



**BIOMEDICAL SYSTEMS**  
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2021, May 28

**Certificate of Analysis:**

Accu-Sed® Plus Kit

**Catalog Number:** DS-71006  
**Kit Control Lot:** 2123500  
**Description:** Normal & Abnormal ESR Control  
**Normal Control Lot:** 212010  
**Normal Control Exp. Date:** 2022, June 07  
**Abnormal Control Lot:** 213110  
**Abnormal Control Exp. Date:** 2022, June 07

This is to certify that the product noted above meets all applicable specifications.

Each human donor unit used to manufacture the product was tested and found non-reactive to: HIV-1/HIV-2 antibody, HBsAg, HCV antibody, HIV-1 and HCV by Nucleic Acid Test (NAT) per current applicable FDA requirements using FDA accepted methods.

The Lot of Normal and the Lot of Abnormal Control material tested negative for bioburden and the total CFU < 10.

TEST PERFORMED	Test Results			
	NORMAL		ABNORMAL	
	Mean Result	Range	Mean Result	Range
Diluted Westergren Methods				
Excyte® 10/M/Mini	7	3 - 11	67	49 - 85
Excyte® 20	6	2 - 10	70	52 - 88
Excyte® 40	6	2 - 10	73	55 - 91
Monitor Family	6	0 - 12	68	50 - 86
MixRate Family	6	0 - 12	59	41 - 77
BD Sedi Family	6	2 - 10	49	39 - 59
Greiner Bio-One Sed-Rate Screener Family	7	1 - 13	67	49 - 85
Polymedco Sediplast™	4	0 - 8	41	26 - 56

Authorized by:

Whitney Lewis, Director of Quality

*Electronically produced and valid without a signature*