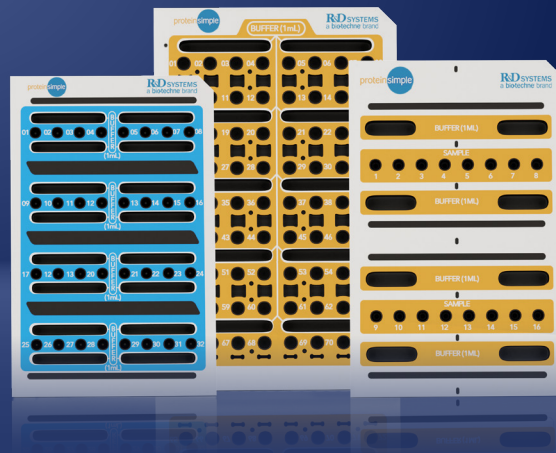
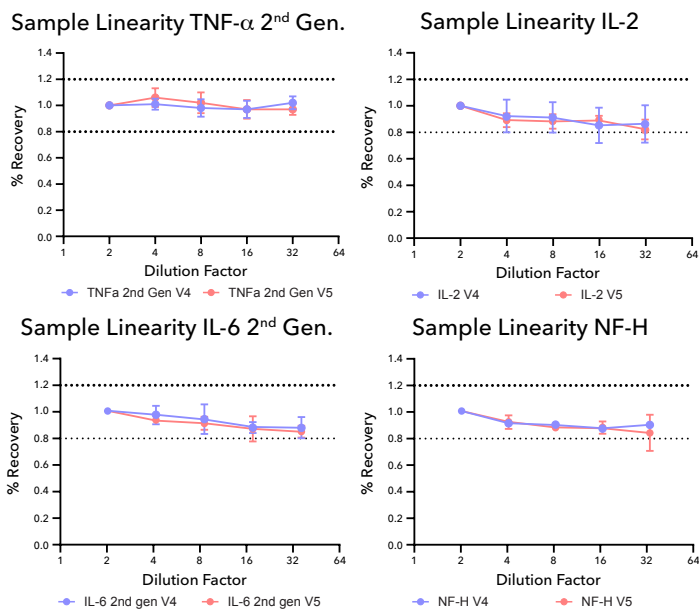


INTRODUCING SIMPLE PLEX 5TH GENERATION CARTRIDGES



INTRODUCTION

We're proud to introduce the next generation of Simple Plex cartridges for the Ella immunoassay platform. These cartridges are our most robust version ever and represent the future for Simple Plex technology, allowing us to meet your needs with scale and reliability. Our 5th Generation (V5) cartridge formats have been enhanced with a new form factor, which includes additional venting ports, identifiable on the cartridge label, to enhance the action of the microfluidic circuits. This ensures that our cartridges continue to deliver the robust and reproducible results that you've come to expect from Simple Plex technology. For those of you who have been working with Simple Plex, we know that continuity is incredibly important to your work. We've undertaken an extensive product validation to ensure you get the same great data in our V5 cartridge format as our legacy products. Read on to learn more!



V5 NATURAL LINEARITY IS CONSISTENT WITH V4 NATURAL LINEARITY

Linearity of dilution experiments are an excellent way to evaluate the extent to which assay accuracy changes as the sample is diluted. In this experiment, Tumor Necrosis Factor Alpha (TNF- α) and Interleukin 2 (IL-2) sample linearity were tested using serum (n=3) as well as EDTA (n=3) or Heparin (n=3) collected plasma. Interleukin 6 (IL-6) linearity was tested using cell culture supernates (CCS, n=2). Finally, Neurofilament Heavy (NF-H) was tested using cerebrospinal fluid (CSF, n=2). As seen in FIGURE 1, V5 sample linearity is indistinguishable from V4 sample linearity, with the mean percent recovery for all samples within the acceptable range of 80%-120%, indicating that V5 cartridges accurately quantify target analytes.

FIGURE 1. Natural samples were serially diluted 1:2, 1:4, 1:8, 1:16, and 1:32. Mean percent recovery was within the acceptable range of 80%-120%.

