

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

**A. 510(k) Number:**

k121399

**B. Purpose for Submission:**

Clearance of New Device

**C. Manufacturer and Instrument Name:**

Luminex<sup>®</sup> Molecular Diagnostics, Inc., FLEXMAP 3D<sup>®</sup> Instrument System with Luminex<sup>®</sup> xPONENT 4.0 SP1 Software; FLEXMAP 3D<sup>®</sup> IVD Calibration Kit, and FLEXMAP 3D<sup>®</sup> IVD Performance Verification Kit

**D. Type of Test or Tests Performed:**

Multiplex nucleic-acid testing

**E. System Descriptions:**

1. Device Description:

The Luminex<sup>®</sup> FLEXMAP 3D<sup>®</sup> instrument includes four subsystems: electronic, fluidic, mechanical, and optical.

Luminex FLEXMAP 3D<sup>®</sup>

The FLEXMAP 3D<sup>®</sup> system is a compact analyzer that performs up to 500 analytes from a single sample. The instrument includes four subsystems: electronic, fluidic, mechanical, and optical; and utilizes xPONENT<sup>®</sup> software version 4.0 SP1 of the xMAP<sup>®</sup> (Multi-Analyte Profiling) technology operating system. The electronics system provides the power for operation and control of the FLEXMAP 3D system and communication between its parts. The fluidics system handles the flow of liquid through the Luminex<sup>®</sup> FLEXMAP 3D<sup>®</sup> instrument. The mechanical subsystem of the Luminex<sup>®</sup> FLEXMAP 3D<sup>®</sup> instrument includes a filter system used to aid in cooling of the instrument and pressurized sheath fluid. The optical sub-system consists of the optical assembly and excitation lasers and does not require manual adjustment by the user.

Luminex xPONENT 4.0 SP1 software

The Luminex xPONENT<sup>®</sup> 4.0 SP1 or higher software will provide complete control of the FLEXMAP 3D<sup>®</sup> instrument and perform the analyses. The FLEXMAP 3D<sup>®</sup> system utilizes software version xPONENT<sup>®</sup> 4.0 SP1 of the

xMAP technology operating system.

**Consumables:**

Luminex FLEXMAP 3D® Calibration Kit (Store 2–8 °C)

The Luminex® FLEXMAP 3D® Calibration Kit contains all reagents needed for 25 calibrations of the FLEXMAP 3D® platform with Luminex® xPONENT® software. The kit includes 25 disposable strip wells (to be inserted into the off plate reagent area); a FLEXMAP 3D Calibration Kit CD which includes an importable \*.lxl file containing the calibration target value data for the specific lots of reagents in the kit; and one 5 mL vial set each of:

1. FLEXMAP 3D Classification Calibrator Microspheres (F3DCAL1) used to calibrate the system for nonmagnetic MicroPlex microspheres. During calibration, the system alters voltages within the optics for classification channels (CL1, CL2 and CL3) until those values match the imported target values, thus calibrating the classification map. The same occurs for the doublet discriminator (DD) channel signal.
2. FLEXMAP 3D e Classification Calibrator Microspheres (F3DeCAL1) used to calibrate the system for MagPlex microspheres.
3. FLEXMAP 3D Reporter Calibrator Microspheres (F3DCAL2) used to calibrate the system for reporter intensity. During calibration, the system alters the voltage on the RP1 parameter within the optics until the MFI values match the input target value.
4. FLEXMAP 3D EDR Calibrator Microspheres (F3DCAL3) used to calibrate extended RP1 range for all xMAP beads.

Luminex FLEXMAP 3D® Performance Verification Kit (Store 2–8 °C)

The Luminex FLEXMAP 3D® Performance Verification Kit is used to run performance verification on the FLEXMAP 3D analyzer. The Luminex FLEXMAP 3D® Performance Verification Kit includes sufficient reagents to perform 25 verifications of the calibration and optical integrity for the Luminex FLEXMAP 3D® System. The kit includes 25 disposable strip wells (to be inserted into the off plate reagent area); a FLEXMAP 3D Performance Verification Kit CD which includes an importable \*.lxl file containing verification target value data for the specific lots of reagents in the kit; and one 5 mL vial set each of:

1. FLEXMAP 3D Classification Verifier Microspheres (F3DVER1) containing eleven microsphere regions internally labeled with classification dyes (CL1, CL2 and CL3) to eleven regions on the 500-plex map that are most sensitive to optical misalignment.
2. FLEXMAP 3D e Classification Verifier Microspheres (F3DeVER1) containing eleven microspheres internally labeled to the 500-plex map, but verifies that the doublet discriminator settings are correct for use with Luminex MagPlex microspheres.

