

Core Equipment ID: LX10006047401

Description: Luminex 200

Room: IQ Building, Rm 2521

Champion: Matthew Bernard

1.0 Purpose

Standardize the process of control, maintenance, and ownership of the Luminex 200 instrument located in IQ Building, Rm 2521.

1.1 Luminex 200 Capabilities

The Luminex is a diagnostic instrument that enables multiplex analysis of up to 100 analytes in a single sample. The Luminex 200 is equipped with 2 lasers: a 635nm classification laser for excitation of beads and a 532nm reporter laser for excitation of the analyte signal (Phycoerythrin). Commercial multiplex kits can be designed or purchased in order to quantify proteins and nucleic acids in a 96-well plate format. A handheld magnetic plate washer, Automated Maintenance Plate (AMP), microtiter plate shaker, bath sonicator, and vortexer are available in the Core Facilities to enable multiplex assay performance. The Luminex 200 has a dynamic range of up to approximately 3-4 logs.

1.2 Luminex xPONENT v3.1 Software Capabilities

- a. Allows you to perform analysis of acquired data, review and print reports, and perform Luminex system maintenance.
- b. Instrument Control - Allows the application to connect to and communicate with an instrument identified by a specific serial number.

2.0 Reason for Issue

Maintain a document that describes the Standard Operating Procedures that allows for the standard safe and optimal use of the Luminex 200 instrument within the Pharmacology and Toxicology Core Facilities.

3.0 Process Description

Allow Core Facility Users within the Pharmacology and Toxicology Department to properly and effectively use the Luminex 200 instrument. The process description details the standard use of the Luminex 200 instrument. The controlled standard must maintain and adhere to proper and approved research and regulatory qualitative conditions.

- 3.1 SOP: 2521.001 for Luminex 200 instrument, authored by Matthew Bernard, created on 08/11/2016, issued on 12/14/2017.
- 3.2 SOP 2521.002 amendment, authored by Matthew Bernard, on 3/31/2020, issued on 4/15/2020.
- 3.3 SOP: LX10006047401.2521 applies to any User and / or Trainer of the Luminex 200.

- 3.4 **Responsibilities:** All Users are responsible for obtaining the proper approval and training before the use of the Luminex 200 instrument. All Users are responsible for the proper use, according to defined protocol, when using the Luminex 200 instrument
- a. **New Users** need a Windows user account created for equipment access, before initial use. New accounts are authorized and created by the Equipment Champion and / or the Core Facility Director/Manager. A new account may be created after training and equipment approval has occurred.
 - b. **All users are expected to have completed EHS training programs Bloodborne Pathogens and Biosafety Principles, as required for respective research projects.**
 - c. All Users must fill out **Appendix I** Questionnaire prior to use of instrumentation in the facility.
 - d. **All Users** must schedule equipment using the iLab Solutions portal.
 - e. **Approved Users** must record all equipment use in the Equipment Usage Logbook (**Appendix II**) post-use on the same day as the recorded use. The Logbook is located on the desk next to the Luminex 200 instrument. Within the Logbook on the current log sheet, Users must record the following: Date, PI, Name, Lab Location, Phone Number, Program, Sample Type, Number of Plates Run, and Error Messages, as appropriate.
 - f. Only covered samples may enter Room 2521. Samples must be brought to the facility in a standard **spill control box/leak-proof secondary container** that will contain any multiple tube or plate spill, per EHS standards (see Section 4.14d). All tubes and plates should be capped to maintain containment of samples. Seal multi-well plates with plate sealer or parafilm. Spill control boxes must be labeled with Biohazard identification for BSL-2 samples.
 - g. If microtiter plate shaker or hand-held magnetic separation block are removed from Rm 2521 for use in another Core Facility (e.g., Cold Room Core Facility), **this equipment must be decontaminated** and returned to Rm 2521 immediately following its use.
 - h. Immediately after use, the Luminex 200 instrument must be appropriately shut down (see Section 4.10).

