

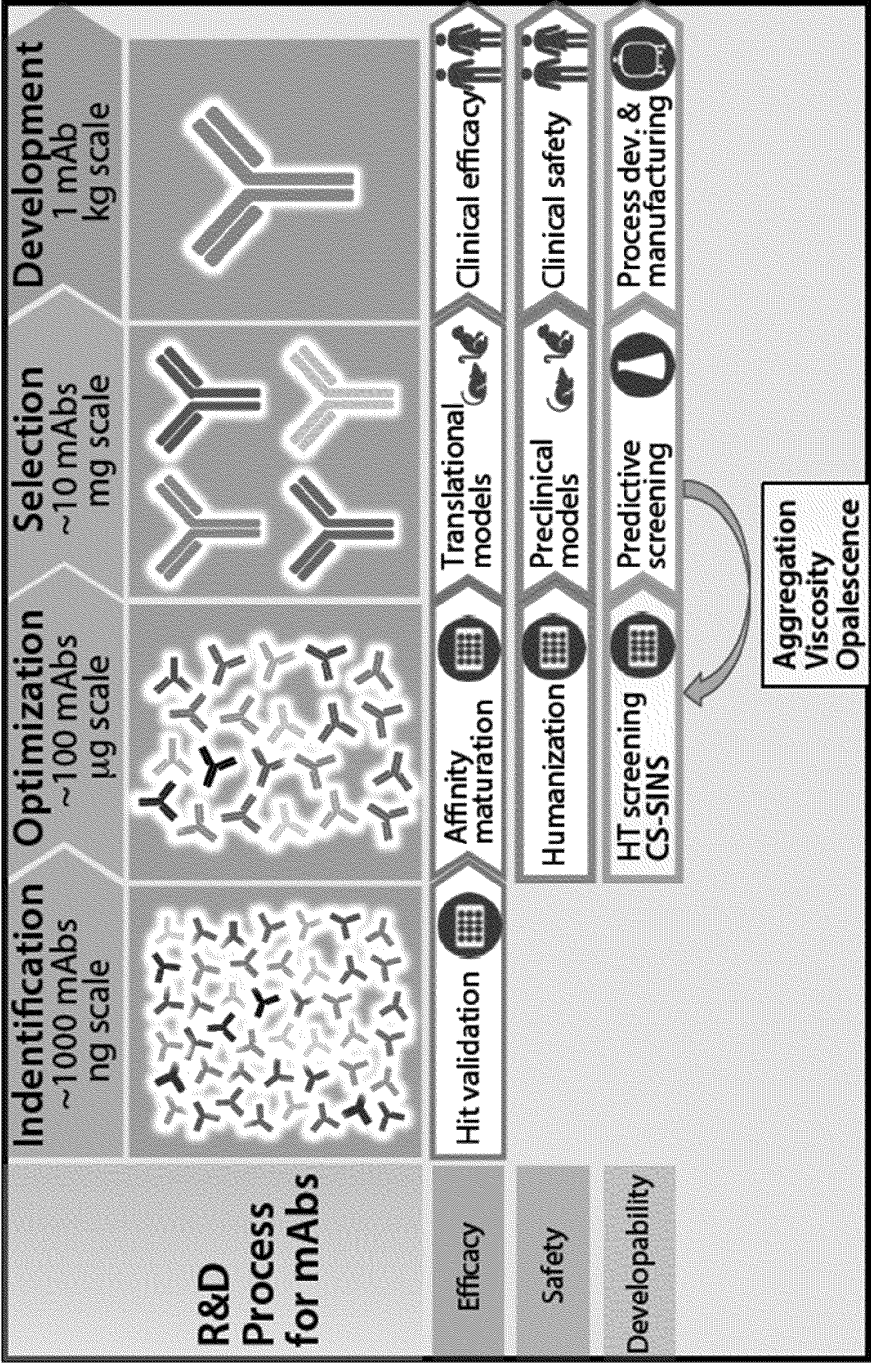


FIG. 1

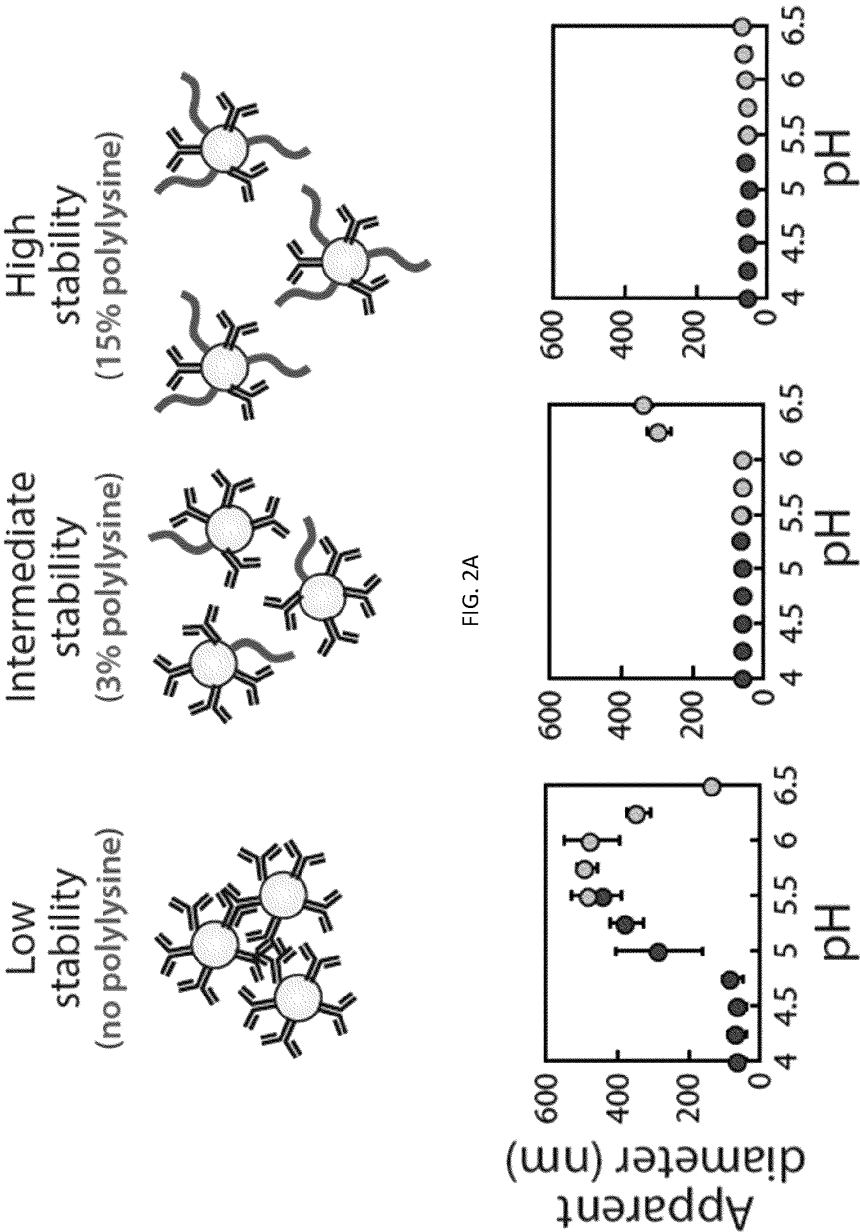


FIG. 2B

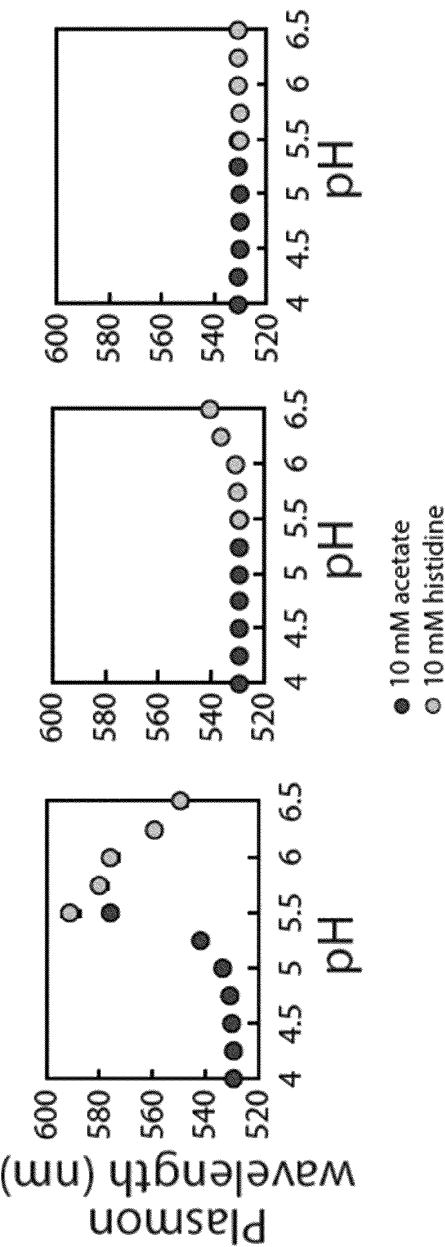


FIG. 2C