3. FLEXMAP 3D Reporter Verifier Microspheres (F3DVER2) containing seven microspheres internally labeled with increasing amounts of reporter dye. F3DVER2 is used to check the reporter channel for reporter response, linearity, and reporter coefficients of variation.
4. xMAP Fluidics 1 Microspheres (FLUID1) containing a single microsphere set used in conjunction with Fluidics2 to measure inter-well carryover and detect issues with sample retention in fluidic lines or inefficient presentation of sample to optics.
5. xMAP Fluidics 2 Microspheres (FLUID2) containing a buffer solution that allows measurement of microspheres originating from Fluidics1.

Luminex xMAP<sup>®</sup> Sheath Fluid and xMAP<sup>®</sup> Sheath Concentrate Pack (Store Room temperature)

The Luminex xMAP<sup>®</sup> sheath fluid is identical to the sheath fluid cleared with previous xMAP submission k073506, and serves as the delivery medium which carries the sample to the optics component of the Luminex xMAP technology based instruments (including the FLEXMAP 3D instrument). The xMAP<sup>®</sup> sheath fluid is available in two formulations, a ready-to-use (20L) and a 1L concentrate pack which is sufficient to dilute to 20L.

2. Principles of Operation:

Luminex's xMAP technology is built on flow cytometry, microspheres, lasers, digital signal processing and traditional chemistry. Systems using xMAP technology perform discrete chemistry on the surface of color coated beads known as microspheres, which are then read in a compact analyzer. The analyzer reads multiplexed assay results by identifying color differences between beads as well as the presence or absence of a fluorescent reporter marker.

The principle of operation for the instrument system is flow cell fluorometry. The fluidics, optics, robotics, temperature control, software, and xMAP microspheres work together to enable simultaneous analysis of up to 500 analytes in a single test sample. Assay analysis requiring temperature control is provided through the enclosed instrument heater block.

There are two fluidics paths in the FLEXMAP 3D analyzer. The first path involves a syringe driven mechanism that controls the sample uptake. This mechanism permits small sample uptake volumes from small reaction volumes. The syringe-driven system transports a specified volume of sample from a sample container to the cuvette. The sample is injected into the cuvette at a steady rate for analysis. Following analysis, the sample path is automatically purged with sheath buffer by the second fluidics path. This process removes residual sample within the tubing, valves, and probe. The second fluidics path is driven by positive air pressure and supplies sheath fluid to the cuvette and sample path.

Sheath fluid is the delivery medium of the sample to the optics component. The

analysis sample is acquired using a sample probe from a 96-well microtitre plate. The sample passes through with sheath fluid at a reduced rate resulting in a narrow sample core to ensure that each microsphere is illuminated individually. The sample injection rate is such that the microspheres are introduced to the optics path as a series of single events. The optics assembly consists of two lasers. One laser excites the dye mixture inside the microspheres and the second laser excites the fluorophore bound to the surface of the microsphere. Avalanche photo diode detectors measure the excitation emission intensities of the color coding classification dye mixtures inside the microspheres and a photomultiplier tube detects the excitation emission intensity of the reporter molecule bound to the surface of the microspheres. High speed digital signal processors and computer algorithms provide analysis of the microspheres as they are processed through the FLEXMAP 3D analyzer. Results of the analyses are provided in a report format.

3. Modes of Operation:

Automatic - the FLEXMAP 3D analyzer utilizes sequential positioning of each well of a 96-well microtitre plate beginning from any well position.

4. Specimen Identification:

The FLEXMAP 3D analyzer utilizes an optional barcode reader that is available for entry of sample IDs, or they may be entered manually

5. Specimen Sampling and Handling:

The samples are manually prepared according to assay manufacturer's suggestions and are transferred to a 96-well microtitre plate for analysis.