3.5 **Equipment Safety Issues**

- a. **Safety Issues** – The Core Facility operates up to BSL-2 plus. Biosafety level and limitations for this facility are restricted to WHO and NIH risk groups defined as:
Risk Group 1 – Agents that are not associated with disease in healthy adult humans (no or low individual or community risk)
Risk Group 2 – Agents that are associated with disease which are rarely serious and for which preventive or therapeutic interventions are often available (moderate individual risk but low community risk).

Examples of risk groups 1 and 2 which may be analyzed include: 1) Plasma or serum from non-primate animals; 2) cell supernatants from cell lines of ATCC origin and those tested negative for human immunodeficiency virus (HIV), hepatitis C virus (HCV), hepatitis B virus (HBV), and Epstein-Barr virus (EBV); 3) primary human serum or plasma if tested for HIV, HBV, HCV, and EBV; 4) Supernatants from primary human cells if tested for HIV, HBV, and HCV; 5) Supernatants from genetically modified cell lines using third generation lentivirus systems.

Research involving BSL-3 or BSL-4 requirements are not supported, which includes WHO and NIH risk groups 3 and 4.

- b. **All samples exposed to or infected with bacterial or viral agents must be approved by EH&S on a case-by-case basis.** A related HURON Click must be submitted and approved by EH&S prior to scheduling analysis.
- c. **Decontamination of Luminex 200 post-operation:**
Following the Shutdown procedures (Section 4.10) will result in appropriate daily decontamination of the instrument between uses.
- d. Wash procedures utilizing the hand-held magnetic separation block should be performed within appropriate biosafety controls according to sample origin (e.g., washing performed in BSC if BSL-2).
- e. **Decontamination of work surfaces:**
External surfaces in front of the Luminex 200, hand-held magnetic plate washer, and plate shaker can be cleaned with Envirocide (or equivalent) or wiped with Sani-Cloth Plus germicidal wipes (or equivalent). Keyboard and mouse can be wiped with Sani-Cloth Plus germicidal wipes (or equivalent).
- f. **Spill control:**
Samples must be brought to the facility in a standard spill control box that will contain any multiple tube or plate spill (see Section 4.14d). All tubes and plates should be capped to maintain containment of samples. Seal multi-well plates with plate sealer or parafilm. Plate sealers will be removed just prior to running plates on the Luminex 200.

Report spills to the Core Facility staff.

In the event of a spill for BSL-2 samples, the spill should 1st be covered with absorbent paper towel, which will then be saturated with 10% bleach and allowed to soak a minimum of 10 minutes. The wet towel should be placed in a biohazard waste container after contact. The spill area will then be covered with 10% bleach, allowed to soak briefly, and then wiped up with an absorbent towel. After cleaning the spill, dispose of the absorbent material and gloves into a biohazard waste container. Squeeze bottles of 10% bleach are made fresh daily for spill control.

Report spills to Core Facility staff.

- g. **Radioactively labeled samples are prohibited.**

- h. Ensure that the Luminex 200 waste tank is filled with enough bleach to result in 10% bleach solution following use. Pour bleach waste down the sink after a minimum contact time of 10 minutes following shutdown.
- i. **Instrument Issues, Plates:**
Only plates supplied with kits or equivalent plates may be used. Greiner flat-bottom, clear-bottom, black micro-titer plates, VWR Catalog #82050-754 are recommended.

