Section 5

510(k) Summary

5.1 Applicant Information

510(k) Owner:	Immucor, Inc.
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5.2 Device Information

Trade Name:	Capture-CMV®
Common Name:	CMV Antibody Detection Test
Product Code:	MZE
Device Classification Name:	Test, Donor, CMV
Device Classification:	Class II
Regulation Number:	866.3175
Predicate Device:	Capture-CMV® (BK950029, BK100033[1], BK170067[2])

5.3 Device Description and Intended Use:

5.3.1 Summary of the Test:

Capture-CMV® is a Solid Phase System for the Detection of IgG and IgM Antibodies to Cytomegalovirus (CMV).

Cytomegalovirus (CMV) is a common human viral pathogen which belongs to the family of herpes viruses. The presence of CMV antibodies in an individual indicates prior infection by the virus. The possibility exists that viral reactivation can occur in such individuals. CMV infection is usually asymptomatic, and can persist as a latent or chronic infection.
Viral transmission may occur through transfusion of blood or transplantation of organs from seropositive donors.

[1] Capture-CMV cleared under BK100033 for use on the Galileo Neo.
[2] Capture-CMV cleared under BK170067 for use on the Galileo Neo. Special 510(k) submission filed to update analyzer modifications only.

Immunocompromised patients, such as premature neonates, organ transplant patients, and oncology patients, are at greater risk of developing more severe manifestations of CMV infections which can be a major direct or indirect cause of mortality in such patients.

Congenitally infected newborns are especially prone to developing severe cytomegalic inclusion disease (CID). The severe form of CID may be fatal or may cause permanent neurological sequelae, such as mental retardation, deafness, microcephaly, and motor dysfunction. A CMV mononucleosis-type syndrome can result from the transfusion of CMV-infected blood products or the transplantation of CMV-infected donor organs in a seronegative immunocompromised patient. Low birth weight neonates are also at high risk to CMV mononucleosis through transfusion of CMV-infected blood products.

One method of preventing or reducing CMV infection in seronegative immunocompromised patients is to select CMV seronegative blood donors or organ donors that have been tested by serological screening test for antibodies to CMV. Capture-CMV is a solid phase red cell adherence antibody detection system based on procedures of Plapp et al. This procedure is a modification of the mixed agglutination tests for antigen and antibody detection of Coombs et al. and Hogman employing anti-IgG and IgG-coated red cells as the indicator system. Capture assays for the detection of antibodies to red cells or platelets use anti-IgG-coated red cells as the indicator. Capture-CMV uses anti-IgG plus anti-IgM-coated indicator red cells.

5.3.2 Intended Use:

The Immucor Capture-CMV is an in vitro qualitative solid phase red cell adherence test system for the detection of antibodies (IgG plus IgM) to cytomegalovirus (CMV) in human serum or plasma. Capture-CMV is intended to be used in screening of blood and plasma donors for serological evidence of previous infection by CMV using NEO Iris.
This assay is not intended for diagnostic use.

