Seravue® ELISA Kit Datasheet

Version: 01

Product Name: Seravue® ELISA Kit

Catalog Number: LCS-001

Assay Type: Sandwich

Detection Method: Colorimetric

Reactivity: Human

Sample Type: Serum

Storage and Stability

- Store unopened kits at 2-8°C upon receipt. The kit is stable for up to 12 months from the date of manufacture.
- After opening, store components at 2-8°C. Keep the microplate in the provided sealed bag with desiccants.

For Research Use Only. Not for Use in Diagnostic Procedures.

1. Intended Use for Research: The Seravue® LC-SPIK ELISA Kit is designed exclusively for research applications to be performed by trained laboratory professionals. Its purpose is the quantitative determination of LC-SPIK levels in human serum samples within a controlled research setting. The performance characteristics of this product for any diagnostic or clinical use have not been established. Data generated should not be used to inform patient care, or be added to a medical record, or be relied upon for any clinical decision-making.

2. User Agreement & Restrictions: By opening or using this product, the purchaser agrees to the terms of this Limited Use Label License.

- **Internal Research:** This product is for the purchaser's internal research purposes only.
- **No Redistribution:** The kit, its components, or any materials derived from its use may not be resold, redistributed, or transferred to any third party without prior written consent from ImCare Biotech, Inc.
- **Commercial and Service Restrictions:** This product may not be used to provide fee-for-service testing, for contract research, or be incorporated into any product for sale or clinical service.
- **Other Uses:** For any use outside of internal research including clinical evaluation a separate license is required. Please contact ImCare Biotech, Inc. to obtain written permission and establish the appropriate agreements.

3. User's Responsibilities: The user is solely responsible for adhering to all applicable laboratory safety practices, validating the performance of the assay for their specific research applications, and ensuring the proper handling, storage, and disposal of the kit and its components.

4. Disclaimer of Warranty: This product is supplied "AS IS" without any warranty, express or implied. ImCare Biotech, Inc. specifically disclaims any warranty of merchantability or fitness for a particular clinical or diagnostic purpose. No medical claims are made or implied.

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Principle of the Assay

This kit employs a quantitative sandwich enzyme immunoassay technique. A capture antibody specific for human LC-SPIK is pre-coated onto a 96-well microplate. When standards and samples are added, the LC-SPIK binds to the immobilized antibody. A horseradish peroxidase (HRP)-conjugated detection antibody is then added, which binds to a different epitope on the captured LC-SPIK. After washing, a TMB substrate solution is added, reacting with the HRP to produce a blue color. The reaction is terminated by a stop solution, turning the color yellow. The optical density is measured at 450 nm, and the intensity is directly proportional to the concentration of LC-SPIK in the sample.

Kit Components

- **LC-SPIK Microplate (1):** 96-well plate (12 strips x 8 wells)
- **LC-SPIK Standard (6 vials):** 10x concentrate (10, 5, 2.5, 1.25, 0.625, 0.31 ng/mL)
- **0 ng/mL Calibrator (1 vial)**
- **Positive Control (1 vial)**
- **HRP Detection Antibody (1 vial):** 100x concentrate
- **Assay Diluent (1 bottle)**
- **Wash Buffer Concentrate (2 bottles):** 20x
- **TMB Substrate (1 bottle)**
- **Stop Solution (1 bottle)**

Materials Required but Not Supplied

- Microplate reader capable of endpoint measurements at 450 nm
- Adjustable single/multi-channel micropipettes (10 µL to 1000 µL) and disposable tips
- Deionized or distilled water
- Plate shaker/mixer
- Automated plate washer (optional)

Assay Protocol

Reagent Preparation

- Bring all reagents and samples to room temperature (18-25°C) before use.
- Briefly spin all tubes before opening.
- **Wash Buffer (1x):** Dilute the 20x Wash Buffer Concentrate 1:20 with distilled water (e.g., add 50 mL of concentrate to 950 mL of water).
- **Detection Antibody (1x):** Prepare within 1 hour of use. Dilute the 100x HRP Detection Antibody 1:100 with Assay Diluent. Mix thoroughly.