3.6 Laboratory Conditions

- a. IQ 2521 is a BSL-2 research lab with negative air pressure air flow. The lab door must be closed at all times. The room contains a sink for hand washing, germicidal soap, emergency eye wash station, and spill control kit/equipment. 500 mL squeeze bottles of 10% bleach are made fresh monthly for use with instrumentation and spill control.
- b. **Signage:** Currents BSL-2 and Chemical safety signs having laboratory practices and emergency contact information will be found at the door of Rm 2521.
- c. **Access:** Access is limited to people with permission to run samples on the Luminex 200, which has been booked through the iLabs web portal. Only individuals involved in training exercises, running samples on the Luminex or other instrumentation in the room, or retrieving data should be in Rm 2521.
- d. **PPE Requirements:** Standard PPE must be used at all times, which includes gloved hands, long-sleeve lab coat over full and coverage shirt and pants, and full coverage shoes with intact soles.
- e. All samples will be handled with BSL-2 precautions, including proper handling, storage, transportation, disposal, and decontamination according to the MSU Biosafety Manual.
- f. **Exposure Control Plan:** Please refer to the Exposure Control Plan available on the MSU EHS website for instructions regarding what to do in the event of an exposure. The MSU Exposure Response Procedure is posted in Rm 2521.
 - i. **Eye/Mucous Membrane Exposure:** Flush immediately at nearest eyewash station for 15 minutes.
Wounds/Needlesticks: Wash the area immediately, use warm water and sudsing soap to scrub the area for 15 minutes.
 - ii. Notify your supervisor immediately if he/she is available.
 - iii. Print Authorization to Invoice MSU Form to take to care facility.
<https://www.hr.msu.edu/benefits/workers-comp/documents/InvoiceMSU.pdf>
 - iv. Report to a Lansing Urgent Care facility for post-exposure follow-up as soon as possible.
<https://www.lansingurgentcare.com/>

- v Be prepared to provide information about the agent or cells involved in the accident. Additionally, route of exposure, dose/concentration, unusual characteristics of the agent, animal infection, cell line, and PI contact information.

Note: Any required follow up visits must also take place at Lansing Urgent Care. The location in Frandor is open 24 hours.

- vi Follow up by completing the Report of Claimed Occupational Injury or Illness Form with your supervisor within 24 hours.
- g. Sample handling and decontamination within IQ Rm 2521 is covered in Section 3.5. All tubes, pipettes, plates, etc. that represent a biological hazard must be removed by the user and returned to their lab. Waste containers are available for non-hazardous waste. A biological waste container for waste generated during a biohazard cleanup is available in the lab. **No needles are permitted in the Core Facility.**
- h. **Eating, drinking, or use of personal care products are prohibited in the facility.** Use of personal electronics will not be allowed if that use interferes with proper operation of the instrumentation in the facility. Those operating instrumentation in the facility must remove gloves and wash their hands before using any personal electronic device. Sani-Cloth Plus germicidal disposable wipes are available for wiping **keyboards and personal electronic devices if cross-contamination accidentally occurs.**
- i. **Medical:** Users of the facility should have all current vaccinations, including those for HepB. Anyone who may be immune-compromised should visit Occupational Health before working in the facility.

3.7 Contact Information

- a. **Matthew Bernard: Core Director**, Office, IQ Building, Rm 2315 (517)355-4076; (585)703-5008 (cell)
- b. **Environmental Health & Safety:** 355-1053
- c. **Occupational Health (University Physician's Office):** 353-8933
- d. **MSU Police:** 355-2221

3.8 Quality Measures

- a. Daily:
When in use, perform Performance Verification prior to running the Luminex 200 instrument to ensure the system is in proper working order before running samples. Once performance verification has completed, the date, time and person who performed the procedure must be recorded in the Luminex Equipment Log (**Appendix III**).
- b. Monthly:
Calibration and Performance Verification should be performed on the Luminex 200

instrument at least once per month. Use the Luminex xPONENT 3.1 Software User Manual (see section 4.14a) to perform these monthly quality assurance measures. Once system calibration has been completed, the date, time and person who performed the calibration and performance verification, must be recorded in the Luminex Equipment Log (**Appendix III**). The instrument should also be recalibrated if the delta calibration temperature exceeds $\pm 3^{\circ}\text{C}$, the system is moved, system acquisition is low/sporadic, or maintenance is performed on the system.

