K970862

510(k) Summary

APR - 8 1997

Prepared: March 5, 1997

Submitted by:

Establishment Address: Quantimetrix Corporation
2005 Manhattan Beach Boulevard
Redondo Beach CA 90278
Phone: 310 536-0006 FAX: 310 536-9977

Establishment Registration Number: 2020715

Contact Person: Evy K. Johnson, Director, Technical Services & OEM

Classification Name: Multi-Analyte Control, All Kinds, Assayed and Unassayed (75JJY)

Common Name: Spinal Fluid Cell Count Control

Proprietary Name: Spinalscopics Spinal Fluid Cell Count Control

Classification: Proposed Class I

Substantial Equivalence:
The Quantimetrix Spinalscopics Spinal Fluid Cell Count Control is supplied liquid in two levels and consists of a human protein matrix containing preservatives to which reagent grade chemicals and stabilized human red and white blood cells and other human components have been added at different concentrations to achieve the two levels.

The Quantimetrix Spinalscopics controls are substantially equivalent to other such controls in general use such as the **QuanTscopics Urine Microscopics Control** sold by Quantimetrix Corp., which is supplied in two levels as a liquid human urine matrix to which stabilized human red blood cells and white blood cells and human protein, other chemicals and nonprotein materials have been added by the manufacturer.

Description:
Spinalscopics Spinal Fluid Cell Count Control is supplied in two levels, 3 mL per bottle. It is a ready-to-use liquid requiring no reconstitution or dilution. It is prepared in a human protein matrix fortified to target levels with purified chemicals and stabilized human red blood cells and human white blood cells. Preservatives, including sodium azide, have been added to inhibit microbial growth.

Intended Use: The Quantimetrix Spinalscopics Control is intended for monitoring cell counts performed manually using a hemocytometer to validate quantitation of red and white blood cells in patient CSF samples. The Spinalscopics Control is intended for use as Quality Control materials having known component concentrations. Daily monitoring of the control values establishes intralaboratory parameters for accuracy and precision of the manual cell counting methods.

Technological Characteristics Compared to Predicate Devices:
The Quantimetrix Spinalscopics control product employs liquid human protein matrix and a stabilized human red and white blood cell constituent formulation equivalent to the predicate device listed above. The predicate device uses a liquid human urine matrix containing human proteins. The Spinalscopics Control also has similar storage and stability requirements as the equivalent device.

Performance Characteristics:
The closed vial stability claim made for this product is 1 year when stored at 2 - 8 C. The overall shelf life of the Spinalscopics control was extrapolated from accelerated stability models using

elevated temperature storage to simulate real time stability.[1] The Spinalscopics control was stored at 5 C and at 25 C to simulate 1 and 2 years storage at 2 - 8 C. Control samples were counted in duplicate hemocytometer chambers at day 0 and at 32 days and at 48 days. Control samples that were refrigerated for 32 days and 48 days were tested in duplicate hemocytometer chambers at the same time as the stressed samples for comparison. A total of 10 samples were counted in duplicate for each storage condition.

The failure criteria for stability for the recovery of cell counts for red and white blood cells was set as a decrease of greater than 15% of the mean cell recovery compared to the initial cell count or a greater than 10% decrease in the range of cells counted in 10 duplicate hemocytometer chambers. Using this criteria the cell count recovery for both red and white blood cells passed accelerated stability with either >85% mean cell recovery or equal recovery of the range of cells counted in the initial sample and at 32 days. After 48 days at room temperature the mean cell recovery was approximately 75% of the initial count. Therefore we have given this product a one year expiration dating. Real time stability testing is on going on multiple lots of product.

The closed vial stability claim for this product when stored at 2 - 8 C is 1 year. Real time testing and accelerated stability models were used to determine the closed vial refrigerated shelf life. To test the real time stability of the unopened control, vials were held at refrigerated temperature for 6.5 months without opening. Cell counts were compared to initial cell counts and cell counts of vials of a second lot which had been stored refrigerated unopened for four months.

The open vial stability claim for this product when stored at 2 - 8 C is 6 months. Open vial studies consisted of removing the control from the refrigerator (2 - 8 C storage) weekly, allowing it to warm to room temperature (20 - 25 C), removing an aliquot of control, followed by returning the vial to the refrigerator (2- 8 C) for storage. Testing was done on one product lot of each level of control initially and after 6.5 months of weekly opening. The RBC and WBC cell counts passed real time open vial refrigerated stability for 6.5 months with >90% recovery.

The open vial stability claim for this product when stored at room temperature (20 - 25 C) is 30 days. Real time open vial studies for this product were performed on three lots of product for each level of control. Open vial studies consisted of storing the product at room temperature (20 - 25 C) and testing the control 20 times (once per day) over a 30 day time period. The RBC and WBC cell counts passed real time open vial room temperature storage stability for 30 days with >90% recovery.

[1] L. Kennon, Stability Prediction Model, Journal of Pharmaceutical Sciences 53:7, 815-818, 1964.