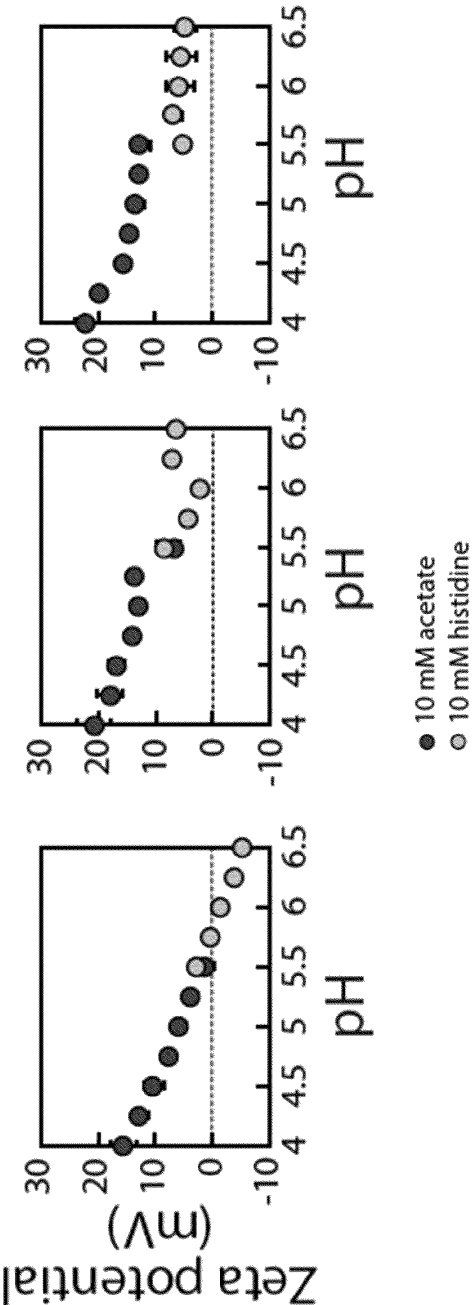


FIG. 2D

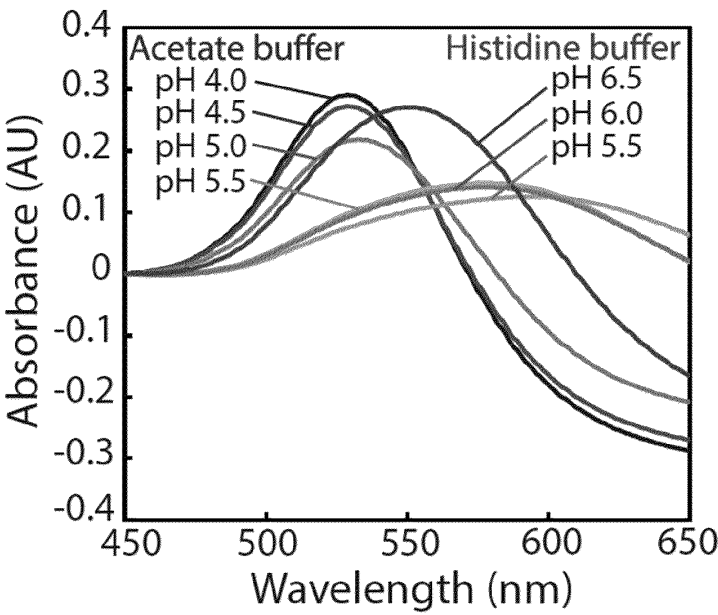


FIG. 2E

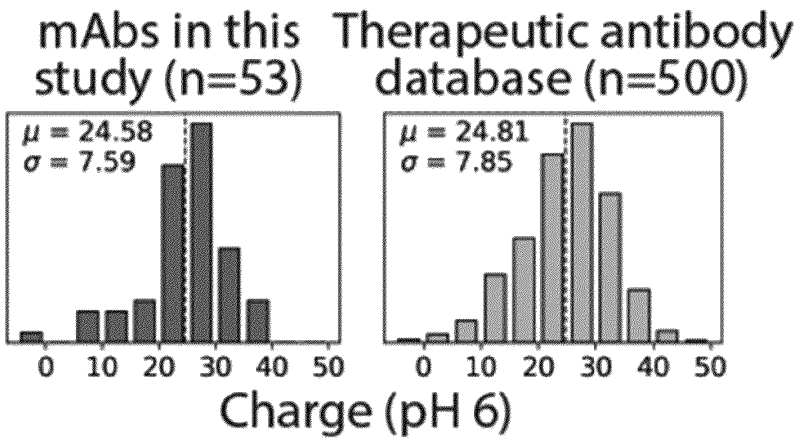


