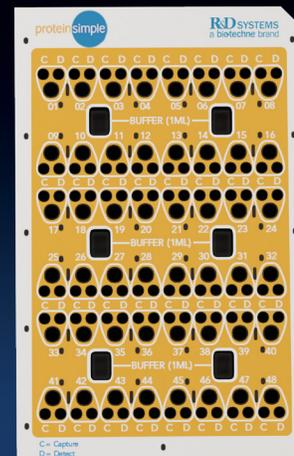


# INTRODUCING THE NEXT GENERATION OF CUSTOMIZABLE 48-DIGOXIGENIN SIMPLE PLEX CARTRIDGES



## INTRODUCTION

Recently, we introduced the next generation of Simple Plex cartridges for the Ella immunoassay platform. The 5th Generation (V5) cartridges are our most robust version ever and represent the future for Simple Plex technology. V5 cartridges allow us to meet your needs with scale and reliability. The updated cartridge format features material upgrades and additional venting ports, identifiable on the cartridge label, to enhance the action of the microfluidic circuits. This update ensures that our cartridges continue to deliver the robust and reproducible results that you've come to expect from Simple Plex technology.

We are now pleased to present the V5 customizable 48-Digoxigenin cartridge. This cartridge gives you the flexibility to build your own assay on the Ella platform. The V5 48-Dig cartridge has been updated to include new anti-digoxigenin antibodies and a new reagent diluent. 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 comparable data with our V5 cartridge format. Read on to learn more!

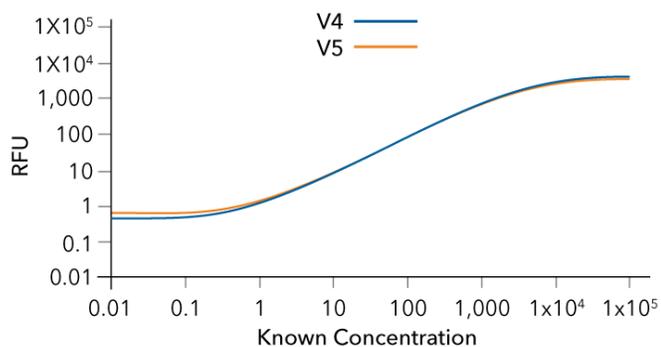


FIGURE 1. Comparison of the V4 standard curve (blue) with the V5 standard curve (orange).

## THE V5 DOSE-RESPONSE CURVE IS CONSISTENT WITH THE V4 CURVE

The V5 48-Dig cartridge assay range varies as a function of the target antibodies utilized. To evaluate this cartridge, we selected a well-characterized antibody pair and compared its standard curve with the V4 cartridge. As seen in figure 1, the V4 and V5 cartridges have nearly identical standard curves.

## THE V5 CARTRIDGE HAS A GREAT CORRELATION WITH THE LEGACY V4 CARTRIDGE

Next, we wanted to determine the degree to which data generated with V5 cartridges correlates with data generated with legacy V4 cartridges. Figure 2 shows that the V5 cartridge has a nearly perfect correlation ( $R^2=0.99$ ) with the V4 cartridge. Our data indicate that the sample values did not change appreciably between the V4 and V5 formats.

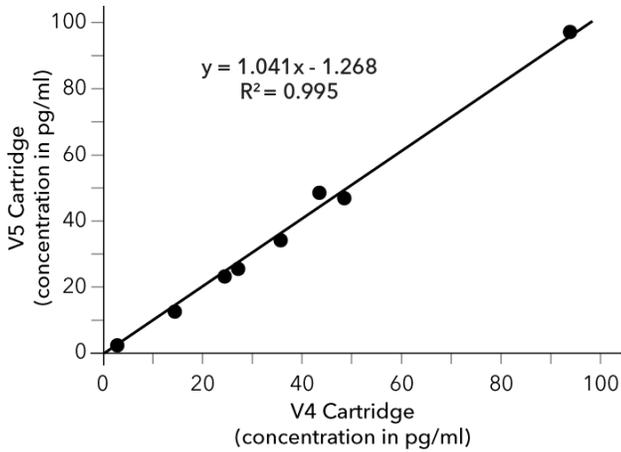
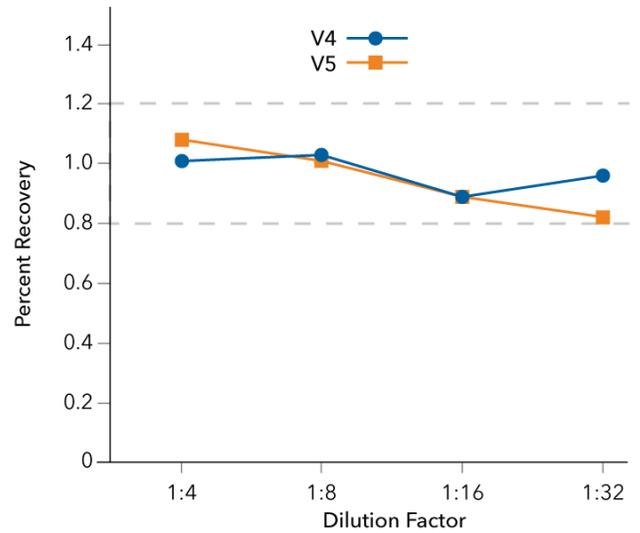


FIGURE 2. Data from the V5 cartridge is highly correlated with data from the V4 cartridge.

