

QC CERTIFICATE

MAIPA Assay

IVD

REF

900006

900016

LOT

6010124



2025-01

1. OD kit controls

	OD				Target	Result
	GPIbIX	GPIIbIIIa	GPIIaIIa	HLA		
Negative control	0,069	0,044	0,042	0,066	< 0,100	OK
Positive control anti-HPA-1a		2,031			> 0,500	OK
Positive control anti-HPA-5b			1,473		> 0,500	OK
Positive control anti-HLA				2,149	> 0,500	OK

2. Analytical sensitivity (OD WHO controls)

	Dilution	OD	Target	Result
Anti-HPA-1a, NIBSC 05/106	1:8	0,814	> 0,300	OK
Anti-HPA-3a, NIBSC 03/190	1:8	1,243	> 0,300	OK
Anti-HPA-5b, NIBSC 99/666	1:1	1,093	> 0,300	OK
Anti-HLA, NIBSC 17/238	1:8	0,554	> 0,300	OK

3. Platelet-antibody identification

	Antibody	Result			Decision
		Anti-HPA-1a	Anti-HPA-3a	Anti-HPA-5b	
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: 2024-02-12

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