FIG. 3A

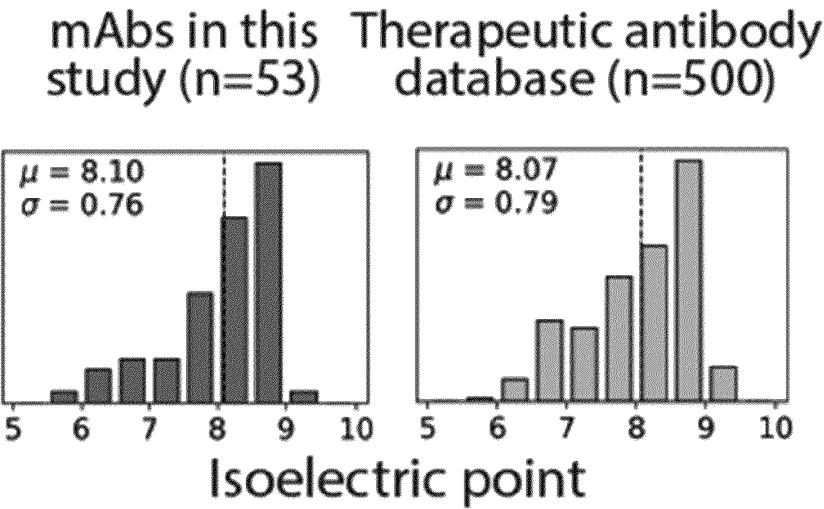


FIG. 3B

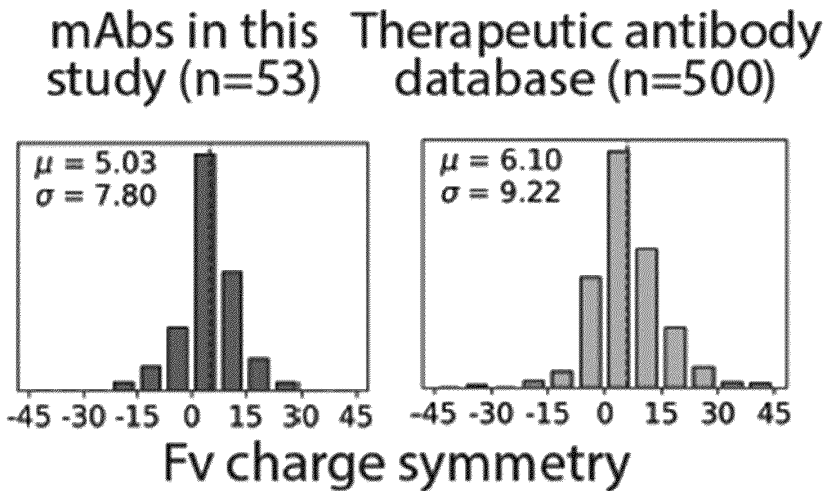


FIG. 3C

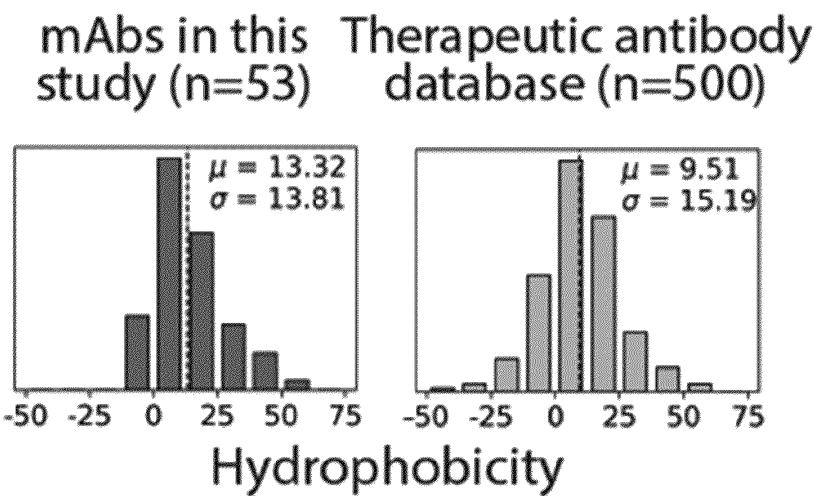