Assay Procedure (Total time: ~2 hours 15 minutes)

1. Secure the desired number of wells.
2. Add **90 µL of Assay Diluent** to each well.
3. Add **10 µL** of Standard, Control, or sample to the appropriate wells.

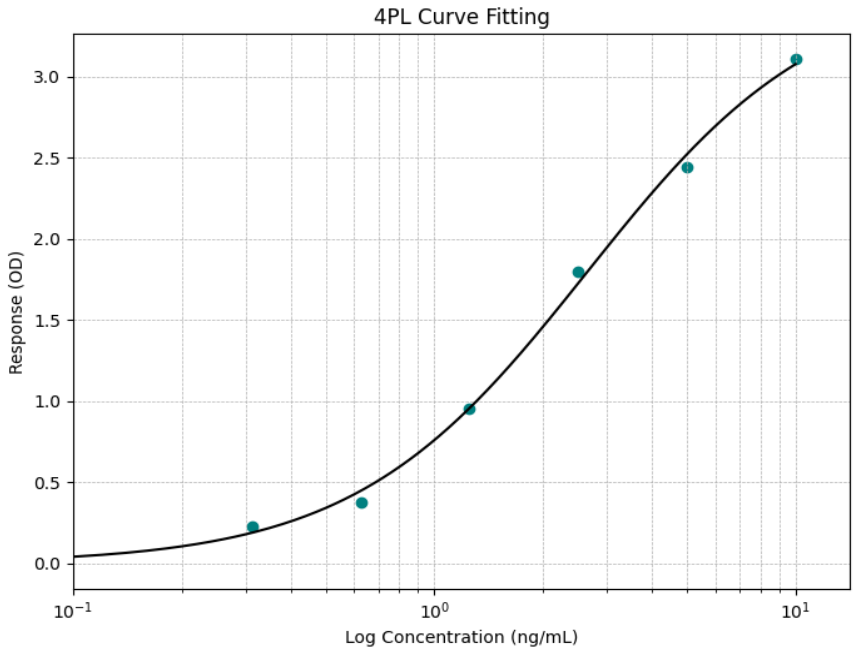
4. Mix on a plate shaker for 30 seconds at 1000 RPM.
5. Cover the plate and incubate for **60 minutes at 37°C**.
6. Wash the plate 5 times with 1x Wash Buffer. Tap plate on absorbent paper to dry.
7. Add **100 µL of 1x HRP Detection Antibody** to each well.
8. Cover the plate and incubate for **45 minutes at 37°C**.
9. Wash the plate 5 times as in step 6.
10. Add **100 µL of TMB Substrate** to each well.
11. Cover the plate and incubate for **10-20 minutes at room temperature in the dark**.
12. Add **100 µL of Stop Solution** to each well.
13. Read absorbance at 450 nm immediately.

Calculation of Results

1. Calculate the mean absorbance for each set of duplicate standards, controls, and samples. Duplicates should have a CV of <20%.
2. Create a standard curve by plotting the mean absorbance (y-axis) against the standard concentration (x-axis).
3. Use a 4-parameter logistic (4PL) curve fit to determine the concentration of samples.
4. **Multiply the concentration read from the standard curve by the dilution factor of 10.**
5. Samples with a calculated concentration greater than 100 ng/mL should be diluted further with Assay Diluent and re-assayed for accuracy.

Performance Characteristics

- **Limit of Detection:**0.04 ng/mL
- **Precision:**
  - **Intra-Assay Precision (CV%):** <10%
  - **Inter-Assay Precision (CV%):** <11%
- **Linearity:** 0.15-10 ng/mL
- **Example Standard Curve:**



Limitations of the Procedure

- For Investigational Use Only. Not for use in diagnostic procedures.
- Do not use kit components beyond the expiration date.
- Do not mix or substitute reagents from different kit lots.
- Follow the protocol exactly. Any deviation may lead to inaccurate results.