SMC™ 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 SMC™ Erenna® platform with electrochemiluminescence (ECL)- based immunoassays. Next, we show that the ultrasensitive SMC™Erenna® immunoassays enable low-abundance biomarker concentrations to be quantified in both healthy and diseased subjects.

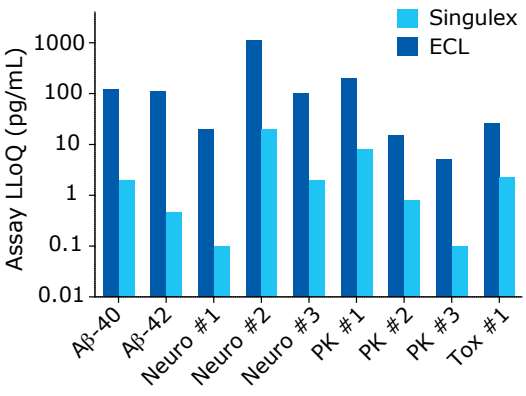
Average 50-fold Improvement in Biomarker Limit of Quantification

Methods

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

Results

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



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

Figure 1. Comparing LLoQ of SMC™ Erenna® vs. ECL platforms.

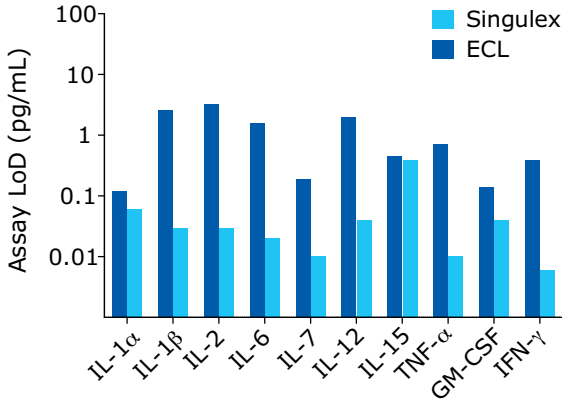
Average 40-fold Improvement in Biomarker Limit of Detection

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 SMC™ Erenna® vs. ECL platforms in plasma samples.

SMC™ Erenna® Technology Can Accelerate Discovery of Low-Abundance Biomarkers

Methods

- Both SMC™ 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.

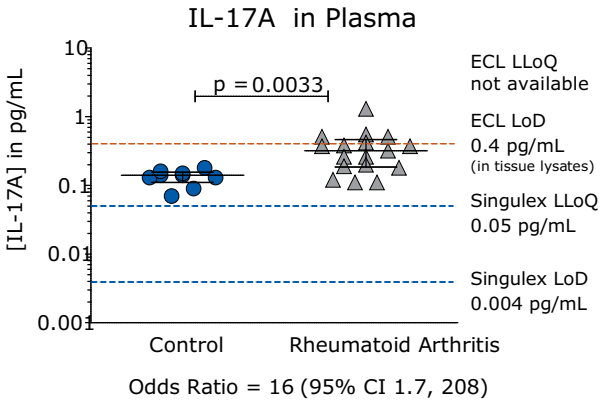


Figure 3. Quantitation of IL-17A in healthy humans and subjects diagnosed with rheumatoid arthritis.

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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.)

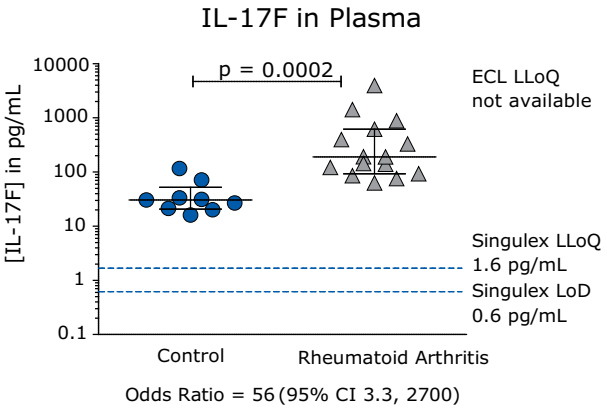
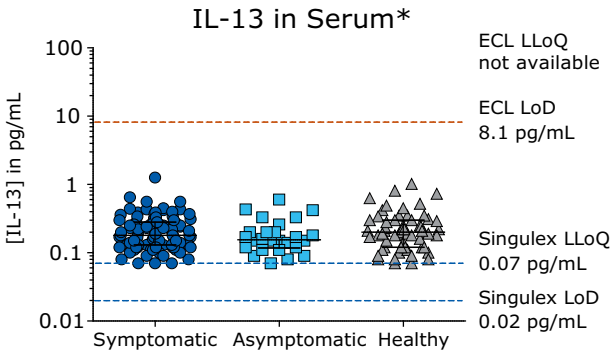


Figure 4. Quantitation of IL-17F in healthy humans and subjects diagnosed with rheumatoid arthritis.

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



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