FIG. 3D

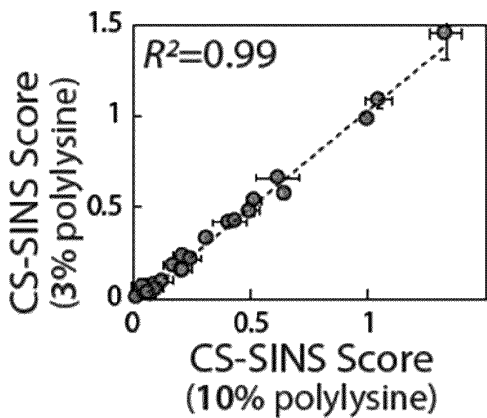


FIG. 3E

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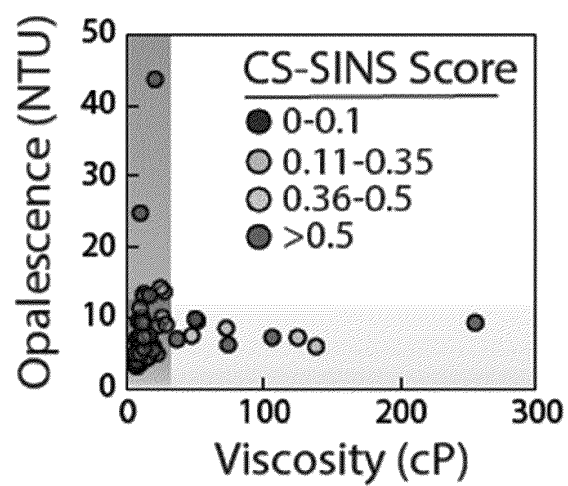


