

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k093128

B. Purpose for Submission:

New instrument and software

C. Manufacturer and Instrument Name:

Illumina, Inc.

BeadXpress Reader System with VeraScan Software (v. 2.0.17.0)

D. Type of Test or Tests Performed:

Microbead array for nucleic acid genotype testing

E. System Descriptions:

1. Device Description:

The BeadXpress® System is an open platform fluidic microbead reader which includes a dual-color laser detection system that enables optical scanning of multiplexed assays developed using the VeraCode digital microbead technology and VeraScan 2.0 software. The instrument performs a routine set of operating steps: Reader Initialization, Fluidic Initialization, Scanning, Data Consolidation and Flushing. Hardware is contained within a single instrument housing. The system consists of four sub-systems (fluidics, opto-mechanical, motion and electrical) that interact with each other to provide the desired results. The fluidic system consists of the parts that move fluids and beads through the system as well as the key groove plate upon which the beads lay to be scanned. The opto-mechanical system contains the two lasers and all the optical components that are involved with the optical alignment and delivery of the beams to the beads and collection of the signals generated. This motion system contains all the hardware that is involved with the physical movement of the internal parts of the reader and utilizes four major axes to control the movement and spacial orientation of the specific sub-systems. The electrical system contains all the electronic components that are responsible for control of the individual components and system overall.

The VeraScan software is installed on a PC directly connected to the BeadXpress Reader. It is used for operating the BeadXpress Reader and through the use of software modules, analyzing the scan results and genotype calls. A PC with the following minimum specifications is required:

- Pentium Dual Core 2.4GHz or higher
- 160GB or more hard drive
- 2GB or more memory
- Minimum monitor resolution of 1024 x 768
- Windows XP Professional, Service Pack 2 or higher
- Adobe Acrobat 8.1 or higher
- .NET framework 3.5 or higher

2. Principles of Operation:

The BeadXpress Instrument works by reading the fluorescence signal given off by dyes that are attached to molecules that have been hybridized to other molecules (capture probes) that have been immobilized on the surface of cylindrical assay-specific holographically inscribed VeraCode microscopic glass beads called VeraCode microbeads that are associated with a unique VeraCode microbead type. During sample hybridization, the assay products anneal to the capture probes, and the fluorescence of each microbead is measured for both red and green fluorescence in the BeadXpress Reader.

The BeadXpress Reader uses fluidics to collect and array the assay-specific holographically inscribed VeraCode microbeads, then scan for their code and red and green fluorescent signals from nucleic acid targets, subsequently reporting the amount of fluorescent material attached to the beads. Data is generated as binary files, which are then used in downstream analysis.

- VeraScan serves as the user interface for managing user accounts and security settings, is the main software interface for the BeadXpress Reader, and can only be run by authorized users. It controls all Reader operations including initialization, scanning, and maintenance routines such as calibration. It provides instrument control and the application for processing the microbead plates and data collection. It also performs system checks and notifies the user when the Reader requires maintenance or is out of specification. VeraScan provides instrument control and the application for processing the microbead plates and data collection.
- The Genotyping (GT) (v. 1.0.11.0) Module configures run settings for the Reader according to a test-specific kit manifest. The GT Module also analyzes scan data to call genotypes. This is done by using a process flow that associates fluorescence data in each color channel with calling thresholds supplied by the kit manifest. Once analysis is completed, the software displays data results and graphical visualizations to help the user interpret run success. **Features and capabilities relating to use with non-FDA cleared VeraCode IVDs are not considered as part of this clearance.**
- The Generic Module is not used by the VeraCode® Genotyping Test for Factor V and Factor II (k093129) cleared for use on this instrument and therefore this module and its function were not reviewed and are not included as part of this clearance.

The VeraReport software (v. 1.0.6.0) is a stand-alone software component which authenticates users, loads a .bxp project file and its associated Module, and displays data results for both diagnostic and non-diagnostic tests. The user interface for viewing data is the same in VeraReport as it is in VeraScan. Through this interface, the user can also regenerate reports. Data results associated with the Generic Module cannot be viewed through VeraReport. **Features and capabilities relating to use with non-FDA cleared VeraCode IVDs are not considered as part of this clearance.**

Upon completion of scanning the microbead plates, the data is passed through

VeraScan 2.0 with use of a GT Module software component to the assay-specific kit manifest containing the parameters and cutoffs used to produce and report a genotype result.