4.0 Procedure: Luminex 200 Use

4.1 Startup

- a. Empty waste tank if needed.
- b. Turn on in order: computer, laser unit, XY stage unit, and fluidics.
- c. Log into the computer. Sign in under User Account Name and password, as appropriate.
- d. Click on the Luminex xPONENT desktop icon to start the software. This software runs the Luminex 200 instrument.

4.2 Adjusting the Sample Probe Height

- a. Open the *Home* page and select the *Probe & Heater* tab. Select the appropriate well that will be utilized for setting the probe height using the Automated Maintenance Plate (AMP), then load with well strips or an appropriate 96-well plate (See Section 3.5i for recommended plates).
- b. Place 2 alignment disks (flat-bottom), 3 large alignment disks (filter-bottom), or one sphere (v-bottom) in the designated well of the appropriate plate. Probe may be sonicated in a tube containing clean deionized H₂O, if cleaning is necessary.
- c. Click *Eject*, place the plate on the plate holder, and click *Retract* plate.
- d. Select the plate type from the *Plate Type* drop-down list.
- e. Remove the plastic shield that houses the sample probe. Gently loosen the front sample probe adjustment screw and click *Move Probe Down*.
- f. Gently move the sample probe down until it touches the alignment discs or sphere, but does not depress the plate holder (view through open XY door while adjusting).
- g. Tighten the sample probe adjustment screw and click *Move Probe Up*.
- h. Open the XY door and click *Move Probe Down* to watch as the probe moves down into the designated well. The plate should not bounce when the probe reaches the bottom.
- i. Click *Sample Probe Up*, *Eject*, remove the plate from the plate holder, retract the plate holder, and return alignment discs or spheres to their appropriate storage location.

- j. Replace the plastic shield that covers the sample probe.

4.3 System Initialization

- a. Perform *Flow Core Revive after Storage* routine if the fluidics have not been run through the Luminex 200 in over 30 days, or as appropriate. Open the *Maintenance* page, *Cmnds & Routines* tab. Click *Revive after Storage* in the *Commands* section at the left of the screen, and delete (*clear*) *Warmup* step (warmup will automatically occur upon instrument startup and will take 30 minutes to complete). Alternatively, perform a *Flow Core Startup* routine if fluidics have been run recently. Setup AMP or equivalent 96-well plate, as appropriate. If using AMP, relocate Wash and Drain wells to appropriate reservoirs. *Eject*, load plate, and click *Retract*. Click the *Run* button at the bottom right to begin the procedure.
- b. Proceed only after the *Warmup* is complete. Complete System Initialization steps d-j if calibration and performance verification are necessary. Complete System Initialization steps k-p if only performance verification is necessary. See Section 3.8 for information regarding when appropriate quality measures should be performed.
- c. On the *Maintenance* page, under the *Auto Maint* tab, click *Calibration/Verification*.
- d. Select the *performance verification kit* from the *Performance Verification kit* list at the right of the tab. Kit information (.lxl filename extension) can be uploaded from CDs accompanying each kit.
- e. Select the *calibration kit* from the *Calibration Kit* list. Kit information (.lxl filename extension) can be uploaded from the CDs accompanying each kit.
- f. Vortex the xMAP calibrator, verification, and fluidics containers to ensure homogeneity. Do not dilute xMAP calibrator or verification agents.
- g. Click *Eject* on the status bar, and then place the microtiter plate on the plate holder.
- h. Load an appropriate microtiter plate or well-strip equipped AMP with at least five drops of the beads from the Calibration and Performance Verification kit as indicated on the plate image and in the kit insert instructions. Add deionized H₂O and 70%, as indicated.
- i. Click *Retract* and *Run*.
- j. If deemed unnecessary to perform Calibration (see Section 3.8), Performance Verification should be performed, at a minimum. On the *Maintenance* page, under the *Auto Maint* tab, click *Performance Verification*.
- k. Select the *performance verification kit* from the *Performance Verification kit* list at the right of the tab. Kit information (.lxl filename extension) can be uploaded from the disc that accompanies each kit.
- l. Vortex the xMAP verification and fluidics containers to ensure homogeneity. Do not dilute xMAP verification agents.
- m. Click *Eject* on the status bar, and then place the microtiter plate on the plate holder.