FIG. 3F

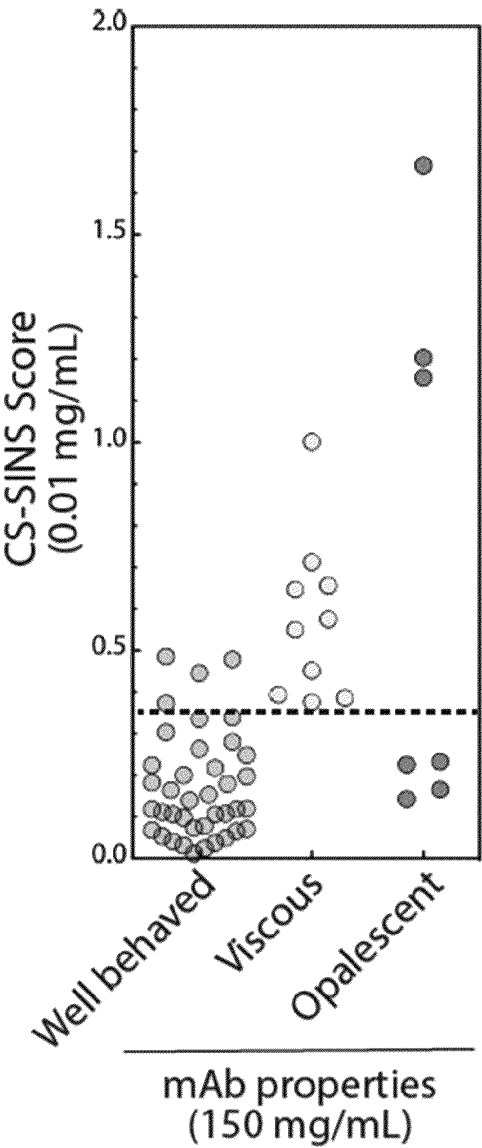


FIG. 3G

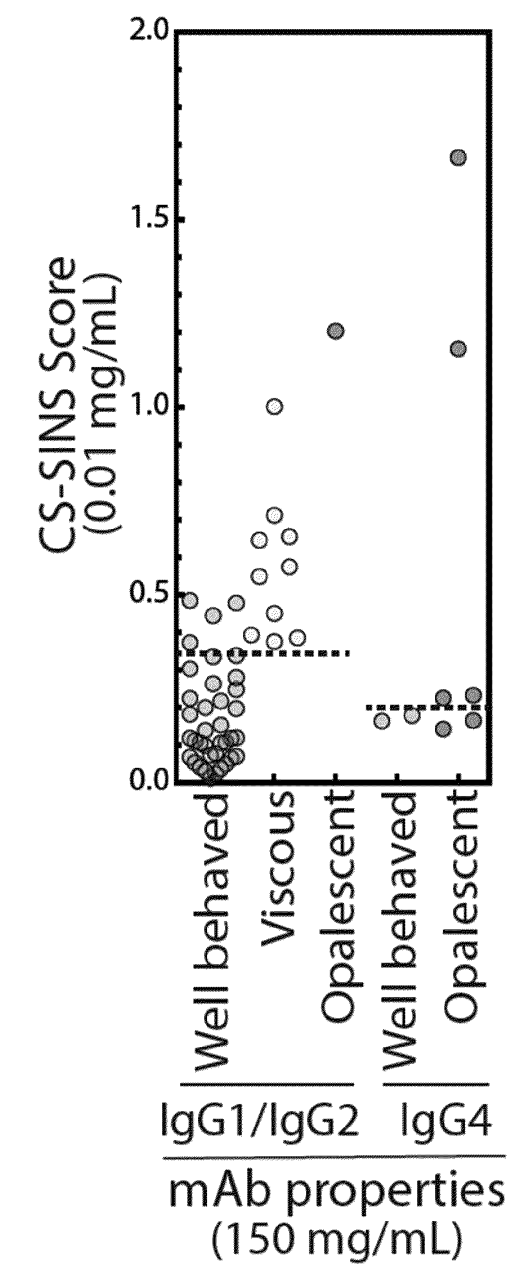


FIG. 3H

Test #1

a. Evaluate is plasmon wavelength measurements of gold anti-Fc conjugates with adsorbed human antibodies are less than 533 nm (NIST mAb) and 534 nm (human polyclonal antibody).

b. If true, proceed to Test #2.

Test #2

a. Perform assay calibration using a panel of six human mAbs

- The six antibodies should display a wide range of self-association behaviors
- Plasmon wavelength measurements are performed for the six reference mAbs (antibodies A, C, D, E, F, K in this study) in each new experiment
- Standard CS-SINS scores for the reference data (i.e., a historical set of data for the reference mAbs) are calculated using the plasmon wavelengths of a low self-association antibody (parameter 1 for mAb A in this study) and a high self-association antibody (parameter 2 for mAb K in this study) using the following equation:

$$\text{CS-SINS Score} = \frac{(\text{mAb} - \text{parameter 1})}{(\text{parameter 2} - \text{parameter 1})}$$

- CS-SINS scores for the reference mAbs in each new experiment are calculated using the same equation but fitting the parameters to maximize the agreement of the linear fit between the new and historical measurements by minimizing the following term:

$$((1 - \text{slope})^2 + (\text{intercept})^2)$$

b. Evaluate if calibration meets criteria for linear fit between new and historical reference data

- Slope of linear fit: $0.9 < x < 1.1$
- Intercept of linear fit: $-0.1 < x < 0.1$
- R^2 of linear fit: > 0.9

c. If all of the criteria in (b) are met, then calibrate CS-SINS scores for entire set of new experimental data using the fitted parameters identified in (a)

FIG. 4

Successful experiment (passes both Test #1 and Test #2)