5.4 Substantial Equivalence and Comparison to the Predicate Device:

Technological Characteristics	PREDICATE DEVICE Capture-CMV® (BK950029) (BK100033[1]/BK170067[2] – Capture-CMV cleared for use on Galileo Neo)	PROPOSED DEVICE Capture-CMV® (for use on NEO Iris)	Comparison
Intended Use	The Immucor Capture-CMV is an in vitro qualitative solid phase red cell adherence test system for the detection of antibodies (IgG plus IgM) to cytomegalovirus (CMV) in human serum or plasma. Capture-CMV is intended to be used in screening of donors or patients for serological evidence of previous infection by CMV.	The Immucor Capture-CMV is an in vitro qualitative solid phase red cell adherence test system for the detection of antibodies (IgG plus IgM) to cytomegalovirus (CMV) in human serum or plasma. Capture-CMV is intended to be used in screening of blood and plasma donors for serological evidence of previous infection by CMV using the NEO Iris. This assay is not intended for diagnostic use.	Equivalent – Indications for use add NEO Iris for donor screening.
Test Principle	Serum or plasma samples are added to the viral-coated wells. The samples are incubated for five minutes during which antibodies specific for CMV proteins bind to immobilized viral proteins. Unbound immunoglobulins are washed from the wells and replaced with a suspension of anti-IgG- plus anti-IgM-coated indicator red cells. Centrifugation brings the indicator red cells in contact with antibodies bound to the immobilized viral proteins. In the case of a positive test, the migration of the indicator red cells to the bottom of the well is impeded as the anti-IgG and anti-IgM bridges are formed between the indicator red cells and the viral-bound antibodies. As a consequence, the indicator red cells adhere over the surface of the microtitration well. In contrast, in the absence of viral antigen-antibody interactions (ie, a negative test) the indicator red cells are not impeded during their migration, and pellet to the bottom of the well as a packed, well-defined cell button.	Serum or plasma samples are added to the viral-coated wells. The samples are incubated for five minutes during which antibodies specific for CMV proteins bind to immobilized viral proteins. Unbound immunoglobulins are washed from the wells and replaced with a suspension of anti-IgG- plus anti-IgM-coated indicator red cells. Centrifugation brings the indicator red cells in contact with antibodies bound to the immobilized viral proteins. In the case of a positive test, the migration of the indicator red cells to the bottom of the well is impeded as the anti-IgG and anti-IgM bridges are formed between the indicator red cells and the viral-bound antibodies. As a consequence, the indicator red cells adhere over the surface of the microtitration well. In contrast, in the absence of viral antigen-antibody interactions (i.e., a negative test) the indicator red cells are not impeded during their migration, and pellet to the bottom of the well as a packed, well-defined cell button.	Identical

Technological Characteristics	PREDICATE DEVICE Capture-CMV® (BK950029) (BK100033[1]/BK170067[2] – Capture-CMV cleared for use on Galileo Neo)	PROPOSED DEVICE Capture-CMV® (for use on NEO Iris)	Comparison
Test Wells	CMV antigen from cytomegalovirus strain AS 169 grown in human foreskin fibroblast cells is inactivated and coated onto microtitration wells and dried.	CMV antigen from cytomegalovirus strain AS 169 grown in human foreskin fibroblast cells is inactivated and coated onto microtitration wells and dried.	Identical
Capture-CMV Positive Control Serum (Weak)	Human serum containing IgG antibodies to CMV viral proteins. Capture-CMV Positive Control Serum (weak) is manufactured to represent the reactivity obtained by weak CMV antibody positive donors. Weak CMV antibody positive donors have a titration endpoint of 1:2 or less. Sodium azide (0.1%) has been added as a preservative.	Human serum containing IgG antibodies to CMV viral proteins. Capture-CMV Positive Control Serum (weak) is manufactured to represent the reactivity obtained by weak CMV antibody positive donors. Weak CMV antibody positive donors have a titration endpoint of 1:2 or less. Sodium azide (0.1%) has been added as a preservative.	Identical
Capture-CMV Negative Control Serum	Human serum containing no antibodies to CMV. Sodium azide (0.1%) has been added as a preservative.	Human serum containing no antibodies to CMV. Sodium azide (0.1%) has been added as a preservative.	Identical
Capture-CMV Indicator Red Cells	A suspension of human red blood cells coated with rabbit anti-human IgG plus goat anti-human IgM molecules. The red blood cells are suspended in a buffered solution to which chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL) and gentamycin sulfate (0.05 mg/mL) have been added as preservatives.	A suspension of human red blood cells coated with rabbit anti-human IgG plus goat anti-human IgM molecules. The red blood cells are suspended in a buffered solution to which chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL) and gentamycin sulfate (0.05 mg/mL) have been added as preservatives.	Identical
Capture-LISS	A low ionic strength solution containing glycine, bromocresol purple dye and the preservative sodium azide (0.1%).	A low ionic strength solution containing glycine, bromocresol purple dye and the preservative sodium azide (0.1%).	Identical
Shelf-life	Test wells – 6 months Controls – 15 months Capture-LISS – 12 months Indicator Red Cells – 60 days	Test wells – 6 months Controls – 15 months Capture-LISS – 12 months Indicator Red Cells – 60 days	Identical
Specimen/Sample	Serum or plasma	Serum or plasma	Identical
Test Methods	Manual (BK950029) Galileo®(BK050050) Galileo Neo® (BK100033[1]/BK170067[2])	NEO Iris™	Equivalent – Indications for use add NEO Iris for donor screening

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5.5 Performance Data and Testing – Non-Clinical

The verification of the Capture-CMV assay was executed under the verification plan for the NEO Iris, in order to demonstrate equivalency with the Galileo Neo.