6. Calibration:

The FLEXMAP 3D analyzer utilizes classification and reporter calibrator microspheres in FLEXMAP 3D® Calibration Kit. Calibration is performed weekly.

7. Quality Control:

The FLEXMAP 3D analyzer utilizes classification and reporter verification microspheres in FLEXMAP 3D® Performance Verification Kit

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes \_\_\_ X \_\_\_ or No \_\_\_\_\_

**F. Regulatory Information:**

1. Regulation section:

21 CFR 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 Luminex® FLEXMAP 3D® system with xPONENT® software version 4.0 SP1 is a clinical multiplex test system intended to measure and sort multiple signals generated in an *in vitro* diagnostic assay from a clinical sample. This instrumentation is intended for use with specific IVD cleared or approved assays citing its use, to measure multiple similar analytes that establish a single indicator to aid in diagnosis.

2. Special Conditions for Use Statement(s):

For prescription use only

**H. Substantial Equivalence Information:**

1. Predicate Device Name(s) and 510(k) numbers:

Luminex LX 100/200 Instrument, k073506

2. Comparison with Predicate Device:

Similarities		
Parameter	Luminex 100/200 (Predicate)	FLEXMAP 3D (New Device)
Intended Use	The LX100/200 is a clinical multiplex test system intended to	The Luminex® FLEXMAP 3D® system is a clinical

Similarities		
Parameter	Luminex 100/200 (Predicate)	FLEXMAP 3D (New Device)
	measure and sort multiple signals generated in an In Vitro Diagnostic assay from a clinical sample. This instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. The device includes a signal reader unit, raw data storage mechanisms, data acquisition software and software to process detected signals.	multiplex test system intended to measure and sort multiple signals generated in an in vitro diagnostic assay from a clinical sample. This instrumentation is intended for use with cleared or approved assays citing its use, to measure multiple similar analytes that establish a single indicator to aid in diagnosis. The device includes a signal reader unit, raw data storage mechanisms, data acquisition software and software to process detected signals.
Assays used to establish performance	One Lambda LABType <sup>®</sup> SSO DNA Typing Tests (Bk020055)	One Lambda LABType <sup>®</sup> SSO DNA Typing Tests
Optics Principle	Lasers/APDs1/PMTs2	Same as predicate
Hardware Principle	Flow Cytometry based	Same as predicate
Calibration	System calibration is performed on a monthly basis as part of regularly scheduled maintenance. This is independent of assay calibration.	Same as predicate.

Differences		
	Luminex 100/200 (Predicate)	FLEXMAP 3D (New Device)
Software	xMAP Technology Operating System IS2.3 and xPONENT 3.1	xMAP Technology Operating System xPONENT 4.0 SP1
500-plex Read Time	Not Applicable	~ 25 mins/96-well plate
Calibration kit	Luminex 100/200 Calibration Kit.	Luminex FLEXMAP 3D Calibration Kit.
Applications	Protein/Nucleic Acid	Protein/Nucleic Acid
Dynamic Range	≥ 3.5 logs	≥ 4.5 logs
Multiplex Capacity	100	500
100-plex Read Time	~ 40 mins/96-well plate	~ 20 mins/96-well plate
Microtitre Plate	96 well	96 well and 384 well (384 well performance not demonstrated as part of clearance)

Footprint	80.0 cm (32")	64.8 cm (24")
Weight Analyzer	49 kg (113 lbs)	77.1 kg (170 lbs)

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

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents, 2002
- IEC 60825 Safety of Laser Products. 2nd Edition, 2007
- IEC62304 Medical Device Software - Software Life Cycle Processes, 2006
- SI 14971 Medical Devices - Applications of Risk Management, 2007
- ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied, 2007

**J. Performance Characteristics:**

1. Analytical Performance:

a. *Accuracy:*

Accuracy was assessed during the clearance of the assay (Bk120024, One Lambda LABType® SSO DNA Typing Tests, reviewed by CBER) and will be addressed for each assay in the future, to be run on this system.