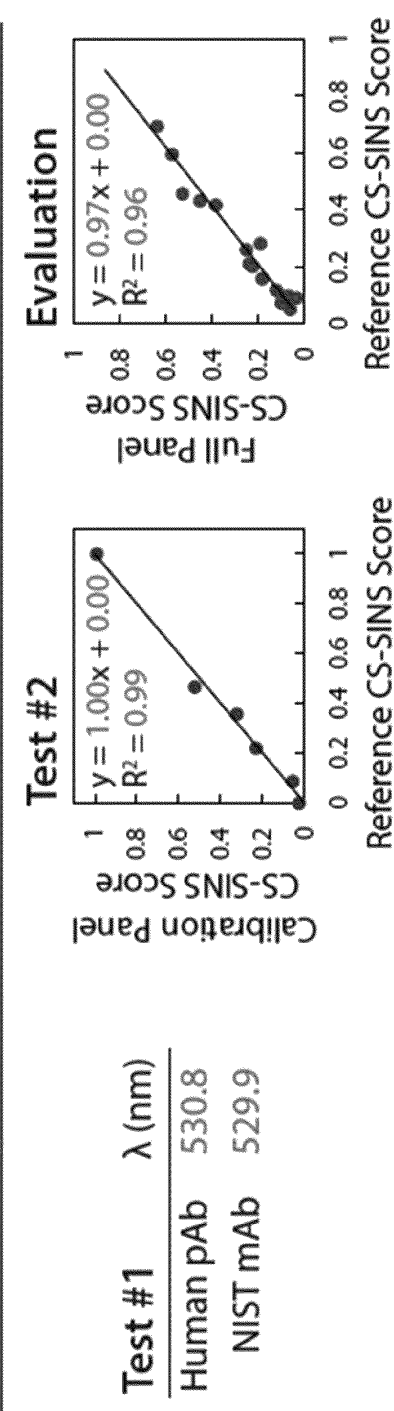


FIG. 5A

Failed experiment (fails Test #1, conjugates slowly mixed)

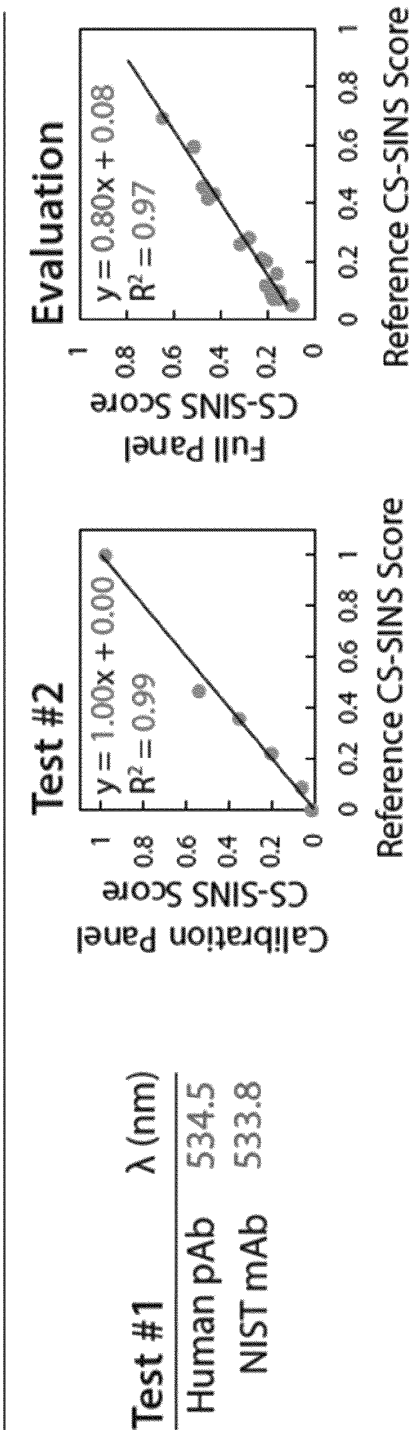


FIG. 5B

Failed experiment (fails **Test #2**, low mAb concentration)

