

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

k100684

B. Purpose for Submission:

Modification of the CellTracks® AutoPrep® System to include: new make and model of waste bottle accessory and labeling changes associated with the accessory waste bottle handling procedure.

C. Manufacturer and Instrument Name:

Veridex, LLC

CellTracks® AutoPrep® System

D. Type of Test or Tests Performed:

The device is an automated sample processing instrument that captures and enriches target cells from whole blood samples by immunomagnetic separation, labels cells with fluorescence-labeled monoclonal antibodies and transfers the processed sample to analysis cartridges to be analyzed.

E. System Descriptions:

1. Device Description:

The CellTracks® AutoPrep® System is a general purpose laboratory instrument used with immunomagnetic reagents that capture and enrich target cells, and labeling reagents that differentiate cells in whole blood. The CellTracks® AutoPrep® System processes up to 8 samples in a batch, performing all required process steps, including red cell detection, plasma aspiration and final transfer to the analysis cartridge. The user is prompted to perform various pre-processing operations such as dilution and centrifugation. Cell analyzers such as the CellTracks Analyzer II®, CellSpotter® System, flow cytometers or microscopes may be used for cell identification and enumeration following processing. The AutoPrep® system uses a series of immunomagnetic separation procedures to isolate the cells of interest and to stain the cells with fluorescence-labeled monoclonal antibodies.

2. Principles of Operation:

The CellTracks® AutoPrep® system uses a series of immunomagnetic separation procedures to isolate the cells of interest and to stain the cells with fluorescence-labeled monoclonal antibodies. During sample processing, the AutoPrep® system performs the following tasks:

- Adds ferrofluid to the sample and incubates the mixture. Ferrofluid is a colloidal mixture of particles with a magnetic core surrounded by a polymeric layer coated with monoclonal antibodies. During the incubation, antibodies in the ferrofluid bind to antigens on the target cells.
- Places the ferrofluid/sample mixture in a strong magnetic field, which causes the labeled cells to move to the side of the tube.
- Aspirates the blood, removes the magnetic field, and resuspends the cells in a small volume of buffer.

- Washes the cells with buffer and uses a strong magnetic field to separate the bound cells during aspiration of the wash solution.
 - Adds fluorescent reagents to the sample and incubates the mixture. The fluorescent reagents are fluorescence-labeled monoclonal antibodies that uniquely identify the target cells. During the incubation, the fluorescence-labeled antibodies bind to antigens on the target cells.
 - Performs another magnetic separation of the cells.
 - Aspirates the unbound fluorescent reagents, removes the magnetic field, and resuspends the cells.
 - Washes the cells with buffer and uses a strong magnetic field to separate the bound cells during aspiration of the wash solution.
 - Adds cell fixative and transfers the processed sample to a cartridge inside the MagNest®, a specialized cell presentation fixture used with the cell analyzer. The strong magnetic field of the MagNest® attracts the magnetically labeled target cells to the surface of the cartridge, preparing the sample for scanning. The operator can then load the MagNest® into the cell analyzer, which identifies the unique staining patterns of the fluorescent reagents, enabling identification and enumeration of the target cells.
3. Modes of Operation:
Batch
 4. Specimen Identification:
Barcode on sample tube
 5. Specimen Sampling and Handling:
Whole blood samples are processed as described in #2 above. Samples should be collected in CellSave Preservation Tubes.
 6. Calibration:
Not applicable
 7. Quality Control:
Quality control is addressed separately for each cleared specific assay to be run on the instrument.
 8. Software:
FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:
Yes___X_____ or No_____

F. Regulatory Information:

1. Regulation section:
21 CFR 864.5240, automated blood cell diluting apparatus
2. Classification:
Class I
3. Product code:
GKH
4. Panel:
Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

The CellTracks® AutoPrep® System is a general purpose laboratory instrument used with immunomagnetic reagents that capture and enrich target cells, and labeling reagents that differentiate cells in whole blood. Cell analyzers such as the CellTracks Analyzer II®, CellSpotter® System, flow cytometers or microscopes may be used for cell identification and enumeration. The system is for invitro diagnostic use.

2. Special Conditions for Use Statement(s):

None

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

CellTracks™ AutoPrep System (k040077)

2. Comparison with Predicate Device:

Differences		
Item	Device	Predicate
Device name	Modified CellTracks® AutoPrep® System	CellTracks® AutoPrep® System.
Total volume of undiluted bleach	.500mL	400mL
New make and model of waste bottle accessory	New Kautex bottles (Part# 3211B17) Leak-proof (yes)	all Nalgene bottles (Part # 2123-0010) Leak-proof (no)
Labeling changes associated with the accessory waste bottle and the waste bottle handling procedure:		
1) Method for mixing waste material and bleach	Swirling	Inversion of bottle
2) Waste volume limit before disposal is required	2L (approximately half full)	Not specified

I. Special Control/Guidance Document Referenced (if applicable):

Not applicable.

J. Performance Characteristics:

1. Analytical Performance: refer to k040077

2. Other Supportive Instrument Performance Data Not Covered Above:

Waste Bottle Handling Procedure Verification and Validation

Due to defect of the original waste bottles, the sponsor changed waste bottles from Nalgene to Kautex bottles and implemented a new waste bottle handling procedure. This new waste handling procedure was validated by Veridex employees at six internal Veridex laboratories. A total of 66 test runs (waste handling events) were conducted using different volumes of waste in the waste bottle. Decontamination of the waste material was confirmed by visual inspection: the color of the contents changed from red to white (clear). The

testers assessed pressure build-up in the bottle by listening for audible sounds of pressure release when removing the solid cap from the bottle.

Bulk Fluid Module (BFM) Verification and Validation

In addition to the labeling changes Veridex is sourcing a new bottle for use on the CellTracks® AutoPrep® System in response to the field action Z-1734-09. The new Kautex bottle will replace all Nalgene bottles on the CellTracks® AutoPrep® system. The new bottles have different dimensions and shape than the predicate bottles; as a result, it was necessary to modify the plastic base and tray that hold the bottles when on the system.

Functional testing was performed to ensure that the modifications made to the BFM do not adversely affect the functionality of the BFM module. The Bulk Fluid Module (BFM) consists of the following components: the 4 bottles used on the system (Waste Bottle, Instrument Buffer Bottle, DI Water Bottle and the Cleaning Solution Bottle) the base (tray support), three bottle trays, and the bottle sensors. In addition, system performance testing was conducted using the CellSearch® Circulating Tumor Cell Control kit. A detailed description of this testing and the results were provided in the test report *D17487 CellTracks® AutoPrep® System Bulk Fluid Module Bottle Upgrade System Verification Test Report*.

Functional Testing:

Functional testing demonstrated that the new BFM parts assembled and fit as expected, and could be properly calibrated when the new Kautex bottles were used on the system.

Performance Testing:

The second part of the testing verified system performance of the modified device. Two predicate CellTracks® AutoPrep® Systems equipped with the predicate BFM and bottle were tested. The same two instruments were then equipped with modified BFM's using the modified bottle. Testing was performed on each instrument configuration using the CellSearch® Circulating Tumor Cell Control cells and the Cellsearch® Circulating Tumor Cells (CTC) reagent kits. The acceptance criteria for this testing were for the control cells to fall within the expected ranges established for each lot (as indicated in the product labeling). All control results for all runs fell within the accepted ranges.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.