THE V5 CARTRIDGE HAS A GREAT CORRELATION WITH THE V4 CARTRIDGE

Next, we wanted to determine the degree to which data generated with V5 cartridges correlates with data generated with legacy V4 cartridges. TNF- α , IL-6, and NF-H were quantified using 12 natural samples and 1 matrix control sample. IL-2 was quantified using 7 CCS samples and 6 matrix control samples. FIGURE 2 shows that the slope for all four assays systems was between 0.9 and 1.1, and the R² value for each correlation was greater than 0.95. These data indicate that the sample values did not change appreciably between the V4 and V5 formats.

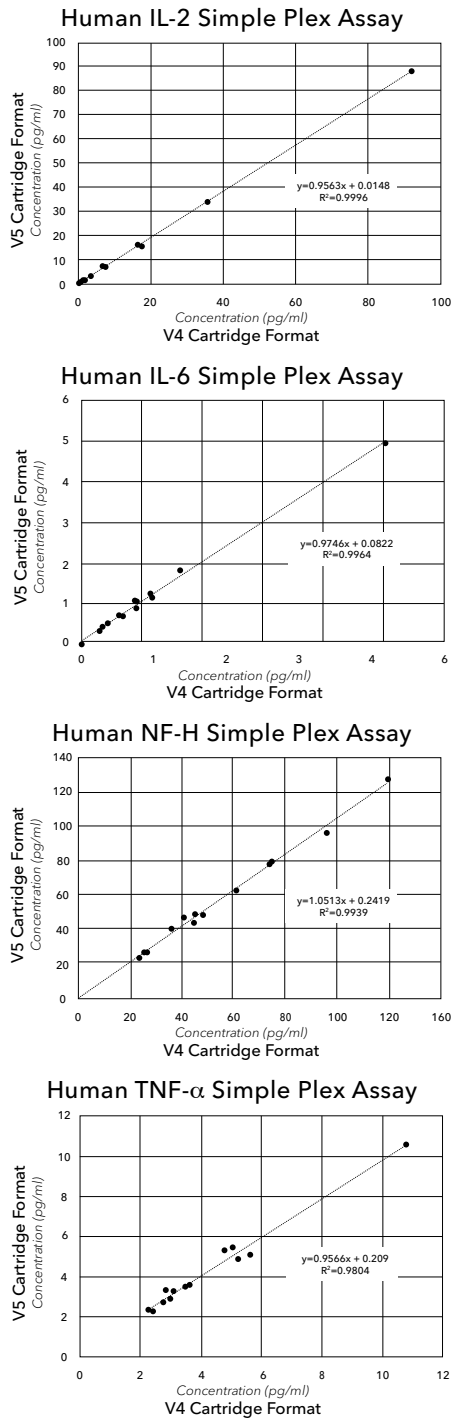


FIGURE 2. Analytes measured in natural samples and matrix control samples show great correlation between V5 and V4 cartridges.

V5 INTRA-ASSAY PRECISION IS COMPARABLE TO V4

Intra-assay precision is a commonly used measure of variability within an individual assay. Recombinant controls at the high or low end of the standard curve and serum/plasma matrix controls were used to compare V5 intra-assay precision to V4. For every target analyte, eight replicates each were run for Low Quality Control (LQC), High Quality Control (HQC) and Matrix Control (Matrix Ctl). V4 and V5 cartridges were loaded side by side and run in parallel. In order to compare V5 data to V4 data, the concentration values of each control were normalized to the mean concentration and represented as the median plus or minus the interquartile range (FIGURE 3). Across all samples, the median was between 98% and 102% and the interquartile range was between 93% and 105%. Thus, intra-assay precision using the V5 cartridge is consistent with the V4 cartridge and well within the acceptable range of 80%-120%.

