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LABScreen™ Multi 510(k) 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: LABScreen Multi

Classification/ Device Code: Unclassified, MZI

Predicate Device: LABScreen Multi (BK080071 & BK140141)

Device Descriptions:
The LABScreen Multi assay is a diagnostic tool to qualitatively measure the presence of human leukocyte antigens (HLA) or human neutrophil antigens (HNA) specific antibody in a human serum or plasma sample. LABScreen Multi uses microbeads coated with human leukocyte antigen (purified Class I or Class II HLA or HNA antigens) and pre-optimized reagents for the detection of HLA/HNA antibodies. Data acquisition and analysis are performed by the LABScan™ 100 flow analyzer or LABScan3D™ (Luminex® FLEXMAP 3D®) for analysis of up to 100 or 500 bead regions, respectively. A negative control serum is used to establish the background value for each bead in a test batch. Data reports on assay results may be generated using HLA Fusion software (version 2.0 or higher).

Both anti-HLA and anti-HNA antibodies have been implicated in the clinical cases of transfusion related acute lung injury (TRALI). The American Association of Blood Banks (AABB) has mandated the introduction of proactive measures to reduce the level of risk of transfusion reactions. Although incomplete information is currently available to define a threshold for "dangerous" levels of antibody, it is of interest to screen blood, platelet, or plasma donations for both types of antibodies, and to remove units that contain a high level of antibody.

Operation Principles:
LABScreen Multi is used for antibody detection tests that utilize a panel of color-coded beads that are coated with purified HLA or HNA antigens. Up to 100 different beads may be combined in one suspension for a single test.

Test serum or plasma is first incubated with LABScreen Multi beads. Any HLA/HNA antibodies present in the test serum bind to the antigens and then are labeled with R-Phycoerythrin (PE)-conjugated Goat anti-human IgG. The LABScan 100 or LABScan3D flow analyzer(s) simultaneously detects the fluorescent emission of PE from a dye signature from each bead, allowing almost real-time data acquisition. The reaction pattern of the test specimen is compared to the lot-specific worksheet defining the antigen array to assign reactivity or specificity.

An indication of the relative strength or titer of the antibody can be inferred from the Fluorescent Intensity (FI) of the signal generated upon binding of antibody to beads coated with a specific antigen. (This applies especially to beads coated with a single antigen, such as the HNA beads). For the HLA Class I or Class II bead pools, a high signal can also be due to detection of multiple antibody specificities in the same test sample, as in the case of clinical samples with high Panel Reactive Antibody (% PRA).

This analysis is conducted using HLA Fusion™ software (BK070070, BK120014 and BK160017). There is no change required to the software for the addition of LABScreen Multi for use with LABScan3D.

Table 1. Device Comparison Table

	Predicate Device	**Substantially Equivalent Device**
	LABScreen Multi for use with LABScan 100	**LABScreen Multi for use with LABScan 3D**
FDA Device Classification	BK080071 Unclassified under CBER Device code: MZI Detecting anti-HLA Class I/Class II antibodies and anti-HNA antibodies (HNA-1, -2, -3)	Unassigned # New Device
	BK140141 Unclassified under CBER Device code: MZI Detecting anti-HLA Class I/Class II antibodies and anti-HNA antibodies (HNA -4 and -5)	
Intended Use	LABScreen Multi is intended for the detection of antibodies to human leukocyte antigens	LABScreen Multi is intended for the detection of antibodies to human leukocyte antigens or detection of antibodies to human neutrophil antigens.
Intended Purpose	The LABScreen Multi assay is a diagnostic tool to qualitatively measure the presence of HLA or HNA specific antibody in human serum or plasma samples. LABScreen Multi can simultaneously detect and identify HLA and HNA antibodies. Immune-mediated Transfusion-Related Acute Lung Injury (TRALI) accounts for the majority of reported cases and is mediated by donor antibodies to HLA and/or human neutrophil antigens (HNA) most commonly associated with plasma or other blood products from female donors with a history of pregnancies. The enactment of the AABB's Standard 5.4.1.2 requires that all plasma or whole blood from potentially sensitized female donors be tested for HLA antibodies. The end of the exemption for AB plasma is likely to have significant effects on blood centers, hospitals, and possibly the plasma supply. This test which can simultaneously screen for HLA and HNA antibodies provides Blood Banks, Transfusion Centers, and Blood Centers with an efficient, cost-effective tool to implement TRALI risk reduction measures and manage their donor pool.	