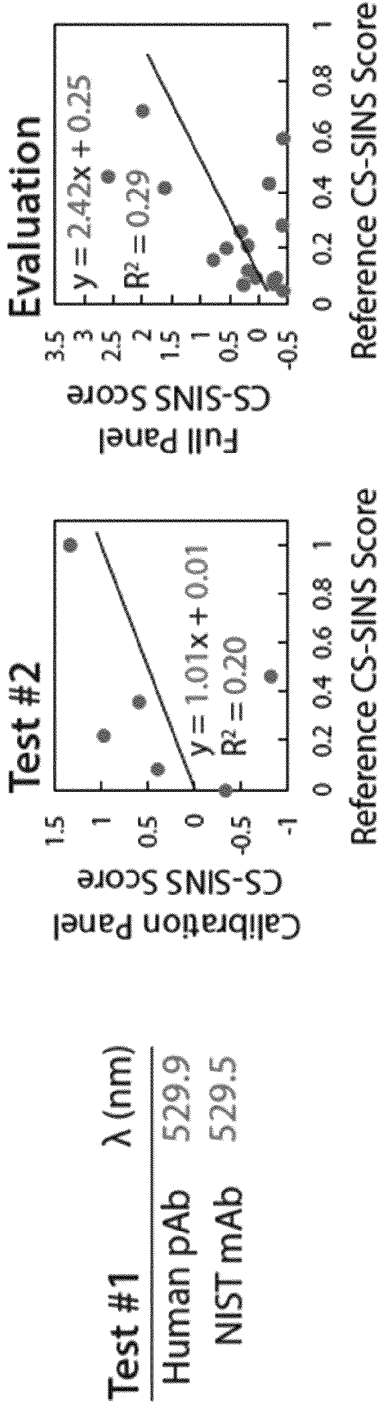


FIG. 5C

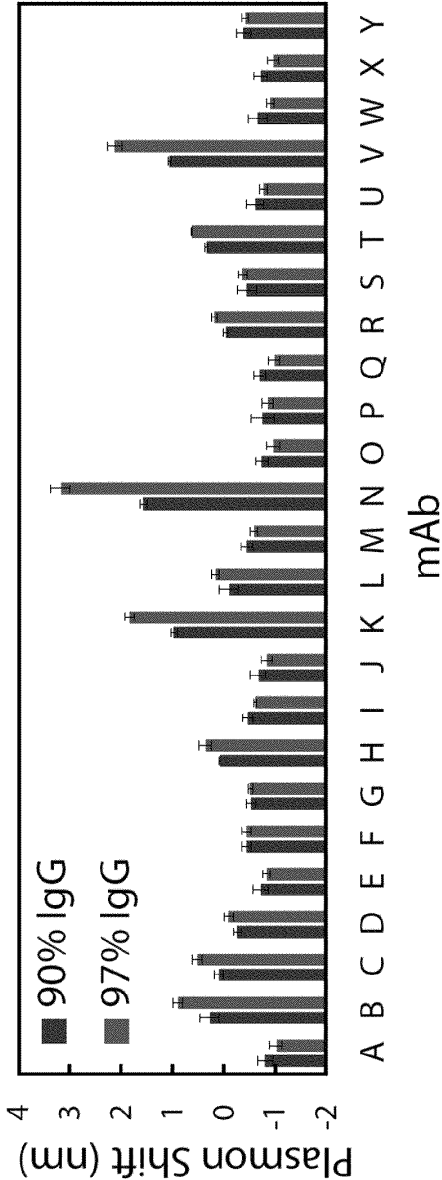


FIG. 6A

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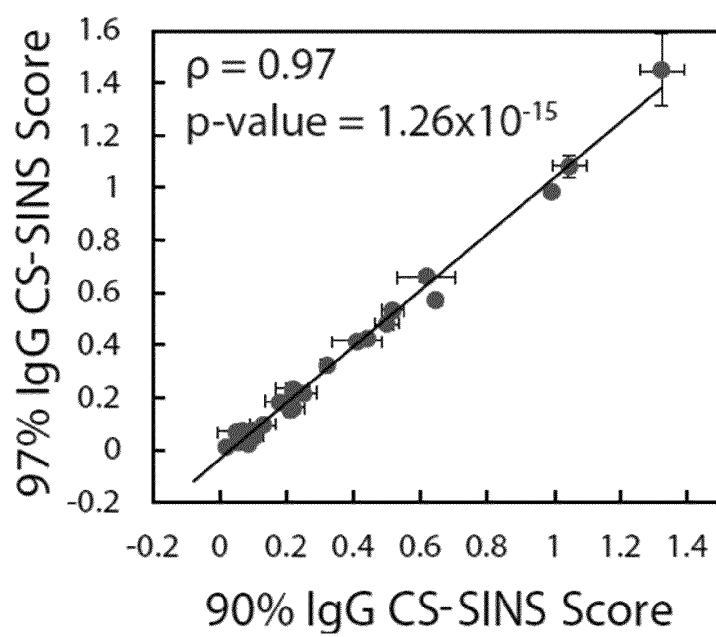


