

# Rapid Biomarker Analysis in Human Serum using Simple Plex



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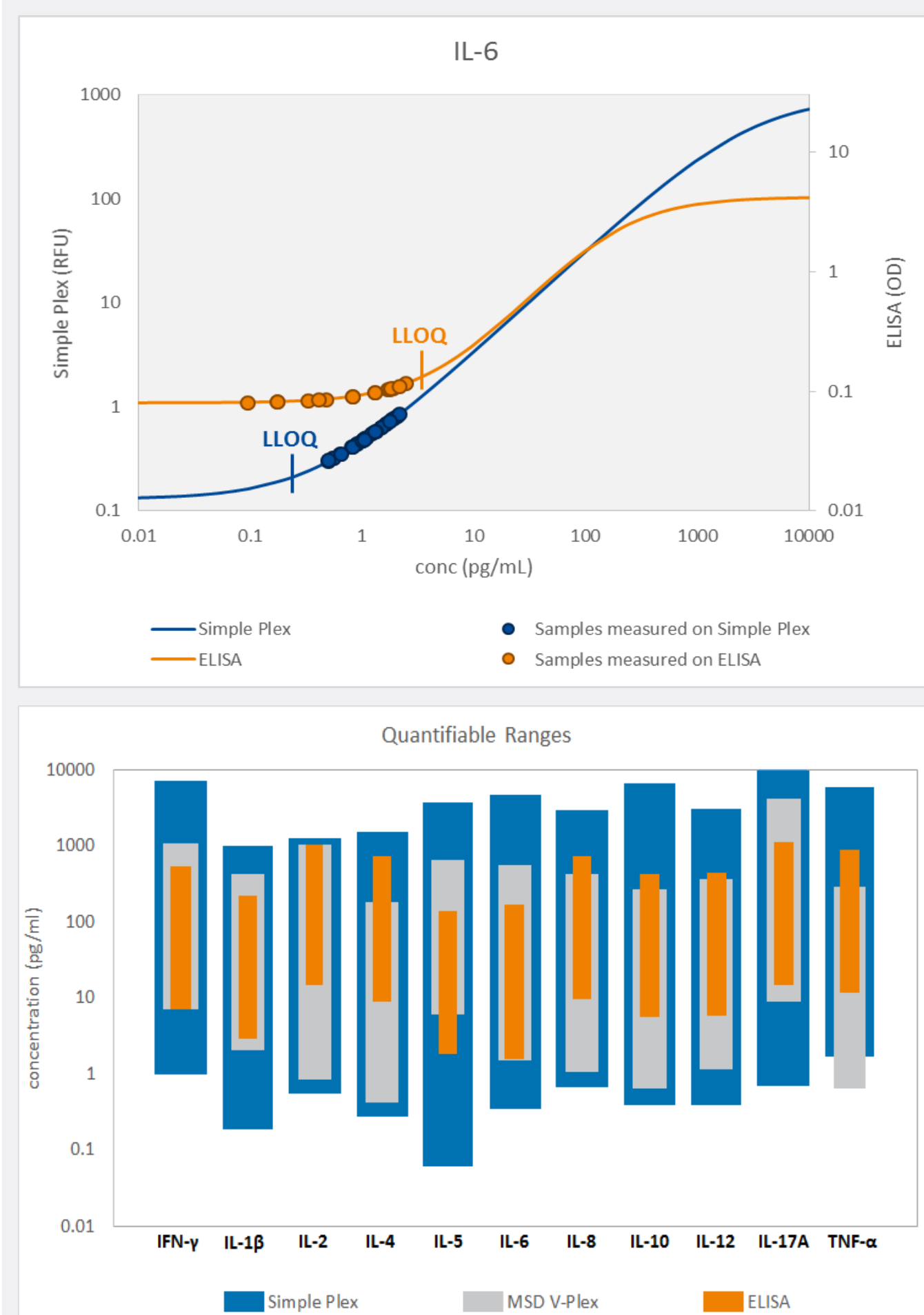
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## Abstract

The standard ELISA techniques used to detect protein biomarkers in the serum or other biological samples often exhibit low sensitivity, analyte cross-reactivity, and poor reproducibility. To eliminate these limitations for multi-analyte or single analyte detection, the Simple Plex platform uses a novel microfluidic format for a low volume assay offering rapid and sensitive analyte detection.

Here we demonstrate the efficiency of this strategy for biomarker screening in blood serum and other sample types using both the multi-analyte cartridge (16 samples for 4 analytes) and the new single analyte cartridge (72 samples for 1 analyte) on the Ella instrument. The workflow demonstrates the speed and ease of the validated assay setup, with no manual washes and the use of factory-generated standard curves. Specific examples will then show the high level of sensitivity and reproducibility for analyte detection in serum/plasma.