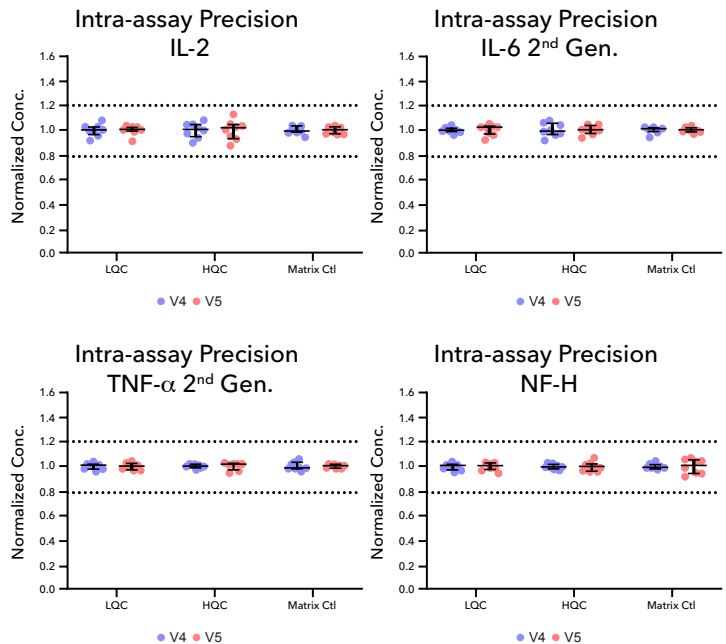


FIGURE 3. Intra-assay precision was evaluated using recombinant control samples and serum/plasma control samples. Data are represented as the median plus or minus the interquartile range. V5 intra-assay precision is within the acceptable range of 80%-120%.

THE V5 COEFFICIENT OF VARIATION (CV) IS COMPARABLE TO V4

The CV, a second measure of intra-assay precision, is a commonly used assessment of the dispersion of data points around the mean. The CV for data generated using V5 is consistent with that generated using V4 and remains below 10%, which is well within the acceptable limit (FIGURE 4). Taken together, FIGURE 3 and FIGURE 4 indicate that you can continue to count on each Simple Plex assay for consistent intra-assay precision.

V5 INTER-ASSAY PRECISION IS COMPARABLE TO V4

To evaluate inter-assay precision, we quantified IL-2, TNF- α , IL-6 and NF-H in recombinant control samples and natural matrix samples in buffer. Four to twelve independent experiments were carried out by a minimum of 3 users using two independent sample preparations. FIGURE 5 shows that V5 inter-assay precision ranges from 2.5% to 11.5%, which is within the acceptable limit of 12%. Our data indicate that V5 inter-assay precision is consistent with that of the legacy V4 cartridges.

