

510K Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

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Device Name: LABType[®] SSO DNA Typing Tests for use with LABScan[™] 3D

**Classification/
Device Code:** Unclassified, MZI

Predicate Device: LABType[®] SSO DNA Typing Tests for use with LABScan[™] 100, BK020055

Device Descriptions:

LABType[®] SSO DNA Typing Tests uses sequence-specific oligonucleotide probes (SSO) bound to fluorescently coded microspheres to identify alleles encoded by the sample DNA. The introduction of a step to amplify the target DNA by polymerase chain reaction (PCR), coupled with hybridization and detection in a single reaction mixture, makes this method suitable for both small and large-scale testing. In contrast to the lymphocytotoxicity reaction scale (1 = negative to 8 = positive), LABType[®] SSO DNA Typing Tests results are either positive or negative. This abolishes the need for complicated interpretation of results. In addition, single nucleotide changes can be discriminatory in PCR-SSO, while cross-reacting groups (CREGs) provide major challenges to serological typing.

Operation Principles:

LABType[®] SSO DNA Typing Tests applies Luminex[®] technology to the reverse SSO DNA typing method. First, target DNA is PCR-amplified using a HLA locus-specific primer. The PCR

product is biotinylated, which allows it to be detected using R-Phycoerythrin-conjugated streptavidin (SAPE). The PCR product is denatured and allowed to rehybridize to complementary DNA probes conjugated to fluorescently coded microspheres.

A bench-top analyzer, the LABScan™100 (Luminex® 100/200) or the LABScan™ 3D (Luminex® FLEXMap 3D) identifies the fluorescent intensity of PE on each microsphere. Positive reactions are identified by comparing the fluorescent signal for each test probe as a percent of positive internal control probe signal to a given cut-off value.

Separately available analysis software, HLA Fusion™ software (BK070070) and (BK120014), can be used to assist in determining the genotyping of the sample DNA.

Pending approval of this 510(k) submission, LABType® products will utilize either the LABScan™ 100 or LABScan™ 3D flow analyzer for data acquisition and analysis.

LABType® SSO DNA Typing Tests for use with LABScan 3D is a modification of our existing LABType® products that have been used with the LABScan™ 100 for over 8 years by clinical labs performing HLA typing.

Both LABType® SSO DNA Typing Tests (BK020055) and the Luminex® 100 Instrument (K073506) have been cleared by the FDA.

Indications for Use:

For the DNA typing of HLA Class I or Class II alleles.

Table 1. Device Comparison Table

	Predicate Device	Substantially Equivalent Device
	LABType [®] for use with LABScan 100	LABType [®] for use with LABScan 3D
FDA Device Classification	BK# 020055 Unclassified under CBER Device code - MZI	Unassigned # New Device
Intended Use	HLA Molecular Typing	
Clinical Usage	Molecular typing of HLA using Luminex technology	
Standards Met	Standards set by ASHI (American Society of Histocompatibility and Immunogenetics) for certification of clinical HLA laboratories	
Where Used and Target population	Preliminary clinical testing for identification (and potential matching) of HLA alleles for donors and recipients of bone marrow, tissue, or organ transplants.	
Assay Method	DNA typing (SSO)	
Reactive Ingredient	HLA sequence-specific oligonucleotide probes	
Specimen Type	DNA	
Controls	Positive (HLA gene PCR amplicon, binding to a universal probe) and Negative (non-HLA gene PCR amplicon, no binding to probes)	
Detection Reagents	Streptavidin-PE (PE = R-Phycoerythrin)	
Software Technology	Uses personal computer. Operates with a Windows [®] 2000 or XP operating system.	
Software Main Components	HLA Fusion [™] Software (BK# 070070 and BK# 120014) version 3.1	
Instrumentation	Probe-Bead Flow Analyzer LABScan [™] 100 (Luminex 100/200)	Probe-Bead Flow Analyzer LABScan [™] 3D (Luminex FM3D)
Positive Reaction	Fluorescent signal due to binding of specific DNA probes	
Evaluation of Results (HLA genotyping is based on published information on HLA DNA sequences, or defined serological reagent specificity).	Assignment of specificity by matching the reaction pattern to the known <i>sequence</i> specificity of the <i>probes</i> included in the panel. Highly complex information needs to be reviewed by a certified HLA professional.	
Performance	Comparable sensitivity and specificities of antibody reactions analyzed by LABScan [™] 100 vs. LABScan [™] 3D	

LABType[®] SSO DNA Typing Tests for use with LABScan[™] 3D is substantially equivalent to the predicate device LABType[®] SSO DNA Typing Tests for use with LABScan[™] 100. Both use Luminex technology for molecular typing and both are tools used in preliminary clinical testing. No new safety or effectiveness issues were raised.

Testing:

The performance of the LABType[®] SSO DNA Typing Tests were verified and testing demonstrates safety and effectiveness (Table 2).

Table 2. Test Results Summary

Testing	Agreement (HLA Typing)
Verification and Validation	
Performance Evaluation	LABScan 100 vs. LABScan 3D
<i>3 LABType product lots vs. 48 samples (in duplicate)</i>	
- Concordance	100%
Detection Limits	LABScan 100 vs. LABScan 3D
<i>LABType product lot tested with 8 sample, in triplicate, using serial dilution of DNA sample</i>	
- Concordance	100% (Need to state the lowest-highest acceptable DNA conc.)
Robustness	LABScan 100 vs. LABScan 3D
<i>LABType product lot tested with 96 samples using 50% vs. 100% probe-bead concentration</i>	
- Concordance	100%
Lot-to-Lot Consistency	3 lots of LABType product
<i>3 LABType product lots tested with 32 samples in triplicate</i>	
- Concordance	100%
Reproducibility	3 techs/3 LABScan 3D devices
<i>LABType product lot tested with 16 samples in triplicate - 2 runs/day on 5 days</i>	
- Concordance	100%
Clinical Testing	
Performance Evaluation	LABScan 100 vs. LABScan 3D
<i>3 LABType product lots tested with 32 clinical samples per instrument</i>	
- Concordance	100%
Reproducibility	3 techs/3 LABScan 3D devices
<i>LABType product tested with 16 samples in triplicate - 2 runs/day on 5 days</i>	
- Concordance	100%
Bead Counts	Expected: ≥ 100 beads per region
<i>All of the above experiments (in-house and clinical testing)</i>	
- Observed	≥ 100

Overall Conclusion:

Extensive data generated from in-house and clinical testing demonstrate that LABType[®] SSO DNA Typing Tests for use with LABScan[™] 3D is safe and effective. Submitted information is complete and supports that LABType[®] SSO DNA Typing Tests for use with LABScan[™] 3D is substantially equivalent to LABType[®] SSO DNA Typing Tests for use with LABScan[™] 100, predicate device.