The samples tested were approved reference samples with quality and quantity that meet the criteria described in the One Lambda LABScreen® assay product inserts. The samples selected for each locus had maximum diversification of HLA typing to test as rigorously as possible. The HLA typing for all samples has been confirmed based on cell or DNA exchange programs or in house sequencing combined with LABType® SSO DNA Typing Test methods.

Technician # 1 typed 48 reference samples in duplicate in a single 96-well PCR tray for each of the three lots of LABType® product on three separate days. Assayed microspheres were analyzed using on LABScan 3D (FLEXMAP 3D) instrument. Technician # 2 typed the same samples using the same lots of LABType® products but instead used the LABScan 100 (Bk020055) for data acquisition.

The concordance analysis of the HLA typing results using 48 reference samples in duplicate at the internal site demonstrated 100% concordance between the results obtained from the two instruments using all three lots. The correlation analysis comparing the MFI values obtained from the LABScan 3D instrument and the LABScan 100 across the three lots of LABType® products equaling 66332 points showed an R-squared values ranging from 0.9885 to 0.9936.

*b. Precision/Reproducibility:*

The reproducibility of LABType® products combined with LABScan 3D instrument was tested using the LABType® 3D Class I A Locus Typing Test, RSS01A3, product against 16 reference samples in two separate runs using three LABScan 3D instruments, operated by three technicians, on five consecutive days. Three technicians typed 16 reference samples in two separate runs per day, over five non-consecutive days, within a 20 day period for each of the three LABscan 3D instruments, respectively. Based on the analysis of 60,000 data points the reproducibility test results demonstrated 100% concordance in HLA typing results.

An additional reproducibility study was performed to provide supplemental reproducibility data using additional two products, LABType® SSO DRB1 Typing Test (RSSO2B1) and LABType® HD B Locus Typing Test (RSSOH1B) of the LABScan 3D system at three external sites. Three operators per site typed 16 reference samples each in triplicate, twice a day, for 5 non-consecutive days for the two additional LABType® products. Concordance analysis showed that all valuable reactions for both LABType® SSO DRB1 Typing Test (RSSO2B1) and LABType® HD B Locus Typing Test (RSSOH1B) had interpretable outcomes that allowed the assignment of HLA typing results that are in 100% agreement with the reference typing in all sessions.

An internal supplemental reproducibility study of the LABScan 3D instrument was performed using all 3 of the products [LABType® 3D Class I A Locus Typing Test (RSS01A3), LABType® SSO DRB1 Typing Test (RSSO2B1) and LABType® HD B Locus Typing Test (RSSOH1B)] and 3 different LABScan 3D instruments. The HLA concordance analysis demonstrates that 100% concordant in HLA typing results were obtained from 166080 total data points obtained across 3 technicians, 3 products, 90 separate runs, and 3 LABScan 3D instruments.

*Lot-to-Lot Reproducibility*

Lot-to-lot reproducibility for the quality of the microsphere was validated using three manufactured product lots of the LABType® SSO DNA Typing Test (RSS01A3) in one study followed by a supplemental study using three manufactured lots of the LABType® SSO Class II DRB1 DNA Typing Test (RSSO2B1), LABType® HD SSO CLASS I B LOCUS DNA Typing Test (RSSOH1B), and LABType® SSO CLASS II DQA1/DQB1DNA Typing (RSSO2Q). Each contained different lots and regions of 125 microspheres and were tested with the 32 reference samples, in triplicate, in 96-well PCR trays. No reactions were excluded and HLA Typing results for all kits demonstrated 100% concordance.

c. *Linearity:*

Not Applicable

d. *Carryover:*

Not Applicable

e. *Interfering Substances:*

Not Applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

**Stability**

*Microsphere Shelf-life Stability:*

Shelf-life, freeze-thaw, and open vial stability of analyte-specific microspheres are determined by the individual assay manufacturer.