- n. Load an appropriate microtiter plate or well-strip equipped AMP with at least five drops of the beads from the Performance Verification kit as indicated on the plate image and in the kit insert instructions. Add deionized H₂O and 70%, as indicated.
- o. Click *Retract* and *Run*.
- p. Once calibration and/or performance verification has successfully finished, document as described in Section 3.8.

4.4 Assay Plate Setup

Refer to the product insert within each kit for protocols pertaining to kit-specific assay procedures.

4.5 Hand-held Magnetic Plate Washing

The hand-held magnetic separation block may be used at appropriate washing steps while following an assay protocol.

- a. Place the plate containing magnetic beads on the hand-held magnetic separation block and secure the plate using the block's adjustable clip system.
- b. Allow the plate to sit on the block for 60 seconds to allow beads to settle by magnetic separator.
- c. Following the 60 second incubation, firmly grasp the base of the block in one hand over an appropriate waste receptacle (See Section 3.4g/3.5d). In one fluid motion turn the top of the plate so that it faces the bottom of the waste receptacle and move the block/plate in one swift downward motion to discard the plate's liquid content's into the waste receptacle.
- d. Gently tap the plate 3-4 times on absorbent towels/pads to remove any residual liquid from the walls of the plate wells.
- e. After discarding the liquid reagents, open the block's adjustable clips and remove the plate from the block.
- f. Using a multi-channel pipette, add 200 µL of wash buffer per well, as appropriate.
- g. Secure a plate sealer to the assay plate and place the plate on the microtiter plate shaker. Shake on a setting of approximately 500-600 rpm for 30 seconds.
- h. Remove the plate from the shaker and remove the plate sealer.
- i. Repeat hand-held magnetic plate washing steps a-h, as appropriate.
- j. Wipe down hand-held magnetic plate with 70% ethanol when washing is completed

4.6 Creating/Editing a Protocol

- a. Select the *Protocols* page to begin. Select *Create New Protocol* or select existing protocol to edit.
- b. Enter or verify the protocol name, version, and manufacturer. If editing a protocol a new version must be entered before proceeding.

- c. Within the *Acquisition Settings* panel enter or verify the bead type (MagPlex for magnetic beads), sample volume, timeout, XY heater (if appropriate), DD gate, and reporter gain (Default or as appropriate).
- d. Select analysis type (quantitative, qualitative, allele call, or none).
- e. Select number of standards and number of controls, if appropriate.
- f. Select *Fit of all Standards* or *Mean of Replicates*.
- g. Select *Analyze results while acquiring samples* if you want to view results in real-time.
- h. Click *Next* to open the *Select Analytes* tab. Select the appropriate analytes by clicking the bead number. The table on the right allows you to name the analyte and select the analysis type, units, and bead count. Do not check the box that states "Stop after total bead count reaches - 100 beads." This will end the acquisition of a well after the overall total bead count reaches 100 beads.
- i. Click *Change* to change the analysis settings.
- j. Click *Next* to open the *Plate Layout* tab. Add standards, controls, and unknowns, as appropriate.
- k. Enter sample *Well ID* and *Dilution*, as appropriate.
- l. Click *Save* to save the protocol.

4.7 **Creating a Kit**

Standards and Controls may be entered as kits where lots can be saved individually. Lots can be reused individually in later applications.

- a. On the *Protocols* page, click the *Stds & Crtls* tab.
- b. Click *Create New Std/Ctrl Lots*. The *Std/Ctrls Details* page appears.
- c. Select the appropriate protocol and click *OK*.
- d. In the *Lot Details* panel, enter the following information, where appropriate:

Kit name, Std/Ctrl lot number, expiration date (must be in the future), and manufacturer

Assay standard or control information such as name, lot number expiration, manufacturer, and standard or control values for each analyte.
- e. Enter the concentration of the top standard in the *Assay Standard* spreadsheet (these are kit- and/or lot-specific). Enter the dilution performed for the standards, highlight appropriate wells for which that dilution will be applied and select the button to *Apply Values*.
- f. Click *Save*. Once kits and lots are created, they can be used with other protocols.