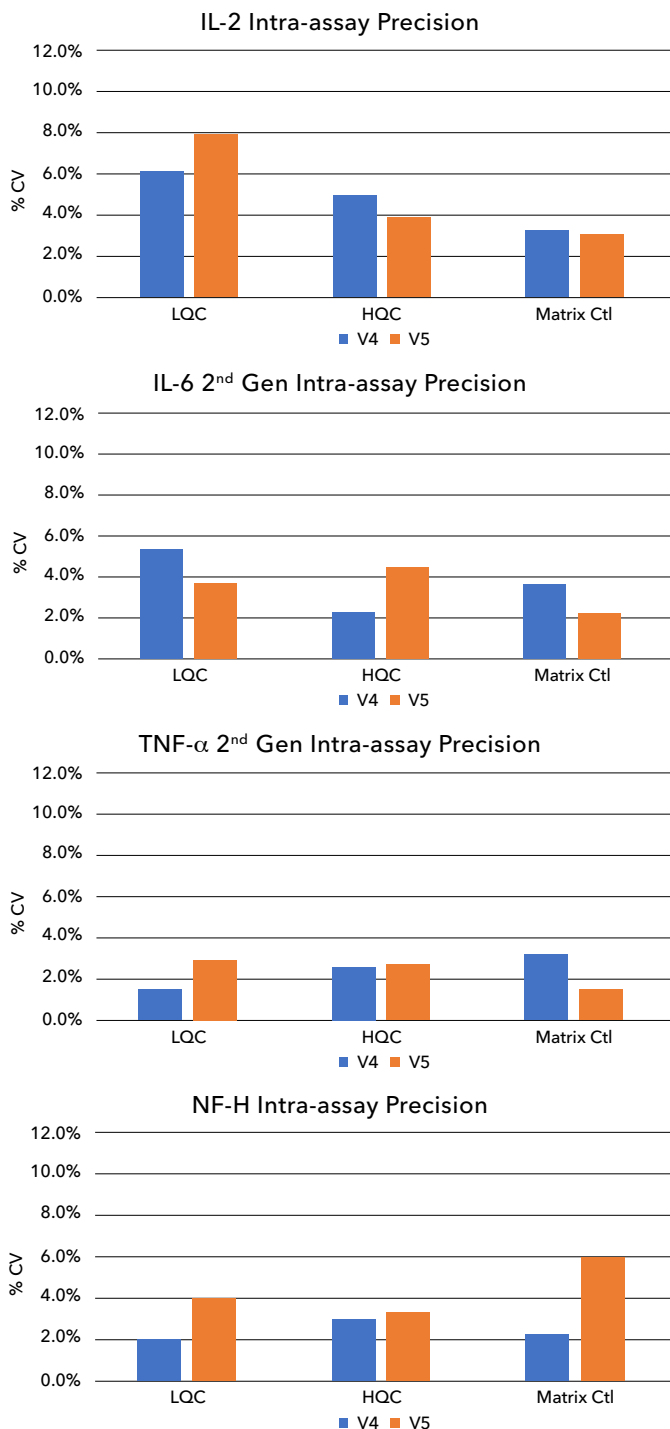


FIGURE 4. Intra-assay precision was evaluated using recombinant controls and serum/plasma matrix controls. Data are represented as the mean coefficient of variation (CV) which ranged from less than 2% to 8%.

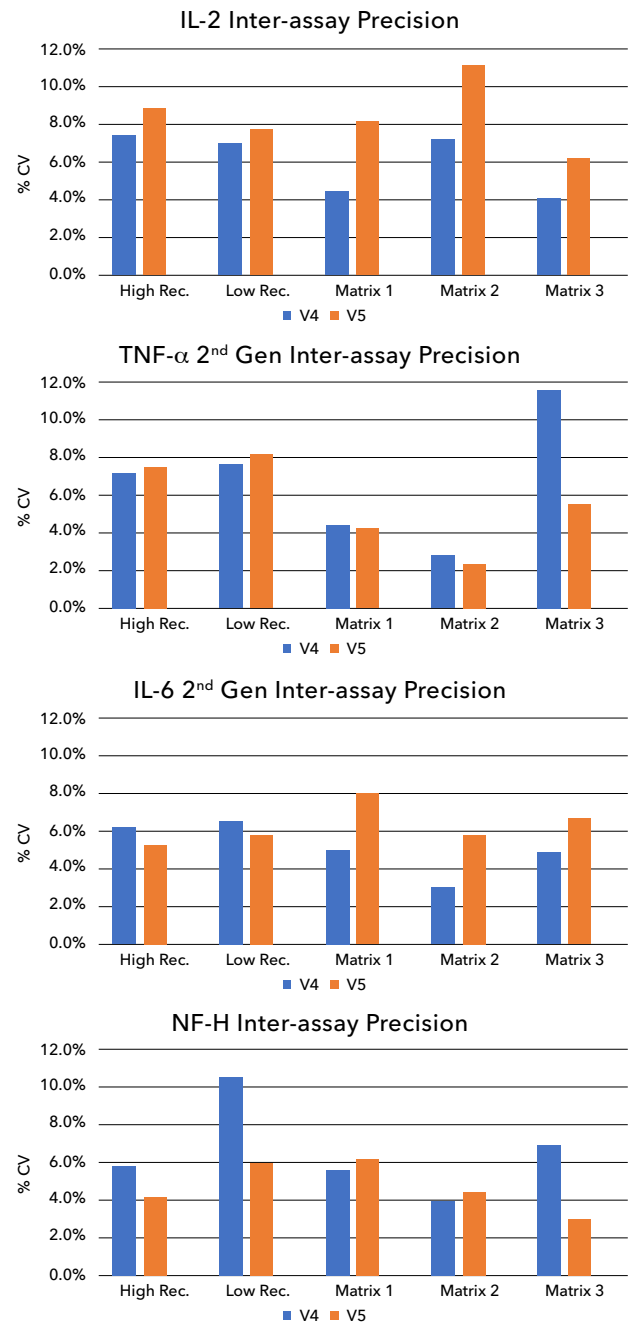


FIGURE 5. Inter-assay precision was evaluated for IL-2, TNF- α , IL-6 and NF-H, using recombinant control samples and serum/plasma control samples. V5 inter-assay precision ranged from 2.5% to 11.5% which was consistent with the acceptable threshold of 12%.

CONCLUSIONS

We have undertaken this extensive product validation to ensure the continuity of your data generated using Simple Plex assays. Here, we demonstrate that the V5 cartridge maintains the same high standards that you expect from Simple Plex Assays. We show that V5 cartridge linearity, intra-assay precision, and inter-assay precision are consistent with the V4 cartridge. Furthermore, data generated using the V5 cartridge has a great correlation with data generated using the V4 cartridge. It is apparent from the data that you can depend on Simple Plex V5 cartridges for the same robust, and reproducible high quality data that you have come to count on from legacy V4 cartridges.

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