*Calibrator and Verifier Shelf-life Stability:*

Three separately manufactured lots of each calibrator microspheres were stored under normal conditions (2–8 °C) and assessed for stability by recovery, aerobic bioburden, and functionality to establish a 24 month shelf-life. The initial 24 month shelf-life was established through tentative accelerated stability studies where the lots were stored at 33 °C. Recovery and aerobic bioburden were assessed at 13, 39, and 59 days; functionality at 0, 26, and 59 days; and FlexMAP 3D fluorescent/scatter profiling at all timepoints (0, 13, 26, 39, 52, and 59 days). Pre-established accelerated shelf-life specifications were: Recovery  $3.5 \times 10^5$  –  $4.5 \times 10^5$  microspheres/mL; aerobic bioburden < 10 CFUs/mL; and for F3DCAL1 the %CV were required to be  $\leq 6.25\%$  for CL1 and  $\leq 6.75\%$  for CL2 and CL3. If the %CV for each channel was > than 6.25% or 6.75%, respectively, the change from baseline was required to be no greater than 1%. The change from baseline for the assigned values was required to be < 8.5% for the DD Peak, < 3.5% for each mean CL, and < 100 MFI for the RP1 mean background. For F3DCAL2, RP1 was required to be  $\leq 8.0\%$  or  $\leq 1\%$  if the change from baseline was > 8.0% and RP1 median was < 3.5% change from baseline value. For F3DCAL3 the RP1 was required to be  $\leq 15\%$  or  $\leq 1\%$  if > 8.0%. The RP1 median was the same as for F3DCAL2.

Shelf-life was assessed through real-time studies on three separately manufactured lots when the lots were greater than 24 months of age. Functionality of the calibrators and verification microspheres was established by comparison to existing reference lots. Shelf-life specifications established by Luminex were: Recovery: Calibrators  $3.3 \times 10^5$  –  $4.7 \times 10^5$  microspheres/mL. Verifiers:  $1.0 \times 10^6$  –  $1.4 \times 10^6$  microspheres/mL for F3DeVER1 and F3DVER1

and  $6.7 \times 10^5 - 8.7 \times 10^5$  microspheres/mL for F3DVER2. The ranges established include an approximate  $\pm 5\%$  tolerance of the averaged finished goods specifications for individual lots. Aerobic bioburden:  $\leq 10$  CFUs/mL. Functionality: results were required to conform within the specific instrument QC tolerances established for the individual instrument utilized. In all cases, the results from the individual kit lots were within the pre-established specifications.

*Freeze-Thaw Stress Stability:*

Freeze-thaw stability was assessed after each material was subjected to 3 freeze-thaw cycles between  $-20\text{ }^\circ\text{C}$  for 8 hours and thawed at  $2-8\text{ }^\circ\text{C}$  for at least 4 hours. Recovery, size homology, and bioburden were assessed for each classification and reporter calibrators (3 lots) and verifiers (2 lots). The predefined specifications for comparison to the reference were as follows: Recovery: Calibrators  $3.5 \times 10^5 - 4.5 \times 10^5$  microspheres/mL and Verifiers: VER1  $1.1 \times 10^6 - 1.3 \times 10^6$  and VER2  $7.1 \times 10^5 - 8.3 \times 10^5$ ; bioburden (calibrators and verifiers)  $< 10$  CFUs/mL; and size homology (calibrators and verifiers)  $\pm 0.3\text{ }\mu\text{m}$  from reference and  $\leq 5.5\%$  CV. Functionality utilized the same specifications as indicated above for real-time stability. Performance specifications were set at: for F3DCAL1 the %CV was required to be  $\leq 7.3\%$  for CL1 and  $\leq 7.0\%$  for CL2 and CL3. For each CL, if the %CV for each channel was  $>$  than  $7.3\%$  or  $7.0\%$ , respectively, the change from baseline was required to be no greater than  $1\%$ . The change from baseline for the assigned values was required to be  $< 8.5\%$  for the DD Peak,  $< 2.5\%$  for each mean CL, and  $< 100$  MFI for the RP1 mean background. For F3DCAL2, RP1 was required to be  $\leq 8.5\%$  or  $\leq 1\%$  if the change from baseline was  $> 8.5\%$  and RP1 median was  $< 2.5\%$  change from baseline value. For F3DCAL3 the RP1 was required to be  $\leq 15\%$  or  $\leq 1\%$  if  $> 8.0\%$ . The RP1 median was the same as for F3DCAL2. For F3DCAL1, there was a noticeable decrease from the assigned value for the DD scatter profile, however all fell within the specified parameters. One lot of the three was only marginally within, demonstrating a  $-8.47\%$  change from the assigned value. The percent difference from the assigned values for remaining parameters for F3DCAL1, all parameters for F3DCAL2, F3DCAL3, VER1, and VER2 were nominal and fell within the pre-defined specifications and supports the claim that the materials are reliable for at least three freeze-thaw cycles at  $-20\text{ }^\circ\text{C}$ .

