

Bản tiêu chuẩn chủ sở hữu công bố áp dụng

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 07 tháng 9 năm 2022

**Người đại diện hợp pháp của cơ sở
GIÁM ĐỐC**

Nguyễn Thị Minh Phương



To whom it may concern

Declaration Letter

Technical Specification

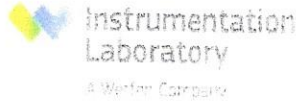
We, Instrumentation Laboratory Company, located at 180 Hartwell Road, Bedford MA 01730 USA, hereby declare that IL Labeled product technical specification information is documented in the Quality Control Monograph (QCM) and on the Certificate of Analysis (CoA) of each specific product.

Date: 07 March 2022

A handwritten signature in blue ink, reading 'Reba Daoust', is written over a horizontal line.

Reba Daoust
Regulatory Affairs Manager II
Instrumentation Laboratory Co

Certificate of Analysis



PRODUCT: <u>HemosIL AcuStar HIT- IgG_(PF4-H)</u>	PRODUCT # : <u>0009802028</u>
EXP. DATE: <u>2022-02-01</u>	LOT # : <u>B33851</u>
VENDOR: <u>INSTRUMENTATION LABORATORY</u>	

TEST DESCRIPTION	SPECIFICATIONS	RESULTS	PASS/FAIL	
Chemical/Physical Characteristics				
Magnetic Particles				
Physical Form	Suspension	Suspension	Pass	
Color	Brown	Brown	Pass	
Assay Buffer				
Physical Form	Liquid	Liquid	Pass	
Color	Green	Green	Pass	
Tracer				
Physical Form	Liquid	Liquid	Pass	
Color	Ochre	Ochre	Pass	
Sample Diluent				
Physical Form	Liquid	Liquid	Pass	
Color	Colorless	Colorless	Pass	
Calibrator 1 & 2				
Physical Form	Liquid	Liquid	Pass	
Color	Colorless	Colorless	Pass	
Functional Characteristics – ACL AcuStar System				
Reactivity of calibrators	Ratio RLU's Cal 2/Cal 1	> 10.0	19.2	Pass
Performance with HemosIL AcuStar Low and High HIT Controls (Cat. No. 0009802122)		Within Range	Within Range	Pass
Comparison with reference lot (n ≥ 20)	Slope (Passing & Bablok)	0.70 – 1.30	0.90	Pass
	r (Pearson)	≥ 0.95	1.00	Pass

HIT-IgG Calibrators Reference Values	U/mL
Calibrator 1	1.02
Calibrator 2	17.04

Packaging meets specifications	(X) YES	() NO
Microbiological control meets specifications (< 100 CFU/mL)	(X) YES	() NO

We hereby certify that the above product(s):

- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents;
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY: Kareame Smith DATE: 3/15/21
Print K Smith
 Signature

TITLE: Sr. Quality Engineer

APPROVAL SIGNATURE: Andrew Chizmadia DATE: 03/15/2021
Print Andrew Chizmadia
 Signature

TITLE: Manager Quality Engineering