



BIOMEDICAL SYSTEMS
 370 West 1700 South
 Logan, Utah 84321 USA
 435 752 6011
 800 453 2725
 fax 435 752 4127
 web www.elitechgroup.com

2022, August 25

Certificate of Analysis:

Accu-Sed® Plus Kit

Catalog Number: DS-71004
Kit Control Lot: 2245500-1
Description: Normal & Abnormal ESR Control
Normal Control Lot: 224010
Normal Control Exp. Date: 2023, June 06
Abnormal Control Lot: 225110
Abnormal Control Exp. Date: 2023, June 06

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 Results				
TEST PERFORMED	NORMAL		ABNORMAL	
	Mean Result	Range	Mean Result	Range
Diluted Westergren Methods	6	2 – 10	67	49 – 85
Excyte® 10/M/Mini	6	2 – 10	66	48 – 84
Excyte® 20	7	3 – 11	73	55 – 91
Excyte® 40	6	0 – 12	65	47 – 83
Monitor Family	7	1 – 13	61	43 – 79
MixRate Family	5	1 – 9	46	36 – 56
BD Sedi Family	6	0 – 12	60	42 – 78
Greiner Bio-One Sed-Rate Screener Family	5	0 – 10	43	28 – 58
Polymedco Sediplast™	6	1 – 11	48	33 – 63
Dispette™ 2				

Authorized by:  08/25/2022

Lyndon Jay Smith, Quality Assurance Associate