

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

- A. 510(k) Number:
K040077
- B. Manufacturer and Instrument Name:
Immunicon Corporation, Immunicon CellTracks™ AutoPrep System
- C. Type of Test or Tests performed:
The device is a semi-automated sample-handling instrument
- D. System Descriptions:
- a. Device Description:*
The Immunicon CellTracks Auto Prep 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.
 - b. Principles of Operation:*
Immunicon has developed reagents that include ferrofluid conjugated with monoclonal antibodies that immunomagnetically separate the cells of interest and fluorescence-labeled monoclonal antibodies to further differentiate the captured cells. The first reagent added is ferrofluid which consists of a magnetic core surrounded by a polymeric layer coated with antibodies for capturing cells. Ferrofluid particles are colloidal and when mixed with a sample containing the target cells, the antibodies conjugated to the magnetic core bind the antigen associated with the target cells. The ferrofluid/sample mixture is placed in a strong magnetic field, which causes the labeled target cells to move to the side of the tube. The blood is aspirated, the magnetic field is removed and the cells are re-suspended in a small volume of buffer. Fluorescent reagents are added for identification and enumeration of target cells. Another magnetic separation step and re-suspension is performed before the final sample is ready for analysis.
 - c. Modes of Operation:*
Batch

d. Specimen Identification:

Barcode on sample tube

e. Specimen Sampling and Handling:

Whole blood samples are processed as described in # 2 above. Immunicon CellSave Preservative Tubes (K030596) must be used to collect blood samples.

f. Calibration:

N/A

g. Quality Control:

The CellTracks Auto Prep system incorporates a self-check procedure when the instrument is turned on. There is a System lock-out that prevents only authorized users to access the program to make changes.

Software:

The computer-user interface utilizes radio buttons and highlight bars as selection tools.

FDA has reviewed the applicant's Hazard Analysis and software

Documentation: Yes X or No

E. Regulatory Information:

h. Regulation Section:

21 CFR 864.5240, Automated blood cell diluting apparatus

Classification:

Class I

Product Code:

GKH

i. Panel:

Hematology (81)

F. Intended Use:

Indication(s) for Use:

The intended use for the Immunicon CellTracks AutoPrep System is as 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, CellSpotter™ System, flow cytometers or microscopes may be used for cell identification and enumeration. The system is for *in vitro* diagnostic use.

Special Condition for use Statement(s)

G. Substantial Equivalence Information:

j. *Predicate device name(s) and 510(k) numbers:*
 Immunicon CellPrep™ Sample Preparation System (K02212)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Function	Blood specimen preparation	Same
Sample Treatment	Cells of interest isolated and plasma aspirated	Same
Cell Separation	Magnetic separation	Same
Blood Sample Size	7.5 ml	Same
Differences		
Item	Device	Predicate
Sample Handling	8 samples	2 samples
Reagent Addition	Programmed on board reagent pack	Manual addition; computer prompt
Quality Checks	Error detection capability	No error detection capability

H. Standard/Guidance Document Referenced (if applicable)

N/A

I. Performance Characteristics:

1. Analytical Performance:k. *Accuracy:*

An accuracy study defined the % recovery of epithelial cell concentrations. The slope of 0.85 demonstrates 85% accuracy using 973 SKBr-3 tissue culture cells.

l. *Precision/Reproducibility:*

Control cells were tested over a total of 20 days at 1 inside and two outside clinical sites using NCCLS EP5-A. Results show that CellTracks Auto Prep System was capable of removing small numbers of control cells reproducibly from 7.5 ml of whole blood (38 cell spike level CV=16.8, 264 cell spike level CV=11.72).

m. *Linearity:*

The CellTracks AutoPrep System demonstrated consistent, linear, recovery of epithelial cells over a broad, clinically relevant range. The % recovery may differ from donor to donor; however, the

slope of 1.0 confirms that, within a donor, the % recovery is constant over the range of cell concentrations tested. The high $R^2=0.9953$ and 0.9946 establish that the linearity of response to the System is suitable to its intended use.

n. Carryover:

Whole blood was collected in CellSave and spiked with one of 6 levels (100, 250, 1000, 5000, 10,000, 20,000 per 7ml) of SKBr-3 tissue culture cells. Cell carryover was observed with some samples; however significant carryover was observed only when very high epithelial cell levels were encountered. The carryover observed when using the CellTracks AutoPrep System was found to be low enough to be suited to its intended use.

o. Interfering Substances:

N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

N/A

J. Conclusion:

The Immunicon CellTracks AutoPrep System is substantially equivalent to the Immunicon CellPrep Sample Preparation System.

