

Certificate of Analysis

Product name: AFP ELISA Kit

Product Number: AFP-001

Lot Number: AFPRUO091125

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

Acceptance Criteria	Performance
Calibrator Level 7	OD at 450 nm - 3.92
Calibrator Level 1	OD at 450 nm - 0.10
Negative control - Blank	OD at 450 nm - 0.01
Intra Assay CV	$\leq 5\%$
Accuracy LLOQ (0.25 ng/mL)	124.34
Accuracy LQC (0.75 ng/mL)	107.52
Accuracy MQC (4.8 ng/mL)	99.90
Accuracy HQC (12.0 ng/mL)	113.05
LOD	0.055 ng/mL
Linearity range	20.0 – 0.50 ng/mL, $R^2 > 0.99$
Slope factor (Sensitivity)	1.211
4PL R^2	0.999

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