4.8 **Creating and Running a Batch (Plate)**

Creating and running a Batch is equivalent to acquiring an individual plate containing samples. To create a new batch from an existing protocol:

- a. Open the *Batches* page.
- b. Click *Create a New Batch from an Existing Protocol*.
- c. Type the batch name in the *Batch Name* box. **Include Lab Name and Date.**
- d. Click the protocol you want to use in the *Select a Protocol* list. If the protocol you select uses standards and/or controls, the active reagents are shown on the bottom of the screen. Verify that these are the correct standards and controls.
- e. Click *Next*.
 - i. If the protocol you selected uses standards and controls, the *Stds & Ctrl's* tab appears. View the details of the active reagents and verify that they are correct; apply different assay standards and controls, or manually enter new information. Click *Next*. The *Plate Layout* tab appears.
 - ii. If the protocol you selected does not use standards and/or controls, the *Plate Layout* tab appears.
- f. On the *Plate Layout* tab, assign well commands for this batch. Add samples to the plate layout if needed.
- g. Click *Run Batch* to begin batch (plate) acquisition, or click *Save* to save the batch information to the *Pending Batch* list, to be run at a later time.
- h. Current and previously run batches can be observed or analyzed on the *Results* page. To view batch data, open the *Results* page, select *Current Batch* or *Saved Batches* tab, as appropriate. Highlight the appropriate batch and click *Open*.
- i. Run an alcohol flush, wash, and/or drain between plates, when appropriate. Open the *Maintenance* page, *Cmds & Routines* tab. Select appropriate wells for each command in the *Commands* section. Setup AMP or equivalent 96-well plate, as appropriate. *Eject*, load plate, and click *Retract*. Click the *Run* button at the bottom right to begin the procedure.

4.9 **Generating Reports**

- a. To run, print, and/or save a report: click the *Results* page, and click the *Reports* tab.
- b. In the *Report* list, click the report you want to view.
- c. In the *Type* list, select the type of report you want to view.
- d. Select the item for which you want to generate the report. If you are creating a *Batch Report*, select the analytes to include in the report.
- e. Click *Generate*. The report will appear in the lower part of the *Reports* tab.

- f. Click *Save* to save the report as a PDF file. Analyte data will save individually unless *Save All* is selected. Data can be exported on a thumb drive.
- g. To view a data interpretation report: open the *Results* page and select the *Reports* tab.
- h. Select *New Report*, then *Batch Report*, then *Data Interpretation*.
- i. Select a previously run batch. Click *Generate Report*.
- j. Click *Save* to save the report as a PDF file. Click *Export (.csv)* to save data in a format that can be opened in Excel. Data can be exported on a thumb drive.

4.10 Shutdown

- a. On the *Home* page, click *Shutdown*. The *Auto Maint* tab opens, with *System Shutdown* selected.
- b. Fill the appropriate wells of an appropriate 96-well plate or AMP with deionized H₂O and 10% bleach, as indicated by the xPONENT software.
- c. Load the plate, click *Retract*, and click *Run*.
- d. Once Shutdown is complete, remove the AMP and rinse with deionized water and let it dry on a paper towel. 96-well plates may be discarded or retained for secondary use of alternative wells on a subsequent initialization or shutdown procedure.
- e. Log out of the xPONENT software and shut down the computer.
- f. **Turn off in order: fluidics, XY stage unit, and laser unit.**
- g. Empty waste tank, containing ~10% bleach down the sink while wearing appropriate PPE (e.g., lab coat, safety glasses, and gloves) and rinse with DI water.
- h. Clean keyboard, mouse, and work surfaces in front of the Luminex 200 with Envirocide (or equivalent) or with Sani-Cloth Plus germicidal wipes (or equivalent).

