

QC CERTIFICATE

MAIPA Assay

IVD**REF**

900006

900016

LOT

6012726



2027-07

1. OD kit controls

	OD				Target	Result
	GPIbIX	GPIIbIIIa	GPIIaIIa	HLA		
Negative control	0,047	0,054	0,059	0,063	< 0,100	OK
Positive control anti-HPA-1a		1,890			> 0,500	OK
Positive control anti-HPA-5b			1,814		> 0,500	OK
Positive control anti-HLA				1,890	> 0,500	OK

2. Analytical sensitivity (OD WHO controls)

	Dilution	OD	Target	Result
Anti-HPA-1a, NIBSC 05/106	1:8	0,509	> 0,300	OK
Anti-HPA-3a, NIBSC 03/190	1:8	0,884	> 0,300	OK
Anti-HPA-5b, NIBSC 99/666	1:1	1,284	> 0,300	OK
Anti-HLA, NIBSC 17/238	1:8	0,788	> 0,300	OK

3. Platelet-antibody identification

	Antibody	Result				Decision
		Anti-HPA-1a	Anti-HPA-3a	Anti-HPA-5b	Anti-PLTL Ab	
Positive sample anti-HPA-1a	GPIIbIIIa	POS				OK
	GPIIaIIa	NEG				
Positive sample anti-HPA-3a	GPIIbIIIa		POS			OK
	GPIIaIIa		NEG			
Positive sample anti-HPA-5b	GPIIbIIIa			NEG		OK
	GPIIaIIa			POS		
Negative sample	GPIIbIIIa				NEG	OK
	GPIIaIIa				NEG	

4. Final decision

Final decision: OK

Date: 2026-08-12

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