*Heat-Stress Stability:*

Two samples per each of three lots of calibrators and two lots of verifiers were subjected to increased storage temperatures from the specified recommended storage temperature to as indicated in the table below:

Set point #	Temperature Type	Temp ( $^\circ\text{C}$ )	Duration (hours)
1	Soak	25	10
2	Ramp to	45	4
3	Soak	45	8

4	Ramp to	30	3
5	Soak	30	6
6	Ramp to	45	3
7	Soak	45	8
8	Ramp to	25	4
9	Soak	25	2

Calibrator and verifier specifications were the same as those used in the freeze-thaw stability studies. All samples were compared to a reference sample for the same parameters measured in the freeze-thaw studies. All results were within the pre-defined parameters and supports the claim that the materials are reliable following a 48 hour heat stress exposure.

Sheath fluid stability:

No additional stability studies were performed

Additional performance data using the One Lambda LABType® SSO DNA Typing Tests assessed during the clearance by CBER under Bk120024, and will be addressed for each assay in the future, to be run on this system.

### **Robustness**

The robustness was tested using 50% less total concentration of microspheres that that specified in the assay protocol to simulate extensive loss of microsphere due to disintegration over a period beyond its shelf life or poor handling during the assay. The use of fewer microspheres is expected to test any effects on performance of the probes due to a change in stoichiometry of the DNA hybridization reaction and a reduction in the number of samples used to generate the mean fluorescent intensity (MFI) values. The LABType® SSO Class II DQA1/DQB1 typing test (RSSO2Q), LABType® SSO DRB1 Typing test (RSSO2B1), and LABType® HD Class I Locus Typing Test (RSSOH1B) with a standard concentration of microspheres was assayed in parallel as the reference assays at a 50% and 100% of the total microsphere concentration defined by the device specification.

The 96 approved reference samples had quantity and quality that meet the criteria described in the product insert. The mean fluorescence intensity values between the test assay with 50% less concentration of microspheres and the reference assay with 100% microspheres concentration showed demonstrated:

Assay kit	Concordance with Reference assays	
	Correlation Coefficient ( $r^2$ )	Overall Agreement (%)
LABType® SSO Class II DQA1/DQB1 Typing test	0.9933	100%
LABType® SSO DRB1 Typing test	0.9958	100%

LABType® HD Class I Locus Typing Test	0.9968	100%
---------------------------------------	--------	------

**Detection Limits**

The detection limits of the LABType® SSO DNA Typing Test Products, using the LABType® SSO DNA Typing Test, LABType® HD Class I B Locus Typing Test (RSSOH1b) and LABType® SSO Class II DQA1/DQB1 Typing test (RSSO2Q) products combined with the LabScan instrument were tested using 8 selected reference samples. Each sample was serially diluted from a concentration of 40 ng/μL down to 20 and 10 ng/μL for a total of 3 different concentrations. All samples tested at all three concentrations had 100% concordance HLA typing results, had average normalized MFI values of 20% or higher for the minimum positive signal and had average positive control probe MFI of at least 500.

**Supplemental External Clinical Study Summary Report**

The purpose of this supplemental external Clinical study was to provide supplemental data for the Reproducibility test using additional two products, LABType® SSO DRB1 Typing Test (RSSO2B1) and LABType® HD B Locus Typing Test (RSSOH1B) of the LABScan 3D system at three external sites.

The scope of this study included supplemental reproducibility testing results of 3 technicians per site who each typed 16 reference samples provided by One Lambda in triplicate, twice a day, for 5 non-consecutive days for the two LABType® products. Concordance analysis showed that all valuable reactions for both LABType® SSO DRB1 Typing Test (RSSO2B1) and LABType® HD B Locus Typing Test (RSSOH1B) had interpretable outcomes that allowed the assignment of HLA typing results that are in 100% agreement with the reference typing in all sessions.

**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.