

Atlas

EV ELISA Datasheet

Revision 2 – November 25, 2024

The Atlas EV ELISA is an immunoassay designed to measure intact extracellular vesicles (EVs) in plasma, serum, urine, cell culture media, cerebrospinal fluid (CSF), and SEC fractions of biofluids.

Assay type: Sandwich (quantitative)

Reactive species: Human

Intended Use: This kit is for research use only and should not be used for diagnostic purposes.

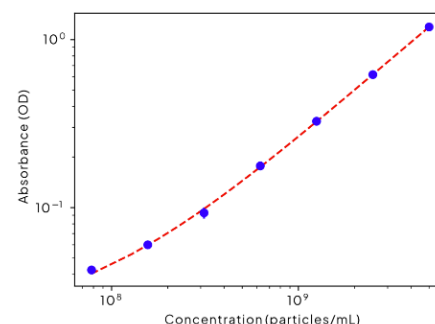
The EV standard provided in this kit was used for the assay validation.

Assay range (O.D): 0.03 – 1.8

Assay range (number of particles): 1e8 particles/mL – 1e10 particles/mL

Standard curve: Typical standard curve – data provided for demonstration purposes only. A new standard curve must be generated for each assay performed.

	Concentration (particles / mL)	Replicate 1 (O.D 450 nm)	Replicate 2 (O.D 450 nm)	Mean O.D
Calibrator A	5e9	1.206	1.173	1.190
Calibrator B	2.5e9	0.628	0.610	0.619
Calibrator C	1.25e9	0.339	0.314	0.327
Calibrator D	6.25e8	0.180	0.174	0.177
Calibrator E	3.125e8	0.098	0.088	0.093
Calibrator F	1.5625e8	0.061	0.059	0.060
Calibrator G	7.8125e7	0.041	0.044	0.043
Blank		0.028	0.034	0.031



Data were fit using a four-parameter logistic (4PL) model (red dotted line) to determine the concentration of analytes.

Pooled CV: Calculated as an average CV across an 8-point standard curve measured in triplicates across four different days.

Mean CV: 5.5%, range: 3%-7.5%

Limit of Detection (LOD): Calculated as 3 standard deviations from the mean background signal measured in triplicates across four different days.

Mean LOD: 9.9e7 (particles/mL), range: 2.7e7 - 2.3e8 (particles/mL)

Lower Limit of Quantification (LLOQ): Calculated as 10 standard deviations from the mean background signal measured in triplicates across four different days.

Mean LLOQ: 3.5e8 (particles/mL), range: 1.1e8 - 6.8e8 (particles/mL)

Minimum Required Dilution (MRD):

Sample Type	Range
Plasma	4X – 64X
Serum	4X – 64X
Urine	2X – 8X
CSF	2X – 32X
Culture Media	2X – 32X

Dilution Linearity: Native EVs were measured in the following biological samples in a 2-fold dilution series. Sample dilutions are made in Sample Diluent.

Dilution factor	Interpolated value	Plasma – 4X	Serum – 4X	CSF – 2X	Urine – 2X	Media – 2X
Undiluted	Particles/mL	4.22e9	1.22e10	5.02e9	1.14e9	2.37e9
	% Expected value	100.0	100.0	100.0	100.0	100.0
2	Particles/mL	2.26e9	6.66e9	2.32e9	5.29e8	1.47e9
	% Expected value	107.1	109.2	92.4	92.8	124.1
4	Particles/mL	1.12e9	3.64e9	1.11e9	2.38e8	7.21e8
	% Expected value	106.3	119.3	88.5	83.5	121.7
8	Particles/mL	5.47e8	1.86e9	6.25e8	Below LOD	3.67e8
	% Expected value	103.7	122.0	99.6	-----	123.9

Spike and Recovery:

Sample Type	Recovery (%), spike 1	Recovery (%), spike 2
Plasma (pooled)	92.9	98.2
Plasma (individual)	102.5 (range: 91.1-123.3)	94.9 (range: 89.0-100.1)
Serum (pooled)	94.2	95.7
Urine	96.6	106.5
CSF (pooled)	97.3	91.1
Culture Media	93.0	96.8

Repeatability: Three samples including standard and two individual plasmas were measured in duplicate over three runs and two reagent lots for three days.

Sample	Mean (particles/ml)	Within run CV	Between run CV	Between lot CV
Standard		5.5%	5.5%	5.6%
Plasma 1	8.49e9	3.8%	8.6%	5.6%
Plasma 2	1.51e10	2.7%	6.9%	6.5%

Assay Validation: The assay was validated with K562 knockouts of CD9, CD63 and CD81.