cm}}_{280\text{nm}} = 10$	64 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 μ m pore size filter.	None, filtered through a 0.22 μ m pore size filter.

FACTOR D FUNCTIONAL ACTIVITY MEASUREMENT (DH50)*

Recommended volume of Factor D-Dpl serum per assay	≤ 40 μ L	30 μ L
Factor DH50 units/mg purified Factor D at the recommended input of Factor D-Dpl serum	$\geq 240,000$ Units/mg	3,325,900 U/mg
Factor DH50 units/mL Factor D in NHS complement Std (1.4 μ g Factor D/mL)	≥ 900 DH50 Units/mL	3,279 U/mL
Ratio: $\frac{\text{Factor DH50/mg Factor D}}{\text{Factor DH50/mg Factor D in NHS Std}}$	≥ 0.50	1.42
Background A_{412} reading of Rabbit E blank at the recommended input of Factor D-Dpl	≤ 0.100	0.032

ALTERNATIVE PATHWAY (AP) ACTIVITY **

APH50/mL Factor D-Dpl Not reconstituted with Factor D	< 1 APH50 Units/mL	< 0.1 APH50 U/mL
APH50/mL NHS Standard	≥ 70 APH50 Units/mL	138 APH50 U/mL
APH50/mL Factor D-Dpl reconstituted with Factor D (1.4 μ g Factor D/mL)	≥ 70 APH50 Units/mL	160 APH50 U/mL
% Alternative Pathway activity of Factor D-Dpl + D relative to NHS standard	$> 60\%$	116%

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Complement Factor D-Depleted Human Serum, Lot # 5 (Continued)

CH50 FUNCTIONAL ACTIVITY***

CH50/mL NHS Std	≥ 75 CH50 Units/mL	164 CH50 U/mL
CH50/mL Factor D-Dpl serum	≥ 75 CH50 Units/mL	232 CH50 U/mL
% Classical Pathway activity of Factor D-Dpl relative to NHS standard	> 60%	141%

IMMUNOCHEMICAL ANALYSIS

Ouchterlony (Immunodiffusion)	No Factor D antigen detectable using various dilutions of anti-Human Factor D antiserum	Conforms
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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 Factor DH50 unit as measured by alternative pathway activation is defined as the amount of Factor D required to yield 50% lysis of 1.5×10^7 rabbit erythrocytes (Er) when incubated in the presence of the recommended volume of D-Dpl serum for 20 minutes at 37°C in a total reaction volume of 100 μ L GVB⁰ containing a final Mg-EGTA concentration of 5 mM.

** One unit of alternative pathway activity (APH50) is defined as the input of D-Dpl reconstituted with purified Factor D or NHS Complement Std yielding 50% lysis of 1.5×10^7 Er when incubated for 30 minutes at 37°C in a total reaction volume of 100 μ L GVB⁰ containing a final MgEGTA concentration of 5 mM.

*** One CH50 unit is defined as the input of D-Dpl 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⁺⁺.

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