

Certificate of Analysis

Product name: Seravue LC-SPIK cGMP ELISA Kit

Product Number: LCS-001 cGMP

Lot Number: 250506011A

The components of this product have been tested and meet all quality specifications.

Acceptance Criteria	Performance
Calibrator Level 6	OD at 450 nm - 3.428
Calibrator Level 1	OD at 450 nm - 0.239
Positive control S2-3 media	OD at 450 nm - 3.377
Negative control - Blank	OD at 450 nm - 0.010
Intra Assay CV	$\leq 5\%$
Accuracy LLOQ (0.312 ng/mL)	120.00
Accuracy LQC (0.937 ng/mL)	115.00
Accuracy MQC (3.00 ng/mL)	115.51
Accuracy HQC (7.5 ng/mL)	119.52
LOD	0.0074 ng/mL
Linearity range	5.0 – 0.312 ng/mL, $R^2 > 0.99$
Slope factor (Sensitivity)	1.022
4PL R^2	0.998

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