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510(k) Summary

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

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Contact:	Angela Estany Director, Regulatory Affairs & Quality Telephone: 818-449-3346 Email: angela.estany@thermofisher.com
Device Name:	LABType™ XR and CWD DNA Typing Test BK160018
Classification/ Product Code:	Unclassified / MZI
Classification Name:	Test, Qualitative, for HLA, Non-Diagnostic
Predicate Devices:	LABType® SSO DNA Typing Tests For Use With LABScan™ 3D (BK120024) and LABType® SSO DNA Typing Tests (BK020055)
Device Description:	LABType™ XR and CWD DNA Typing Test products encompass exons 2-5 for A and B loci, and exon 2 for DRB1 locus and also contains probes that will type for Common Well Documented HLA alleles based on the current CWD catalog available on the IMGT/HLA database. The typing test products are used in conjunction with the LABScan3D™ instrument (Luminex® FLEXMap 3D® instrument). The typing tests apply Luminex technology to the reverse SSO DNA typing method. The LABScan3D™ instrument combines dyed fluorescent microsphere sets to allow multiplexing of up to 500 unique assays within a single sample. In this assay, target DNA is PCR-amplified using a group specific primer. The Polymerase Chain Reaction (PCR) product is biotinylated, which allows it to be detected using R-Phycoerythrin-conjugated streptavidin (SAPE). The PCR

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	product is denatured and allowed to rehybridize to complementary DNA probes conjugated to fluorescently coded microspheres. A bench-top analyzer (LABScan3D™) identifies the fluorescent intensity of Phycoerythrin (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™) can be used to assist in determining HLA typing.
Operational Principles:	HLA antigens are polymorphic heterodimers encoded by genes located on the short arm of chromosome 6 and regulate the immune response to pathogens and distinguish "self" from "non-self" in transplantation immunology. Histocompatibility testing allows the matching of organ recipients and donors with the degree of matching accuracy impacting the clinical outcome of organ and bone marrow transplantation. Molecular-based typing methods have been refined for practical testing in the clinical lab setting. LABType™ XR and CWD DNA Typing Test 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 tube, makes this method suitable for large-scale testing.
Accessories:	HLA Fusion Software Version 4.0 (BK160017) LABScan3D™ [Luminex® FLEXMAP 3D® - instrument system (K121399)]
Intended Use:	For use to determine HLA A, B, DRB1 locus typing to aid in transfusion and transplantation donor recipient matching.

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Table 1. Device Comparison Table

	Predicate Device	Predicate Device	Substantially Equivalent Device
	LABType® SSO DNA Typing Tests	**LABType® SSO DNA Typing Tests For Use With LABScan 3D**	**LABType™ XR and CWD DNA Typing Test**
FDA Device Classification	BK020055 Unclassified under CBER Device Code - MZI	BK120024 Unclassified under CBER Device code - MZI	Unassigned #160018 New Device Unclassified/MZI
Intended Use	DNA typing of HLA Class I or Class II alleles	DNA typing of HLA Class I or Class II alleles	For use to determine HLA A, B, DR locus typing to aid in transfusion and transplantation donor recipient matching.
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	HLA Fusion software (BK007070)	HLA Fusion Software (BK120014)	HLA Fusion 4.0 Software (BK160017)
Instrumentation	LABScan™ 100 (K073506)	LABScan3D™ (Luminex® FLEXMAP 3D®) instrument system (K121399)	
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 sequence specificity of the probes included in the panel. Highly complex information needs to be reviewed by a certified HLA professional.		
Performance	Comparable sensitivity and specificity of typing results		

LABType™ XR and CWD DNA Typing Test is substantially equivalent to the predicate device LABType® SSO DNA Typing Tests for use with LABScan3D™ and the predicate device LABType SSO® DNA Typing Tests. LABType™ XR and CWD DNA Typing and the 2 predicate devices use Luminex technology for molecular typing and both are tools used in preliminary clinical testing. No new safety or effectiveness issues were raised.

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Testing:

The performance of the LABType™ XR and CWD DNA Typing Test were verified and testing demonstrates safety and effectiveness (Table 2).

Table 2. Test Results Summary

Testing	Agreement (HLA Typing)
Verification and Validation	
Performance Evaluation	**LABScan3D™**
6 LABType™ XR and CWD DNA Typing Test product lots (90-96 approved samples)	
- Concordance: with the reference typing where one pair of the reported alleles is the same as the typing results of the reference sample.	100% where one pair of the reported alleles is the same as the typing results of the reference sample.
Detection Limits	**LABScan3D™**
LABType™ XR and CWD DNA Typing Test product lots tested with 8 samples, in triplicate, using serial dilution DNA sample. The selected range of DNA concentrations covered two-fold higher and two fold lower than the optimal 20 ng/µL concentration.	
- Concordance	100%
Robustness	**LABScan3D™**
LABType™ XR and CWD product lots tested with two sets of 96 approved samples (1 set for Class I products and 1 set for Class II products) using 50% and 100% probe-bead concentration	
- Concordance	100%
Lot-to-Lot Consistency	**LABScan3D™**
3 LABType™ XR and CWD DNA Typing Test product lots tested with 32 samples in triplicate (96 samples total)	
- Concordance	≥95%
Reproducibility	**3 Technicians / 1 LABScan3D™ device**
3 LABType™ XR and CWD DNA Typing Test product lot tested with 16 DNA samples in duplicate; 3 technicians on 2 runs/day on 5 days within a 20-day period	
- Concordance	≥95%
Clinical Testing	
Performance Evaluation	**LABScan3D™**
6 LABType™ XR and CWD DNA Typing Test product lots tested with ≥32 samples per site	
- Concordance:	100%
Reproducibility	**3 technicians/LABScan3D™**
6 LABType™ XR and CWD DNA Typing Test product lots tested with 16 samples in duplicate; 3 technicians, 2 runs/day on 5 non-consecutive days within a 20 day period	
- Concordance:	≥95%
Bead Counts	Expected ≥100 beads per region
All of the above experiments (in-house and clinical testing)	
- Observed	≥ 100

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Overall Conclusion:

Extensive data generated from in-house and clinical testing demonstrates that LABType™ XR and CWD DNA Typing Test for use with the LABScan3D™ is safe and effective. Submitted information is complete and supports that LABType™ XR and CWD DNA Typing Test is substantially equivalent to LABType® SSO DNA Typing Tests for use with LABScan™ 3D predicate device and the predicate device LABType SSO® DNA Typing Tests.