4.11 Core Materials

Core Materials for the Luminex 200 instrument include: A handheld magnetic plate washer, Automated Maintenance Plate (AMP), microtiter plate shaker, bath sonicator, vortexer, Calibration bead kits, Verification bead kits, sheath solution, ethanol, and bleach.

4.12 User Materials

Luminex 200 system User Materials may be located and purchased from the below web addresses. The available materials typically include stocked or custom multiplex kits. Users are individually responsible for the compatibility, maintenance, and purchase of these materials.

https://www.emdmillipore.com/US/en/life-science-research/protein-detection-quantification/Immunoassay-Platform-Solutions/milliplex-multiplex-assays-using-luminex/UjGb.qB.8WQAAAE_rn8RHeN,.nav

<http://www.bio-rad.com/en-us/category/bio-plex-multiplex-immunoassay-system>

<https://www.thermofisher.com/us/en/home/life-science/protein-biology/protein-assays-analysis/luminex-assays.html>

<http://www.ebioscience.com/application/gene-expression/quantigene-plex-assay-workflow.htm>

<https://www.rndsystems.com/products/luminex-assays-and-high-performance-assays>

4.13 Records

- a. **Records of Use** – All Luminex 200 system use must be recorded. Refer to 3.3e.
- b. **Error Messages / System Issues** – All error messages and system issues must be relayed to the Equipment Champion and the Core Facility Director/Manager and appropriately recorded, refer to 3.3e, on the same day as equipment use.

4.14 Resource Index

- a. Luminex 200 and xPonent User Guide:
Luminex 200 instrument and xPONENT software literature and resources for the following items can be found at the link below. Printed versions of these resources can also be found in the cabinet above the Luminex 200 instrument in room 2521. For detailed information about the functions, features, and use of Luminex xPONENT 3.1 software, see the Luminex xPONENT 3.1 Software User Manual, available at:

<http://www.luminexcorp.com/support/>

- b. xMAP Calibrator and Verification Bead User Guide:
Before you can calibrate the system, you will need to add xMAP Calibrator and Verification bead lot information. This information is located on the CDs that accompany the Calibration and Performance Verification kits (.lxl file extension) and are also available on the Luminex website at:

<http://www.luminexcorp.com/support/supportresources/>

- c. Luminex Technical Support is available to users in the U.S. and Canada by calling 1-877-785-BEAD (2323). Inquiries can also be sent by email to support@luminexcorp.com.

Millipore Company Representatives:

Dana Patcas
Field Applications Scientist
dana.patcas@emdmillipore.com
1-800-645-4567 ext. 6807

Jason Lemberg
Customer Support/Biomarker and Cytometry Specialist
jason.lemberg@emdmillipore.com
(317) 379-1062

- d. **Transport of Biological Materials:**
For detailed information about the transport of biological materials, see the EHS recommended procedures available at:

<https://ehs.msu.edu/lab-clinic/shipping/bio-transport-local-vehic.html>

5.0 Competences, Authorization and Training

New Users must receive proper authorization from either the Equipment Champion and / or Core Facility Director/Manager before equipment use. A new User may contact the Equipment Champion or Director/Core Facility Manager to schedule training. Training includes SOP and instrument familiarization and any additional required or specialized training. Once training is complete authorization may be issued and a system account and password may be set up. All Users are individually responsible for current SOP familiarization. All New Users must refer to 3.3a during new Luminex 200 instrument account creation.

6.0 SOP Performance and Equipment Review

The effectiveness of the SOP: LX10006047401.2521.001 will be monitored by the Core Facility Director/Manager, Equipment Champion and All Users. Any procedural or qualitative deviations will be reflected within an updated SOP. Any Approved User should aptly report any procedural or qualitative issues and / or errors to the Core Facility Director/Manager or Equipment Champion. The Core Facility Lab Director/Manager and Equipment Champion's name and contact information can be found on the Pharmacology and Toxicology Core Laboratory in iLabs. Updated SOPs will be published and Approved Users will be notified. SOP: LX10006047401.2521 reviews will occur every two years.

