

5. 510(k) SUMMARY

Applicant Information:

Date Prepared: March 16, 2007
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Device Information:

Device Name: DAT Positive Control Cell
Common Name: Quality Control for Routine Blood Bank Reagents
Classification: 21 CFR 864.9650, Class II (BK040023)
Classification Name: Quality Control for Blood Banking Reagents / KSF

Predicate Devices:

Immucor DAT Positive Control Cell (BK040023), 4/23/2004
Immucor Capture-R Control Cells (BK020054), 1/27/2003

Device Description and Intended Use

DAT Positive Control Cell is a single vial pool of group O red blood cells coated with Anti-D and suspended in diluent. These red blood cells have been prepared as a 4-6% suspension in a buffered preservative solution containing adenosine and adenine to retard hemolysis during the dating period. Chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL) and gentamycin sulfate (0.05 mg/mL) are added as preservatives.

Anti-IgG is bound to red blood cells to produce an indicator reagent that is used in solid phase adherence tests as the antiglobulin reagent. Anti-Human Globulin reagents can be rendered nonreactive by unbound serum immunoglobulins, leading to falsely negative test results. Therefore, it is essential that appropriate controls be included to ensure proper performance of the reagent. DAT Positive Control Cells, a pool of group O red cells sensitized (coated) with IgG, is used to confirm the validity of the DAT assay and other assays using the direct antiglobulin test (IgG specific) on Immucor instruments.

DAT Positive Control Cells are intended for use on the Galileo and Galileo Echo blood bank analyzers. These are instruments designed to automate standard immunohematology assays

using a microplate-based platform. The Galileo instrument is currently marketed as a 510(k) cleared device.

Note: The Galileo Echo is not a currently cleared device and is the subject of a separate 510(k) premarket notification.

Comparison to Predicate Device(s):

A comparison between the predicate DAT Positive Control Cells, the new DAT Positive Control Cells, and Immucor Capture-R Control Cells is presented in the table below. DAT Positive Control serves the same function as Capture-R Control Cells (BK020054) used with ABS2000 instrument. The devices are compared based on intended use, material, and shelf-life.

Intended Use	DAT Positive Control Cell (Current)	DAT Positive Control Cell (New)	Capture-R Control Cells
Used as a control to confirm the validity of the of the DAT assay and other assays utilizing the direct antiglobulin test	X	X	
Used to determine if the anti-IgG coated Capture-R Ready Indicator Red Cells are present/have become neutralized.			X
Used on the Galileo instrument.	X	X	
Used on the all Immucor automated Instruments.		X	
Used on the ABS2000 instrument			X
Material			
Pooled group O red blood cells. * Can also use single donor	X	X	X*
Prepared as a 4-6% suspension in a buffered preservative solution containing adenosine and adenine to retard hemolysis during the dating period.	X	X	
Prepared as a dilute suspension (less than 2%) in a buffered preservative solution containing adenosine and adenine to retard hemolysis during the dating period.			X
Shelf-life			
60 day expiration period	X	X	X

Comparison Discussion

Intended Use: The current device is used as a positive control in direct antiglobulin tests on the Galileo to determine if Capture-R Ready Indicator Red cells are active in the test system. The additional intended use will allow the DAT Positive Control Cell to also be used on the other Immucor automated instruments as a control to confirm the validity of the of the DAT assay and other assays (by confirming the presence/ activity of the Capture-R Ready Indicator Cells in the test system). The predicate Capture-R Control Cells are also used to determine if the anti-IgG-coated Capture-R Ready Indicator Red Cells have become neutralized on the ABS2000 blood bank analyzer.

Materials (Formulation): The new device is manufactured according to the same manufacturing procedures as the current device. There are no changes being made to the formulation of the device.

Summary of Bench Testing

Verification of substantial equivalence between the new and the current DAT Positive Control Cell consisted of determining whether the design outputs met the functional and operational requirements. Verification studies were performed to evaluate the performance of the DAT Positive Control Cell in DAT, Weak D and Crossmatch assays on Capture-R Select strips on the Galileo Echo under failure mode conditions. The DAT positive control well performed correctly to produce invalid results when Capture-R Indicator Cells exhibited a loss of activity and also when a wash failure occurred.

In conclusion, these studies demonstrate that the DAT Positive Control Cell is substantially equivalent to the predicate devices for the quality control of routine blood bank reagents.

Summary of Clinical Tests

The DAT Positive Control was used as a positive run control for verifying the validity of negative test reactions in the DAT, Crossmatch and Weak D assays on the Galileo Echo. A total of 2391 samples were tested by DAT (699), Crossmatch (1099) and Weak D (593) Galileo Echo assays. A total of four lots of DAT Positive Control cells were tested. All tests demonstrated Positive reactions with the DAT Positive Control cell and there were no test failures due to neutralization of the Capture-R Ready Indicator Cells. There was 100% agreement between the Galileo Echo test results and the expected results.

In conclusion, these studies confirm the proper performance of the DAT Positive Control cell and its suitability as a positive control reagent for DAT, Crossmatch and Weak D assays on the Galileo Echo blood bank analyzer.

6. TRUTHFUL AND ACCURACY STATEMENT

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURACY STATEMENT

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Vice President World Wide Regulatory Affairs of Immucor, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

J. Scott Webber
J. Scott Webber

3/16/2007
(Dated)

BK040023
Premarket Notification [510(k)] Number

7. CLASS III SUMMARY AND CERTIFICATION

N/A