## V5 CARTRIDGE LINEARITY IS COMPARABLE TO V4 CARTRIDGE LINEARITY

Linearity of dilution experiments are used to evaluate the extent to which assay accuracy changes as the sample is diluted. Immunoassays should return approximately 80-120% recovery to be considered accurate. In figure 3, we demonstrate that the V5 cartridge recovery is comparable to the legacy V4 cartridge.

3A



3B

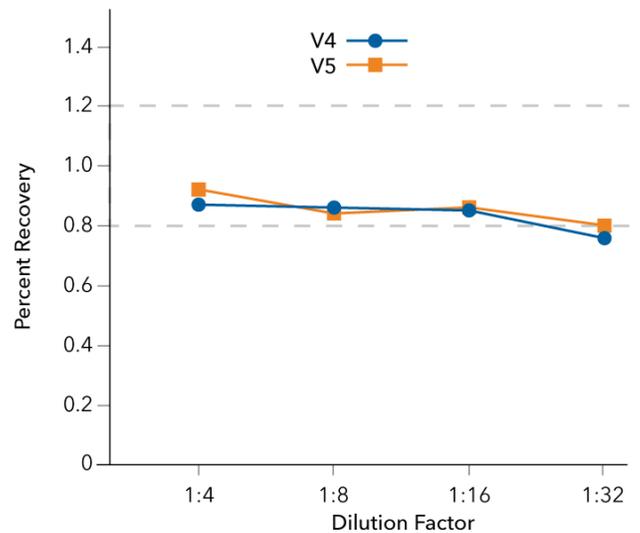


FIGURE 3. V5 sample linearity is comparable to V4 linearity in two samples, 3A and 3B.

## THE V5 CARTRIDGE HAS GREAT INTRA-ASSAY PRECISION

Intra-assay precision is a commonly used measure of variability within an individual assay. Recombinant controls, at the high and low end of the standard curve, were used to compare V5 intra-assay precision to V4. As seen in figure 4, the V5 cartridge maintains acceptable intra-assay precision.

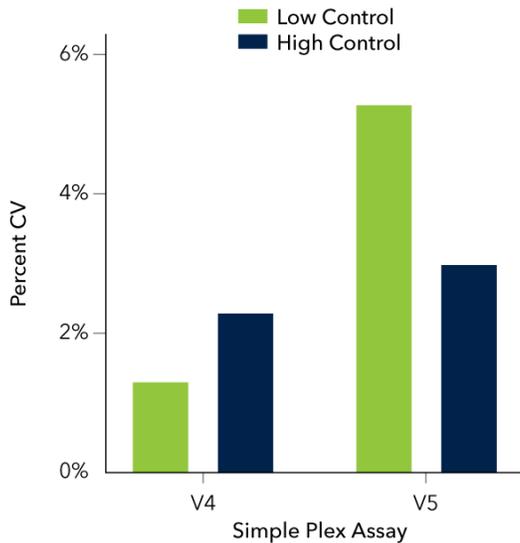


FIGURE 4. The V5 cartridge intra-assay precision is less than 15%.

## THE V5 CARTRIDGE ALSO HAS GREAT INTER-ASSAY PRECISION

Inter-assay precision is a measure of variability between assays. To evaluate inter-assay precision, we used low and high recombinant controls to compare the V5 cartridge to the legacy V4 cartridge. Figure 5 demonstrates that the V5 cartridge maintains excellent inter-assay precision.

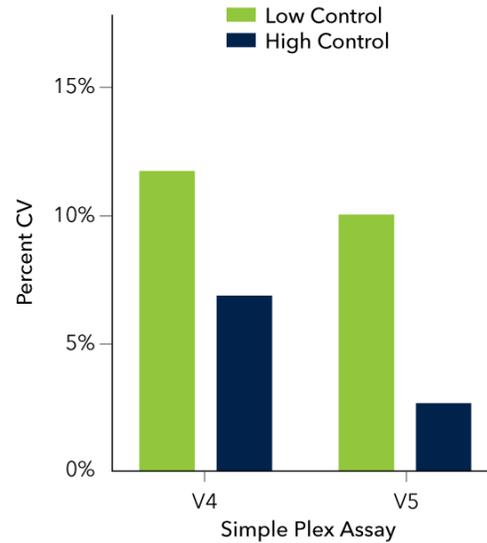


FIGURE 5. The V5 cartridge has excellent inter-assay precision.

## CONCLUSION

We have undertaken this extensive product validation to ensure the continuity of data generated using Simple Plex 48-Digoxigenin cartridges. 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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