

# EC Certificate

**Directive 98/79/EC Annex IV, excluding Sections 4 and 6  
Full Quality Assurance System  
In Vitro Diagnostic Medical Devices**

Registration No.: HL 1804147-1

Manufacturer: Immucor, Inc.  
3130 Gateway Drive  
Norcross GA 30071  
USA

Products: Replaces EC Certificate, Registration No.: HL 60139595 0001

Annex II List A Products:

corQC Test System  
corQC EXTEND Standard  
corQC EXTEND 1, 2 and 3  
corQC EXTEND Complete  
Monoclonal Control  
Weak D cells  
Referencells-4 (Group A1, A2, B and O)  
Referencells-2 (Group A1 and B)  
Referencells-1 (Group A2)  
WB corQC



The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 3332513-570

Effective date: 2020-12-17

Expiry date: 2024-05-26

Issue date: 2020-12-17



Katja Mierisch  
TÜV Rheinland LGA Products GmbH  
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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**Annex II List B Products:**

Checkcell  
Checkcell (Weak)  
Panoscreen I and II  
Panoscreen I, II and III  
Panoscreen EXTEND  
Panocell-16  
Panocell-20  
Panocell-10  
Panocell-10, Ficin-Treated  
Hemantigen  
Capture-CMV (Plates)  
Capture-CMV Indicator Red Cells  
Capture-R Ready-Screen (I and II)  
Capture-R Ready-Screen (Pooled Cells)  
Capture-R Ready-ID  
pHix

Capture-R Ready-ID EXTEND I  
Capture-R Ready-ID EXTEND II  
Capture-R Ready-Screen (3)  
Anti-Jka (Monoclonal) Gamma-clone®  
Anti-Jkb (Monoclonal) Gamma-clone®  
Gamma PeG  
Capture-R Ready-Screen (3)

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A handwritten signature in blue ink is written over a circular blue stamp. The stamp contains the TÜV Rheinland logo and the text "TÜV Rheinland LGA Products GmbH" and "Zertifizierungsstelle".

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## Directive 98/79/EC Annex IV, excluding Sections 4 and 6 Full Quality Assurance System In Vitro Diagnostic Medical Devices

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USA

### Capture-R Ready-Screen (4)

Anti-Human Globulin, Anti-IgG,-C3d  
Polyspecific (Murine Monoclonal) Gamma-Clone®  
Anti-Human Globulin, Anti-IgG (Murine Monoclonal)  
Gamma-Clone®  
Gamma N-HANCE

### Capture-CMV Controls (Kit):

Capture-CMV Positive Control Serum (Weak)  
Capture-CMV Negative Control Serum

Capture-R Ready Indicator Red Cells  
Capture LISS

### Capture-R Controls (Kit):

Capture-R Positive Control Serum (Weak)  
Capture-R Negative Control Serum

Bovine Albumin Solution 22%  
ImmuAdd  
Anti-Fya (Monoclonal) Gamma-clone®  
Anti-Fyb (Monoclonal) Gamma-clone®

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