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	Predicate Device	Substantially Equivalent Device
	LABScreen Multi for use with LABScan 100	**LABScreen Multi for use with LABScan 3D**
Clinical Usage	Preliminary clinical testing for detection and identification of human leukocyte antigen (purified Class I or Class II HLA or HNA antigens) and pre-optimized reagents for the detection of HLA/HNA antibodies.	
Standards Met	Standards set by ASHI (American Society of Histocompatibility and Immunogenetics) for certification of clinical HLA laboratories.	
Where Used and Target population	HLA antibodies are proteins that are present in the blood of all humans. As such, the target population is all humans. While HLA antibody frequencies vary in different sub-populations, there are no contra-indications or population limitations for antibody screening.	
Assay Method	Fluorescence detection	
Reactive Ingredient	Purified Class I or Class II HLA or HNA antigens	
Specimen Type	Serum or Plasma	
Controls (Accessory)	Negative Control Serum (Catalog ID: LS-NC)	
Detection Reagents (Accessory)	PE-conjugated 2nd Ab (anti-Human IgG) [Catalog ID: LS-AB2]	
Software Technology	Compatible with computer running Microsoft Windows® 7 or 10.	
Software Main Components	HLA Fusion™ software (BK070070, BK120014 and BK160017)	
Instrumentation	Probe-Bead Flow Analyzer LABScan 100 (Luminex® 100/200) [k#073506]	Probe-Bead Flow Analyzer LABScan3D (Luminex® FLEXMAP 3D) [k#121399]
Positive Reaction	Fluorescent signal due to binding of labeled 2nd Ab	
Evaluation of Results	Assignment of antibody specificity by matching the reaction pattern to the known composition of the antigen panel	
Performance	Comparable sensitivity and specificities of antibody reactions analyzed by LABScan 100 vs. LABScan3D.	

LABScreen Multi for use with LABScan3D is substantially equivalent to the predicate device LABScreen Multi (for use with LABScan 100). Both use Luminex® technology to detect antibody specificity and both are tools used in preliminary clinical testing. No new safety or effectiveness issues were raised.

Testing:
The performance of the LABScreen Multi assay was verified and testing demonstrates safety and effectiveness (Table 2).

Table 2. Test Results Summary

Testing	Agreement	
Accuracy	LABScan 100 vs. LABScan 3D	
176 samples run on 3 LABScreen Multi lots, including a negative control		
Concordance	Lot T1: 97.67%	
	Lot T2: 98.20%	
	Lot T3: 98.32%	
Negative Agreement	Lot T1: 98.00%	
	Lot T2: 98.65%	
	Lot T3: 98.77%	
Positive Agreement	Lot T1: 100.00%	
	Lot T2: 99.14%	
	Lot T3: 99.14%	
Limit of Detection	LABScan 100 vs. LABScan 3D	
8 test sera tested neat and at 11 serial, two-fold dilutions, from 1:2 to 1:2048 on 3 lots of LABScreen Multi. 2 sera, 1 positive for CI, HNA-3a and -3b and the other for CI, CII, and HNA-4, available only at a 1:10 dilution, were tested at 1:10 and at 11 serial, two-fold dilutions, from 1:20 to 1:20480.		
Result	Each analyte was able to be detected at a dilution past neat. This demonstrates that the product is able to detect antibodies against the respective analytes beyond an undiluted sample. Note: IFU did not change from current: undiluted serum or plasma is used for the test.	
Robustness	LABScan 100 vs. LABScan 3D	
168 sera/plasma samples and controls; for each lot 1,848 tests were performed using the full bead protocol and 1,848 tests were performed using the half bead protocol		
Concordance	Full T1: 97.56%	Half T1: 97.47%
	Full T2: 98.20%	Half T2: 96.63%
	Full T3: 98.32%	Half T3: 97.10%
Negative Agreement	Full T1: 97.91%	Half T1: 97.85%
	Full T2: 98.59%	Half T2: 98.22%
	Full T3: 98.71%	Half T3: 97.91%
Positive Agreement	Full T1: 100.00%	Half T1: 100.00%
	Full T2: 100.00%	Half T2: 90.83%
	Full T3: 99.08%	Half T3: 96.33%

Lot-to-Lot / Repeatability	LABScan 100 (reference) vs. LABScan 3D
33 serum/plasma samples; 3 lots of LABScreen Multi, one user (T2) - 2 runs/day, 5 non-consecutive days within a 20-day period	
Concordance	Lot T1: 99.29% Lot T2: 98.47% Lot T3: 98.38%
Negative Agreement	Lot T1: 99.49% Lot T2: 98.73% Lot T3: 98.79%
Positive Agreement	Lot T1: 100.00% Lot T2: 99.80% Lot T3: 99.78%
Reproducibility	LABScan 100 (reference) vs. LABScan 3D
33 serum/plasma samples; 3 lots of LABScreen Multi, 3 users - 2 runs/day, 5 non-consecutive days within a 20-day period	
Overall average Concordance	98.99%
Overall Negative Agreement	99.00%
Overall Positive Agreement	98.99%

Overall Conclusion:

Data generated from analytical performance (verification) study demonstrates that LABScreen Multi for use with LABScan3D is safe and effective. Submitted information for this Special 510K supports that LABScreen Multi for use with LABScan3D is substantially equivalent to the predicate device LABScreen Multi for use with LABScan 100.

LABScreen Multi for use with LABScan3D is a modification of our LABScreen Multi product that has been used by clinical labs for the detection of HLA antibodies for over 10 years.

LABScreen Multi (BK080071 and BK140141) and the Luminex® 100 Instrument (K073506) and LABScan3D (FLEXMAP 3D Instrument System, K121399) have been cleared by the FDA.

Data analysis is using HLA Fusion Software. No software update was required for the proposed addition LABScreen Multi for use with LABScan3D.