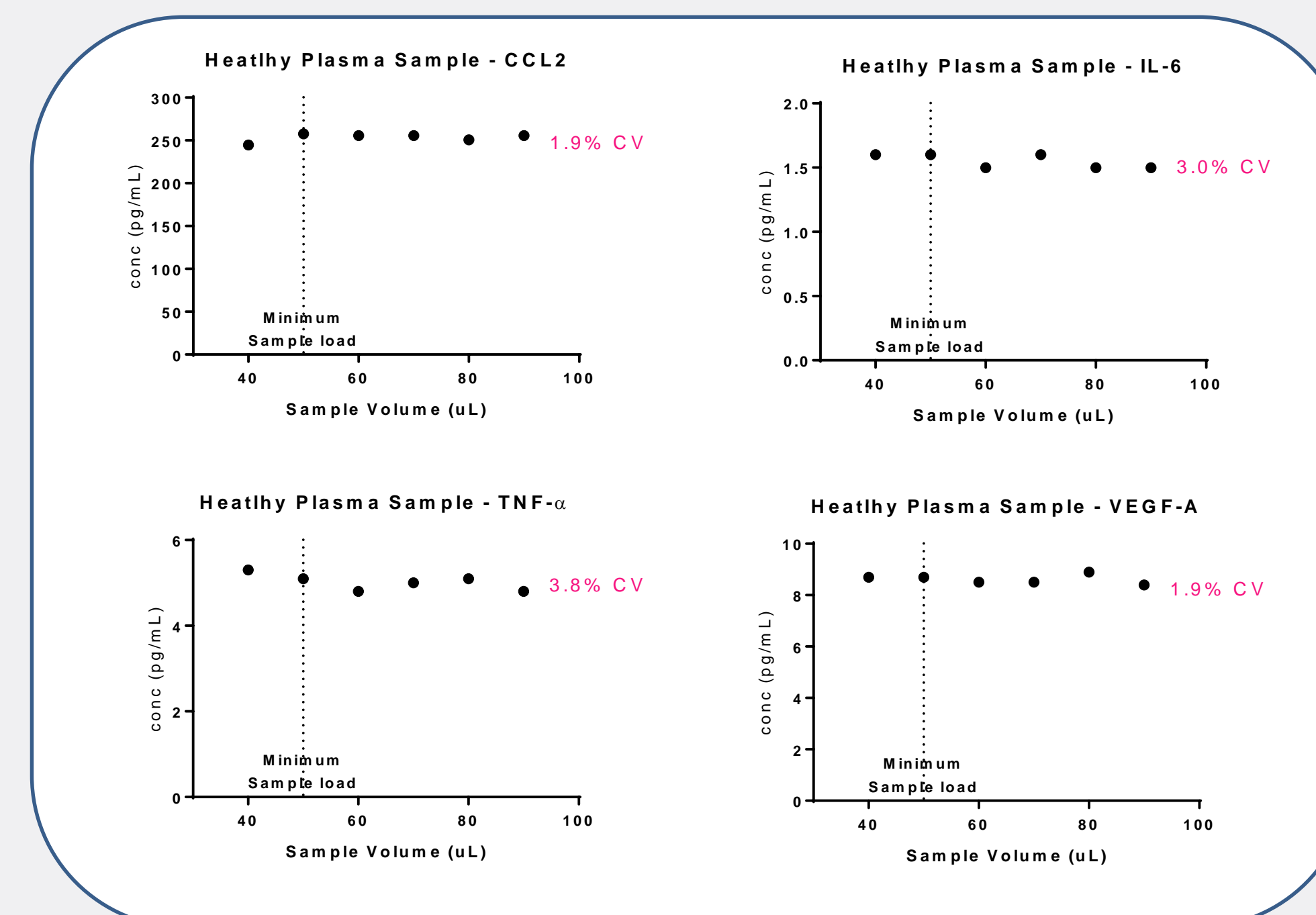
## Comparison of Sensitivity and Dynamic Range



**Figure 2.** Simple Plex's 72x1 cartridge for single analyte testing of 72 samples confirm accurate detection down to picogram/ml limits consistently for IL-6 cytokine, with more sensitive results at 25 ul sample volume versus a high quality plate-based ELISA.

**Figure 3.** Simple Plex offers greater dynamic range at 4-5 logs than plate-based ELISA and other competitive technologies, enabling detection of endogenous levels in normal samples and disease states simultaneously.