7.0 Definitions

- 7.1 **SOP:** Standard Operating Procedure, which is a standard guide that officially standardizes the process of control, maintenance, and ownership of the Luminex 200 instrument. The SOP number stands for (xxx . xxx . xxx) equipment serial number . room number . SOP version number.
- 7.2 **Originator / Author:** The individual representing the Pharmacology and Toxicology Core Facilities that created SOP: LX10006047401.2521.
- 7.3 **Stakeholder:** Any individual that uses or performs the task of which is the subject of the SOP, including the Pharmacology and Toxicology Core Facilities Department.
- 7.4 **New User:** An individual who has not completed the requirements of section 3.4.
- 7.5 **Approved User:** An individual who uses the Luminex 200 instrument and has fulfilled section 3.4. This title may only be given by the Equipment Champion and / or the Core Facility Director/Manager.
- 7.6 **Champion:** An individual whose direct expertise with the Luminex 200 instrument has been recognized by the Pharmacology and Toxicology Core Facility Committee. This title may only be awarded by the Pharmacology and Toxicology Core Facility Committee.

8.0 Approvals

The below signatures and dates are required for full SOP approval and implementation.

This SOP was written/authorized by:

Dr. Matthew Bernard Matthew Bernard 4/13/20

This SOP was reviewed by:

Dr. Daniel Vocelle Daniel Vocelle 4/13/2020

Issue Date: 4/13/20

Department of
**Pharmacology
& Toxicology**



Appendix I

MSU Flow Cytometry Biosafety Questionnaire

The MSU Flow Cytometry core facility is now operating under BSL-2 laboratory conditions. This questionnaire serves to gather information important information that will help us render effective core facility services. Part I provides information about the Principal Investigator, each of the independently funded research projects, and the researchers associated with each project. Part II will identify the samples to be analyzed.

Part I

Principal Investigator:
Department: College:
Office Location (building/room):
Office Phone:
E-mail:

The following questions are designed to ID individual grants or projects.

Funding agency:
Project Title:
Grant # or project #:
Account # to be charged for services rendered:
Business Office Address:

Please ID the instrument samples will be analyzed on: Select an instrument

Identify researchers working on this project:

Part II - The Samples

List the type of samples (e.g., animal, human, plant, bacteria) and sources (e.g., spleen, bone marrow, cultured cells):

Has the research protocol used to generate these samples been reviewed by the appropriate Animal (IACUC, please provide AUF #) or Human use Committees (please provide IRB identification and/or EH&S BMR ID#/CLICK#)?

Biosafety level required:

Will the samples be fixed prior to flow cytometric analysis or sorting? Yes No

If yes, describe the fixation protocol:

Required for BSL-2 samples:

Were tissue/blood donors screened for the following pathogens: HIV, SIV, HepB, HepC, HepD, Herpesvirus simiae, HTLV-1, HTLV-2, LCMV, SARS, Mycobacteria tuberculosis, Mycobacterium bovis, Neisseria meningitides?

Yes: (List pathogen and the test results)

No: Unknown

Does the sample contain any other known infectious agents, if so please describe?

Has the infectious agent been inactivated? If so, please describe the method:

What precautions does the facility need to employ to safely handle these samples?

Required for Genetically modified samples:

Identify the method of cell transformation. If a virus was used, please identify it:

Were the cells genetically engineered? Yes No

If yes, how were they genetically altered?

What precautions should be taken with these cells?

Once completed and reviewed by the PI, please sign and date the form.

Researcher (Print)

Researcher (Signature)

Date

PI (Print)

PI (Signature)

Date

Return the completed form to your appropriate core manager:

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