

Technical Brief

Singulex Erenna® single molecule counting immunoassays outperform electrochemiluminescence (ECL) methods

Single molecule counting (SMC™) technology, originally developed by Singulex, Inc., enables ultrasensitive biomarker detection, with lower limits of quantitation in the femtogram/mL level.

In this technical brief, we first compare the performance of the Singulex Erenna® platform with electrochemiluminescence (ECL)-based immunoassays. Next, we show that the ultrasensitive Singulex Erenna® immunoassays enable low-abundance biomarker concentrations to be quantified in both healthy and diseased subjects.

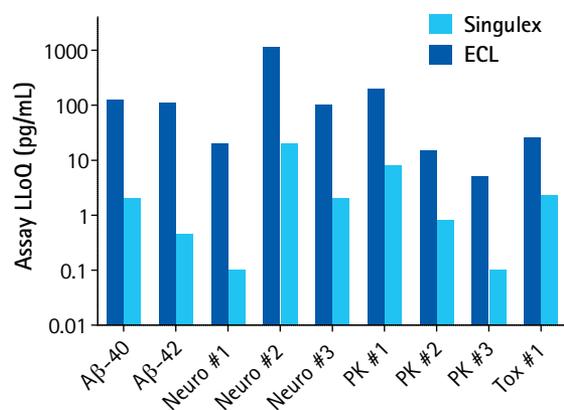
Average 50-fold Improvement in Biomarker Limit of Quantification

Methods

- For both Singulex and ECL assays, we assessed LLoQ: Lower Limit of Quantification with $\leq 20\%$ CV and $\leq 20\%$ Bias
- Nine different pharma and academic evaluations of nine different analytes
- Identical antibodies and analyte on both Singulex and electrochemiluminescence (ECL) platforms

Results

For all nine analytes, Singulex Erenna® assays showed lower LLoQ than ECL assays.



* A β -40 & A β -42 in CSF; Neuro Markers in plasma; Pharmacokinetics (PK) Markers in Plasma; Toxicity (Tox) Marker in Urine.

Figure 1. Comparing LLoQ of Singulex Erenna® vs. ECL platforms.

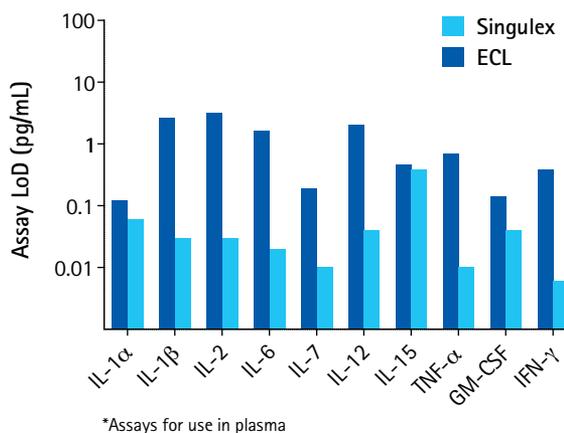
Average 40-fold Improvement in Biomarker Limit of Detection

Methods

- Bar graph below shows Lower Limit of Detection (LoD) as defined by each assay manufacturer
- LoD specifications were available on respective supplier's website. For Singulex Erenna® assays, the LoD is defined as two standard deviations above the background signal

Results

For eight of ten analytes evaluated, Singulex Erenna® assays showed lower LoD than ECL assays.



*Assays for use in plasma

Figure 2. Comparing LoD of Singulex Erenna® vs. ECL platforms in plasma samples.

Singulex Erenna® Technology Can Accelerate Discovery of Low-Abundance Biomarkers

Methods

- Both Singulex Erenna® and ECL assays were used to quantify cytokine biomarkers IL-17A, IL-17F, and IL-13.

Results

Compared to ECL methods, the Erenna® IL-17A and IL-17F assays can more accurately quantify minute differences in plasma biomarker concentrations between age- and gender-matched control and rheumatoid arthritis (RA) patients (Figures 3 and 4). IL-17A has been shown to mediate the pathogenesis of RA by activating fibroblasts and chondrocytes¹.

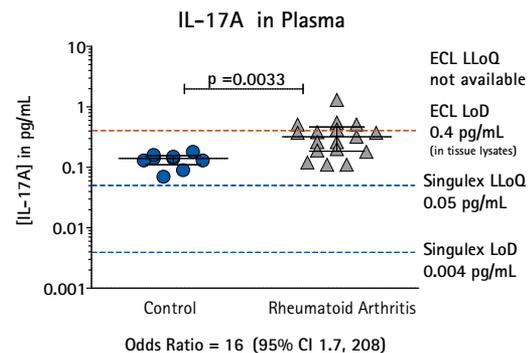


Figure 3.

Quantitation of IL-17A in healthy humans and subjects diagnosed with rheumatoid arthritis.

There is a need for measuring plasma IL-17F in addition to IL-17A. The Erenna® IL-17F immunoassay provides highly specific and sensitive quantification of IL-17F (Figure 4.)

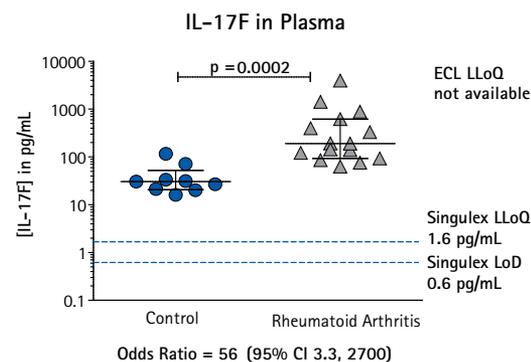


Figure 4.

Quantitation of IL-17F in healthy humans and subjects diagnosed with rheumatoid arthritis.



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The Singulex Erenna® IL-13 immunoassay enables quantification of serum IL-13 and biomarker assessment across multiple disease states, as shown in Figure 5.

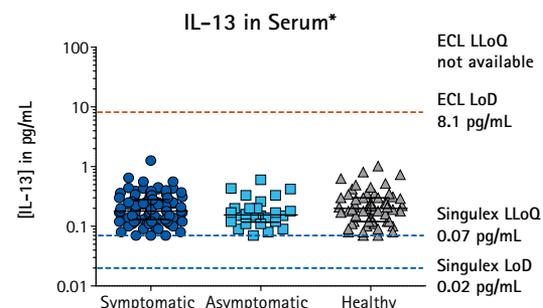


Figure 5.

Quantitation of IL-13 in symptomatic and asymptomatic subjects with a variety of diagnoses and in healthy subjects. Note that the LLoQ of the ECL assay for this analyte could not be determined.

Reference 1. McInnes IB and Schett G. The Pathogenesis of Rheumatoid Arthritis. N Engl J Med 2011; 365:2205-2219

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