

CERTIFICATE OF ANALYSIS

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

Product: Factor P-Dpl
Catalog # A339 Lot #
Exp. Date:

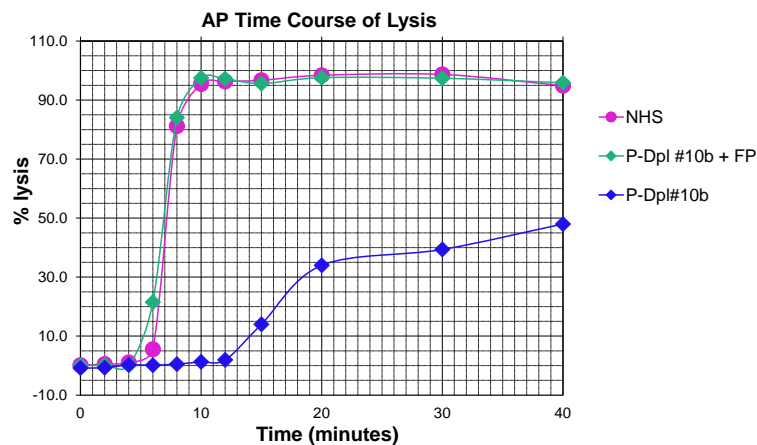
Description: Factor P-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥35 mg/mL employing an extinction coefficient of E1%/280nm = 10	67 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 7.3	Conforms
PRESERVATIVE	None, filtered through a 0.22 µm pore size filter.	None, filtered through a 0.22 µm pore size filter.

ALTERNATIVE PATHWAY (AP) ACTIVITY

AP Lysis Time Course:*

Recommended volume of Serum per 100µl assay	≤ 40 µl	20 µl
Time to 50% Lysis with P-Dpl		43 minutes
Time to 50% Lysis with P-Dpl + P@10 ug/ml		6.95 minutes
Time to 50% Lysis with NHS std		7.2 minutes
Activity Ratio: $\frac{\text{Time to 50% (P-Dpl)} - \text{Time to 50% (P-Dpl + P)}}{\text{Time to 50% (P-Dpl)} - \text{Time to 50% (NHS)}}$	≥0.6	1.0



* Amount of lysis measured at 37°C over time in 100 ul reaction mixtures containing 5 mM MgEGTA and 1.5 x 10⁷ Er and the recommended volume of serum in GVB buffer. Samples tested: P-Dpl or P-Dpl reconstituted with purified Factor P or NHS standard.

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Complement Factor P-Depleted Human Serum Lot # 10b (Continued)

APH50 Activity: **

APH50/mL NHS Standard	≥ 50 APH50 Units/mL	121 APH50 U/mL
APH50/mL Factor P-Dpl reconstituted with Factor P (10 μ g Factor P/mL)	≥ 50 APH50 Units/mL	83 APH50 U/mL
Ratio: $\frac{\text{APH50/mL Factor P-Dpl} + \text{Factor P}}{\text{APH50/mL NHS Std}}$	> 0.60	0.69

** One unit of alternative pathway activity (APH50) is defined as the input of P-Dpl reconstituted with purified Factor P or the input of 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 GVB^o containing a final concentration of 5 mM MgEGTA.

CLASSICAL PATHWAY ACTIVITY ***

CH50/mL NHS Std	≥ 75 CH50 Units/mL	154 CH50 U/mL
CH50/mL Factor P-Dpl reconstituted with Factor P (10 μ g Factor P/mL)	≥ 75 CH50 Units/mL	168 CH50 U/mL
Ratio: $\frac{\text{CH50/mL Factor P-Dpl} + \text{Factor P}}{\text{CH50/mL NHS Std}}$	≥ 0.50	1.1

*** One CH50 unit is defined as the input of P-Dpl reconstituted with purified Factor P 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⁺⁺.

IMMUNOCHEMICAL ANALYSIS

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

HBsAg 3.0	Negative	Negative
Anti-HIV 1/ 2	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
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.

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