## Reproducible Detection at Low Volumes



**Figure 4.** Human plasma results for cytokines on a 16x4 multi-analyte cartridge shows that the Simple Plex assay is tolerant of low volumes and quantitative.

| Day # | Control Level 1 (25 pg/ml) |      |       |       | Control Level 2 (500 pg/ml) |      |       |       |
|-------|----------------------------|------|-------|-------|-----------------------------|------|-------|-------|
|       | IL-1β                      | IL-6 | IL-10 | TNF-α | IL-1β                       | IL-6 | IL-10 | TNF-α |
| 1     | 24.3                       | 24.7 | 23.2  | 25.6  | 504                         | 527  | 536   | 541   |
| 2     | 24                         | 24.1 | 23.8  | 24.7  | 576                         | 524  | 551   | 511   |
| 3     | 22.6                       | 22.4 | 23.1  | 24    | 539                         | 528  | 513   | 467   |
| 4     | 25.2                       | 24.4 | 23.9  | 24    | 674                         | 555  | 535   | 484   |
| 5     | 26.5                       | 24.7 | 24.4  | 25.9  | 570                         | 555  | 535   | 483   |
| 6     | 27.5                       | 24.7 | 24.5  | 26.1  | 569                         | 573  | 531   | 530   |
| 7     | 28.2                       | 24.5 | 24.3  | 28    | 613                         | 575  | 521   | 550   |
| 8     | 24.2                       | 24.5 | 23.1  | 24.1  | 530                         | 556  | 520   | 479   |
| 9     | 25.4                       | 24.4 | 24.7  | 24.2  | 589                         | 546  | 523   | 489   |
| 10    | 24.2                       | 24.2 | 23.1  | 23.8  | 560                         | 536  | 508   | 519   |
| CV    | 7%                         | 3%   | 3%    | 5%    | 8%                          | 3%   | 2%    | 6%    |

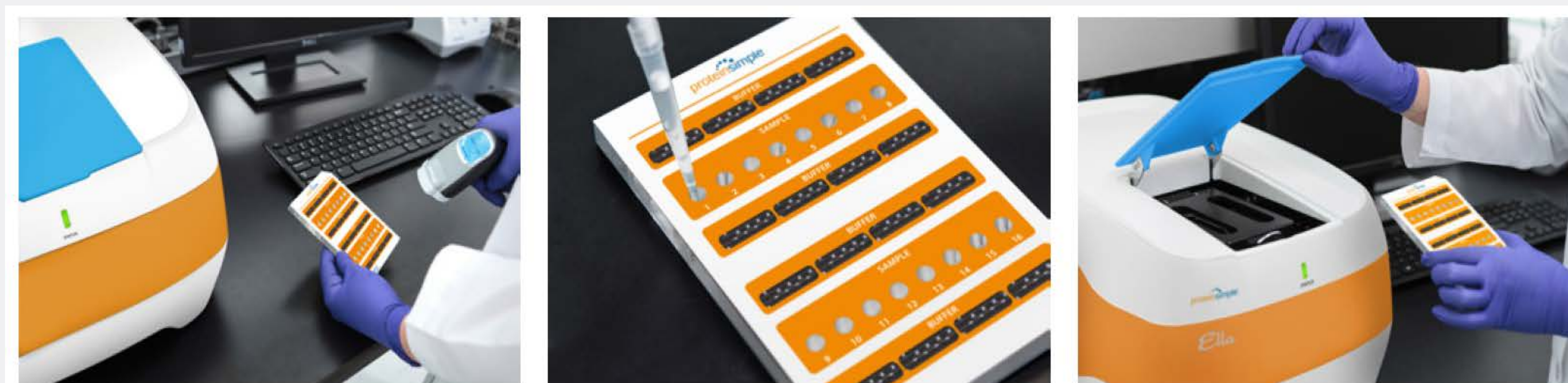
**Figure 5.** The average of 3 reportable results for each recombinant protein control, over 10 consecutive days, show CVs of less than 10%.

## Conclusion

Simple Plex delivers high-performance and quantitative results at low volumes for blood samples, in a novel microfluidics format with 3 reportable results per sample.

- Streamlines time to results: 10-15 minutes assay set up, no manual washes, results in an hour from fully automated Ella analyzer.
- Highly reproducible and sensitive results for biomarker detection from blood, with 4-5 logs of dynamic range.

## Fast Set Up & Convenient Operation



**Figure 1.** Pipette 25 ul of sample into the Simple Plex cartridge, place into the Ella instrument, start run, and get results in an hour.

By using the Simple Plex cartridge on the Ella™ instrument, you have the convenience of a fully automated immunoassay, with no manual washes. Operation is rapid, requiring only a few minutes to pipette 25 microliters of sample into the cartridge, followed by a quick barcode scan of the cartridge to start the run, and fully analyzed data in an hour. Obtain triplicate results per sample due to 3 separate assays occurring within embedded glass nano-reactors (GNR).