



**CERTIFICATE OF ANALYSIS**

Allegro PT / INR Test Cartridge  
Lot Number 25196008

Ref Number 58006  
Exp Date 2026-07-15  
Date of Manufacture 2025-07-15  
UDI# (01)00385480580069(11)250715(17)260715(10)25196008

	Ctl Level 1		Ctl Level 2	
	<u>Spec</u>	<u>Pass/Fail</u>	<u>Spec</u>	<u>Pass/Fail</u>
PT sec.	7.5 - 14.5	Pass	PT sec.	17.0 - 35.0
INR	0.70 - 1.50	Pass	INR	1.60 - 3.60

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector  
Title

9/2/2025  
Date