7.0 510(k) Summary

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510(k) Owner

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Establishment Registration Number: 1034569

Contact Information

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Device Name

Trade Name:	Capture Positive Control Cell
Common Name:	IgG-coated red blood cells
Device Class:	II
Classification:	21CFR§864.9650
Classification Name:	Quality control kit for blood banking reagents
Panel:	Hematology
Product Code:	KSF
Registration Number:	1034569

Predicate Device Information

Trade/Device Name:	DAT Positive Control Cell
Clearance:	BK110050 (cleared September 1, 2011)

Device Descriptions

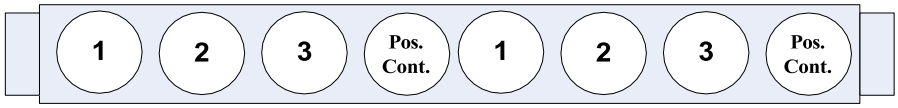
Capture Positive Control Cell (CPCC) well of certain Capture-R Ready products contains the dried membranes of red blood cells coated with an IgG antibody (anti-D). CPCC is tested along with each specimen tested. The function of the CPCC well is that of an antiglobulin control ("anti-IgG check cells"). In addition to the test wells containing the donor red blood cells for antibody detection or identification, the specimen is also added to the CPCC well to monitor washing efficacy and reactivity of the Capture-R Ready Indicator Red Cells (CRRIRC). The CRRIRC are indicator red blood cells coated with murine monoclonal IgG anti-human IgG antibodies; they function as the anti-human globulin reagent does in a traditional tube test.

Capture Positive Control Cell is manufactured by first coating red blood cells with IgG anti-D using the same process as for manufacture of the predicate DAT Positive Control Cell product. Then, the coated cells are added to the positive control well during the solid-phase manufacturing of Capture-R Ready Reagent Red Blood Cells. The placement of the Capture Positive Control Cell is product specific as described below.

Please note that in the Instructions for Use for Capture-R Ready-Screen (3), Capture-R Ready-ID, Capture-R Ready-ID Extend I, and Capture-R Ready-ID Extend II Capture Positive Control Cell is referred to as "Positive Control Well".

Capture-R Ready-Screen (3)

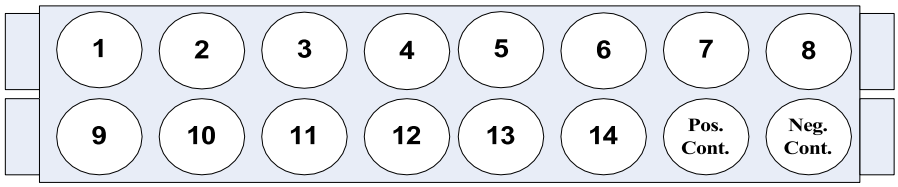
Capture-R Ready-Screen (3) (CRRS3) is intended for use in the detection of unexpected IgG antibodies to red blood cells. CRRS3 is manufactured as a three-cell screening set of Group O red cells. The CRRS3 plates consist of 1 x 8 strips with a sequence of wells carrying the bound and dried red blood cell (RBC) membranes of three different group O donors in separate wells followed by a well containing bound and dried IgG antibody-coated RBC membranes. Refer to the illustration below for a depiction of the CRRS3 strip configuration (Capture Positive Control Cell is labeled “Pos. Cont.” in the illustration).



Capture-R Ready-ID (including Capture-R Ready-ID Extend I and Capture-R Ready-ID Extend II)

Capture-R Ready-ID (CRRID) is intended for use in the identification of unexpected IgG antibodies to red blood cells. The CRRID plates consist of 2 x 8 strips with a sequence of wells carrying the bound and dried red blood cell (RBC) membranes.

Capture-R Ready-ID is a panel of group O single donor red cells from 13 different donors which is used in the identification of antibodies to red cells. The red cells are bound to the surfaces of the plastic microtitration strip wells and preserved. The panel includes one well each for an autologous control, Capture Positive Control Cell and negative control. Refer to the diagram below for a depiction of the strip configuration for CRRSID (Capture Positive Control Cell is labeled “Pos. Cont.” in the illustration).



Intended Use

Capture Positive Control Cell is used as an antiglobulin control to monitor washing efficacy and reactivity of the Capture-R Ready Indicator Red Cells.

Technological Comparison to Predicate Device

Below is a summary of the technological characteristics of Capture Positive Control Cell (proposed device) compared to the predicate device (BK110050).

Characteristic	Predicate Device	Proposed Device
Reagent System	DAT Positive Control Cell (BK110050)	Capture Positive Control Cell
Device Class, Regulation Code	Class II, 21CFR§864.9650	Same
Classification Product Code	KSF	Same
Instrument Platform	Galileo Echo, Echo Lumena, Galileo NEO, or NEO Iris	Same
Intended Use	Immucor's DAT Positive Control Cell is designed to be used only with the Immucor automated instruments. DAT Positive Control Cell are IgG-coated red blood cells used as a control to confirm the validity of the DAT assay and other assays utilizing the direct antiglobulin test on Immucor automated instruments.	Capture Positive Control Cell is used as an antiglobulin control to monitor washing efficacy and reactivity of the Capture-R Ready Indicator Red Cells.
Reagent Cells	Red blood cells coated with (b) (4) human IgG anti-D	Same
Monoclonal IgG anti-D Source	(b) (4)	Same
Interpretation of results	In the case of a positive result, the migration of the indicator red blood cells to the bottom of the wells is impeded as anti-IgG-IgG complexes are formed on the surface of the immobilized reagent layer. As a consequence of antibody bridging, the indicator cells adhere to the screening cells as a second immobilized layer. In the absence of detectable antigen-antibody interactions (negative result), the indicator red blood cells will not be impeded during their migration and will pellet to the bottom of the wells as tightly agglutinated red blood cell buttons.	Same

Non-Clinical Performance

(b) (4) anti-D (b) (4) was successfully used to manufacture Capture Positive Control Cell. The three validation lots of Capture Positive Control Cell manufactured with (b) (4) IgG anti-D (b) (4) demonstrated better performance (lower failure rates) compared with the current CPCC manufactured using (b) (4) IgG anti-D.

Basis for Claim of Substantial Equivalence

The proposed device is substantially equivalent to the predicate device relative to technological characteristics, formulation, and manufacturing process. The Indications for Use of the proposed device is similar to the legally marketed, predicate device.