3. Modes of Operation:
Batch via 96 well plate or tube strip
4. Specimen Identification:
Entered by user manually or with a barcode scanner
5. Specimen Sampling and Handling:
Specimens are processed and handled according to assay instructions.
6. Calibration:
The BeadXpress Reader is calibrated by the user using a standardized VeraCode Test & Calibration Kit and an auto-calibrating utility in the VeraScan software. The VeraScan test and calibration utility is performed to ensure that the BeadXpress reader is functioning within normal specifications. The Test and Calibration Kit beads (T&C beads) are tagged with Cy3 and Cy5 dyes contained in a buffer solution. Beads are provided in a 96 well Stripwell plate as twelve 8 well strip sets. Each set is sufficient to provide 12 reader tests. Strips of T&C beads are intended for one time use. One 8 well T&C bead strip containing the fluorescently tagged beads is loaded into the reader and scanned to measure overall and individual fluorescence values, cell background fluorescence levels, code classification and misclassification, and carryover. Each calibration is only valid for 30-days.
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 or No

F. Regulatory Information:

1. Regulation section:
21CFR §862.2570 - Instrumentation for clinical multiplex test systems.
2. Classification:
Class II
3. Product code:
NSU - Instrumentation for clinical multiplex test systems
4. Panel:
Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:
The BeadXpress® System is an in vitro diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample utilizing VeraCode holographic microbead technology. The BeadXpress System consists of the BeadXpress Reader and VeraScan software.
2. Special Conditions for Use Statement(s):

For prescription use only with separately cleared VeraCode genotyping tests.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
k060564, INFINITI System for Factor II and Factor V
2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
	BeadXpress® Reader System with VeraScan Software	INFINITI™ System for Factor II and Factor V
Test principle	Microarray-based genotyping test for simultaneous detection (multiplex system) of DNA sequences	Same
Specimen Type	Human genomic DNA isolated from EDTA whole blood samples	Same
Sample Preparation	Performed off-line	Same
Sequence detection	Detects specific DNA sequences through direct recognition of DNA targets	Same

Differences		
Item	Device	Predicate
Indications for Use	The BeadXpress® System is an in vitro diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample utilizing VeraCode holographic microbead technology. The BeadXpress System consists of the BeadXpress Reader and VeraScan software.	The INFINITI™ System Assay for detection and genotyping of Factor II (Prothrombin) G20210A and Factor V G1691A mutations is intended to be used as an aid to diagnosis in the evaluation of patients with suspected thrombophilia.
Array substrate	Holographically inscribed microscopic glass beads	BioFilmChip microarrays.
Detection Method	Performs signal detection using fluorescence.	Performs optical detection of stimulated fluorescence

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

Guidance for Industry and FDA Staff-Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May, 2005); Food and Drug Administration CDRH Guidance Document.

Guidance for Industry and FDA Staff - Class II Special Controls Guidance, Instrumentation for Clinical Multiplex Test Systems; (March 10, 2005); Food and Drug Administration, OIVD, Division of Chemistry and Toxicology Devices

J. Performance Characteristics:

1. Analytical Performance:
 - a. Accuracy:
Accuracy was assessed during the clearance of the assay (k093129) and will be addressed for each assay to be run on this system.

b. Precision/Reproducibility:

Precision/Reproducibility was assessed during the clearance of the assay (k093129) which includes separate instruments at each site and will be addressed for each assay to be run on this system.

c. Linearity:

Linearity was assessed during the clearance of the assay (k093129) and will be addressed for each assay to be run on this system.

d. Carryover:

Carryover was assessed during the clearance of the assay (k093129) and will be addressed for each assay to be run on this system. In addition, the use of good laboratory practices to minimize cross-contamination is recommended.

e. Interfering Substances:

Interfering substances was assessed during the clearance of the assay (k093129) and will be addressed for each assay to be run on this system.

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.