

## Critical Reagents for Critical Assays

### Highly Consistent Conferma® ELISAs

Recently there has been an increased focus on the reliability of critical reagents within ligand binding assays. Our Conferma® ELISAs are specifically engineered to meet this need for greater transparency and manufacturing consistency in Research Use Only (RUO) immunoassays. At a high level we:

- Physiochemically test each lot of monoclonal antibodies (mAb) and calibrator material.
- Undertake finished kit lot testing based on calibrator consistency and an established sample library.
- Provide an in-house verification report and lot-specific certificate of analysis for each assay.

### Key Conferma® ELISA Factors

- Each calibrator is assessed by mass spectrometry (LC-MS and RP-LC-UV-MS) for sequence coverage and intact mass before being compared to the reference sequence.
- Surface Plasmon Resonance (SPR) confirms the high affinity of mAbs toward the calibrator lot to lot, pre- and post-biotinylation.

Analyte	Lot No.	Mature Sequence Coverage	Daltons	Reference Sequence	Intact Mass Agreement (Da)
IL-6	015M4836V	88.5%	20977	P05231	100%
IL-6	028M4878V	81.9%	20977	P05231	100%

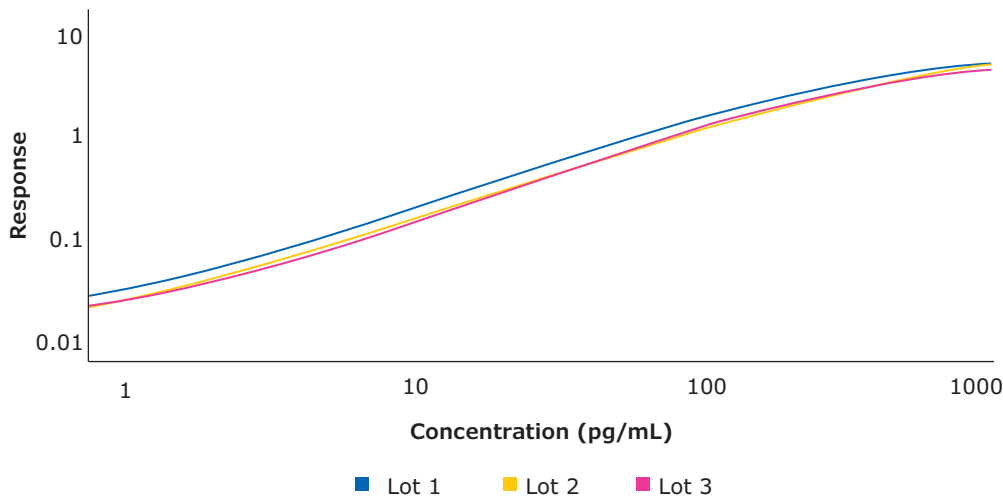
Example of lot-specific mass spectrometry data for the IL-6 calibrator used in the IL-6 ELISA (Cat. No. **EZIL6-98K**). Our IL-6 calibrator was compared with the reported sequence from UniProt accession # P05231, AA30-212.

mAb	mAb Lot No.	Calibrator Lot No.	KD (nM)
MCP-1 Capture	RB1811009	046M4767V	0.031
MCP-1 Capture	RB1907012	046M4767V	0.023
MCP-1 Detection	RB1811010	046M4767V	0.061
MCP-1 Detection	RB1907014	046M4767V	0.053
MCP-1 Capture Bt	RB1811010	046M4767V	0.089
MCP-1 Capture Bt	RB1910009	046M4767V	0.072

Example of lot-specific capture and detection mAbs analyzed for affinity and activity (pre- and post-biotinylation for the capture mAb) from the MCP-1 ELISA (Cat. No. **EZMCP1-99KRM**) verification report. A KD of <2 nM indicates high affinity.



- Lot-to-lot consistency is monitored using both component level testing and finished kit testing, using calibration curves and library samples, to ensure quality is maintained over time.



Curve	Parallelism
Lot 2 vs. Lot 1	0.983
Lot 3 vs. Lot 1	0.992

Example of finished kit testing of the TNF- $\alpha$  ELISA (Cat. No. **EZHTNFA-150K**). Calibration curves from 3 lots were compared for mathematical similarity where a value of 1 is considered perfect parallelism. Lots 1, 2, and 3, are represented by the blue, yellow, and magenta lines respectively.

## Summary

- Conferma<sup>®</sup> ELISAs are developed using high-affinity mAbs toward well-characterized calibrator material.
- Physiochemical critical reagent testing aligned with finished kit testing ensures a high degree of lot-to-lot reproducibility.

## Conferma<sup>®</sup> ELISA Ordering Information

Analyte	Range	Curve LLOQ	Cat. No.
IL-6	1.17 - 150 pg/mL	1.17 pg/mL	<b>EZIL6-98K</b>
IL-8	0.82 - 200 pg/mL	0.82 pg/mL	<b>EZHIL8-100K</b>
MCP-1	7.81 - 1,000 pg/mL	7.81 pg/mL	<b>EZMCP1-99KRM</b>
TNF- $\alpha$	1.65 - 400 pg/mL	1.65 pg/mL	<b>EZHTNFA-150K</b>

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MK\_FL9845EN Ver. 1.0 44166 09/2022



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1800 ABACUS (AUS) 0800 222 170 (NZ) | [info@abacusdx.com](mailto:info@abacusdx.com) | [www.abacusdx.com](https://www.abacusdx.com)

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