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Revision 03

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Document Owner PROD-QC

Title K7012 Cellbind Direct Type release

K7012



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Cellbind Direct Type

IVD 2-8°C REF K7012 6 CE

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

Date: 30 June 2026 Approved by QA:

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