



Certificate

Product:	IH-Card ABO/D(DVI-)+Rev A1,B	REF	813 112 100
Intended Use:	IH-Card ABO/D(DVI-)+Rev A1,B is intended to be used for the performance of the ABO/RhD antigen typing conducted with anti-A (ABO1), anti-B (ABO2), anti-D (RH1) Blood Grouping Reagents, and the serum/ or plasma test conducted with the A1,B Reagent Red Blood Cells on a single Gel Card.	LOT	9309050
			2024-07-03
			18...25°C

Reagents:

Reagent	Clone	Source	Raw Material Lot.-No.:
Anti-A	15750F7	Murine Monoclonal	64444302
Anti-B	X9	Murine Monoclonal	64451850, 64400920
Anti-D	B9A4	Human Monoclonal	64400863, 64455670
Negative Control	/	Neutral Gel+preservative	/
None	/	Neutral Gel+preservative	/
None	/	Neutral Gel+preservative	/

- **Information, Instructions and Safety:**

- For further information, instructions and safety refer to the included instructions for use of this product.

- **Analytic Results, Quality Control:**

- The product lot was released following evaluation of sensitivity and specificity.

- **Regulation:**

- DIN EN ISO 13485
- MDSAP
- FDA 21 CFR Part 820, 809, 600

This document has been produced electronically and is valid without a signature, according to SOP SV-D:A-042-00