

# CERTIFICATE OF ANALYSIS

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## Complement Technology, Inc.

4801 Troup Hwy, Suite 701

Tyler, Texas 75703, USA

Product: **Factor B-Dpl**

Catalog # **A335** Lot #

Exp. Date:

Description: Factor B-Depleted Human Serum

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	$\geq 35$ mg/mL employing an extinction coefficient of E1%/280nm = 10	69 mg/ml
FILL VOLUME	1.0 – 1.1 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 $\mu$ m pore size filter.	None, filtered through a 0.22 $\mu$ m pore size filter.

### FACTOR B FUNCTIONAL ACTIVITY MEASUREMENT\*

Recommended volume of Factor B-Dpl serum per assay	$\leq 40$ $\mu$ L	20 $\mu$ L
Factor BH50 units/mg purified Factor B at the recommended input of Factor B-Dpl serum	$\geq 1,200$ Units/mg	7,100 U/mg
Factor BH50 units/mL Factor B in NHS complement Std (200 $\mu$ g Factor B/mL)	$\geq 240$ Units/mL	1,300 U/mL
Ratio: $\frac{\text{Factor BH50/mg Factor B}}{\text{Factor BH50/mg Factor B in NHS Std}}$	$\geq 0.50$	1.00
Background A <sub>412</sub> reading of Rabbit E blank at the recommended input of Factor B-Dpl	$\leq 0.200$	0.049

### CH50 FUNCTIONAL ACTIVITY\*\*

CH50/mL NHS Std	$\geq 75$ CH50 Units/mL	152 CH50 U/mL
CH50/mL Factor B-Dpl serum	$\geq 75$ CH50 Units/mL	180 CH50 U/mL
Ratio: $\frac{\text{CH50/mL Factor B-Dpl}}{\text{CH50/mL NHS Std}}$	$\geq 0.50$	1.18

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Complement Factor B-Depleted Human Serum, Lot # 21a (Continued)

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

APH50/mL NHS Standard	$\geq 70$ APH50 Units/mL	174 APH50 U/mL
APH50/mL Factor B-Dpl reconstituted with Factor B (200 $\mu$ g Factor B/mL)	$\geq 70$ APH50 Units/mL	174 APH50 U/mL
Ratio: $\frac{\text{APH50/mL Factor B-Dpl} + \text{Factor B}}{\text{APH50/mL NHS Std}}$	$> 0.60$	1.0

## IMMUNOCHEMICAL ANALYSIS

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

HBsAg	Negative	Negative
Anti-HBc	Negative	Negative
Anti-HIV 1 and 2 Plus O	Negative	Negative
Anti-HCV	Negative	Negative
Anti-Syphilis	Negative	Negative
HIV-1/HCV/HBV by NAT	Negative	Negative
HTLV I/II	Negative	Negative
West Nile Virus (WNV) by NAT	Negative	Negative
Zika RNA by NAT	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 BH50 unit measured by alternative pathway activation is defined as the amount of Factor B required to yield 50% lysis of  $1.5 \times 10^7$  rabbit erythrocytes (Er) when incubated in the presence of the recommended volume of B-Dpl serum for 30 minutes at 37°C in a total reaction volume of 100  $\mu$ L GVB<sup>0</sup> containing a final Mg-EGTA concentration of 5 mM.

\*\* One CH50 unit is defined as the input of B-Dpl 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<sup>++</sup>.

\*\*\* One unit of alternative pathway activity (APH50) is defined as the input of B-Dpl reconstituted with purified Factor B or NHS Complement Std 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  $\mu$ L GVB<sup>0</sup> containing a final Mg-EGTA concentration of 5 mM.

**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**

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Signature of Analyst

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Date of Analysis