The system verification activities for NEO Iris were performed as defined in Verification Plan 14-012-VRPLN at Immucor's facility in Norcross, GA. The verification activities included all testing performed related to the CMV assay as appropriate including assay performance for establishing equivalency. All documents generated to support the development, and operations of the system adhere to standard procedures. Testing was executed properly, in accordance with the execution and test procedure instructions. Additional and detailed information about the system verification can be found under the NEO Iris™ premarket notification BK180243.

The results of the verification have been found acceptable to confirm safety and performance.

5.6 Performance Data and Testing – Clinical

Performance in Donor Populations on NEO Iris:

Method comparison studies were performed at four (4) clinical sites, three (3) external sites and internally at Immucor, Inc. Donor specimens were tested on NEO Iris and Galileo Neo. Test results were evaluated for agreement between analyzers. Specimens with discordant results were further tested with a commercially available particle agglutination assay for total antibody (IgG+IgM) to CMV.

Sites	Total Donor Specimens Tested	Donor Specimens	
		Serum	Plasma
1	474	57	417
2	289	59	230
3	103	20	83
Immucor	382	70	312

CMV Initial Results Donor Samples (Total) N=1248		**Galileo Neo**	
		Positive	Negative
NEO IRIS	Positive	612	8
	Negative	27	601
CMV Resolved Results		**Galileo Neo / Anti-CMV PA***	
		Positive	Negative
NEO IRIS	Positive	612	8
	Negative	1	627
Sensitivity 99.8% (99.1%, 95% 2-sided LCI)			
Specificity 98.7% (97.5%, 95% 2-sided LCI)			

CMV Initial Results Donor Serum Samples N=206		Galileo Neo	
		Positive	Negative
NEO IRIS	Positive	103	1
	Negative	5	97
CMV Resolved Results		Galileo Neo / Anti-CMV PA*	
		Positive	Negative
NEO IRIS	Positive	103	1
	Negative	0	102
Sensitivity 100.0% (96.5%, 95% 2-sided LCI)			
Specificity 99.0% (94.7%, 95% 2-sided LCI)			

CMV Initial Results Donor Plasma Samples N=1042		Galileo Neo	
		Positive	Negative
NEO IRIS	Positive	509	7
	Negative	22	504
CMV Resolved Results		Galileo Neo / Anti-CMV PA*	
		Positive	Negative
NEO IRIS	Positive	509	7
	Negative	1	525
Sensitivity 99.8% (98.9%, 95% 2-sided LCI)			
Specificity 98.7% (97.3%, 95% 2-sided LCI)			

*Only discordant samples were tested by IgG/IgM Anti-CMV PA

NEO Iris Reproducibility

The reproducibility of Capture-CMV assay on the NEO Iris was determined using a panel of ten (10) coded samples, five (5) CMV antibody-positive and five (5) CMV antibody-negative, at three (3) test sites, two (2) external sites and internally at Immucor. The samples were tested by two (2) operators, in duplicated on two (2) runs per day for five (5) nonconsecutive days. The summary of reproducibility results by site are presented in the following table:

Concordance by Site							
Site	**Total Tests**	**Expected Positive**	**Observed Positive**	**% Concordance (95% LCI)**	**Expected Negative**	**Observed Negative**	**% Concordance (95% LCI)**
1	400	200	200	100.0% (98.2%)	200	200	100.0% (98.2%)
2	400	200	200	100.0% (98.2%)	200	200	100.0% (98.2%)
3	400	200	200	100.0% (98.2%)	200	199	99.5% (97.2%)
Total	1200	600	600	100.0% (99.4%)	600	599	99.8% (99.1%)

5.7 Conclusion

The non-clinical and clinical study data demonstrate the safety and effectiveness of the device when used for the defined indications for use.