



Doc. nr. REA-S003-00-04-0498

Versie 2.0

Datum 06 May 2021 13:23:08 (GMT+01:00)

Pagina 1 van 2

Document eigenaar BBR

Titel **Cellbind Direct Type release (K7012)**

K7012



Sanquin Plesmanlaan 125 1066 CX Amsterdam NL

**Cellbind Direct Type**

IVD 2-8°C REF K7012 6 CE

Analysis	Requirement	Result
Specificity	Negative with DAT positive (IgG and/or C <sub>3</sub> d) patient cells	Conform requirements
	Negative with A, B and O cells	Conform requirements
	Negative with CCC, C <sub>3</sub> b cells and Cellbind A <sub>1</sub> and B reagent red cells	Conform requirements
Avidity	Reaction with anti-D (IgM) at least comparable with reference method	Conform requirements
	Typing of A <sub>1</sub> , B and O donors at least comparable with reference methods	Conform requirements
	Typing of DAT positive (IgG and/or C <sub>3</sub> d) patient cells at least comparable with reference methods	Conform requirements

Date : 23 March 2026 Approved by QA/QC

VERTROUWELIJK