FIG. 6B

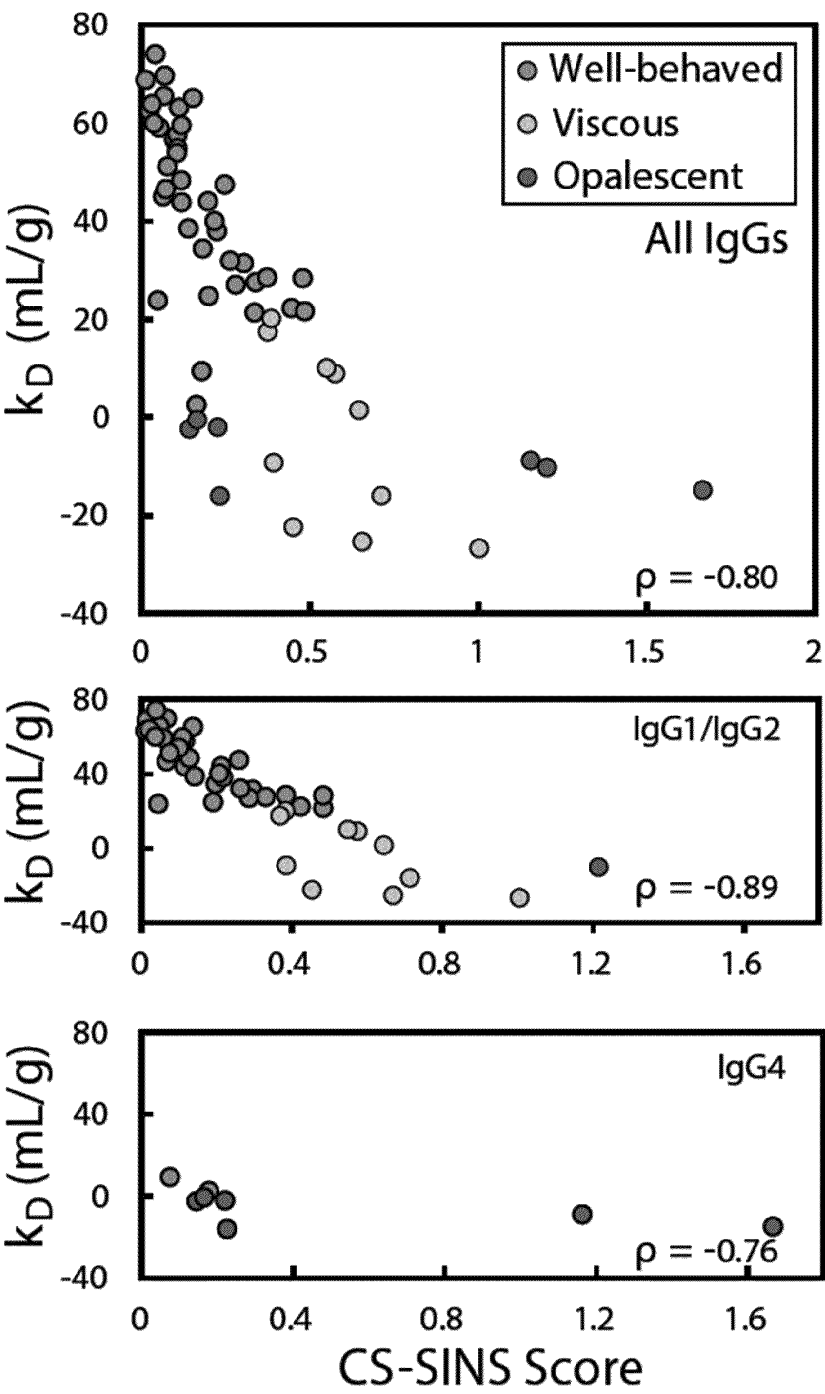


FIG. 7A

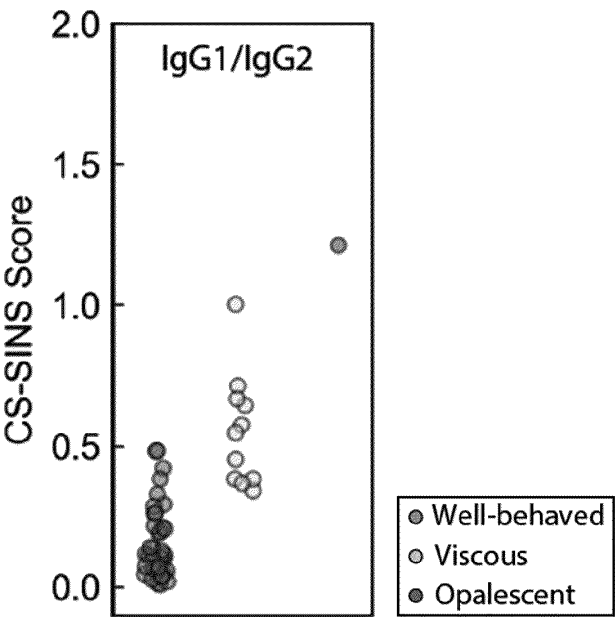


FIG. 7B

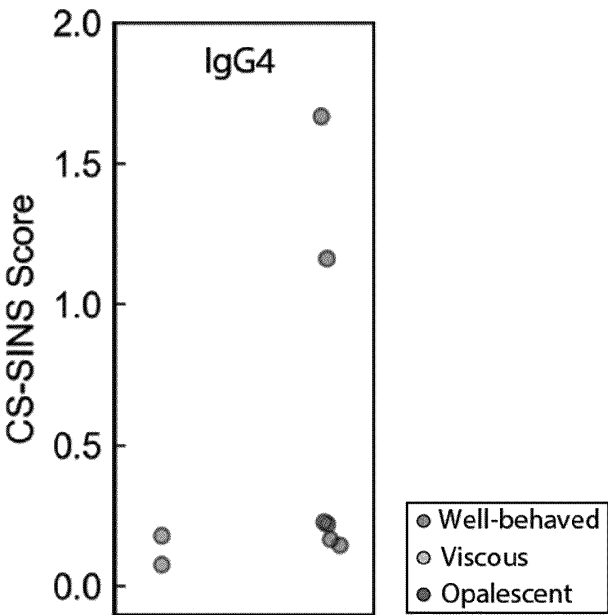


FIG. 7C

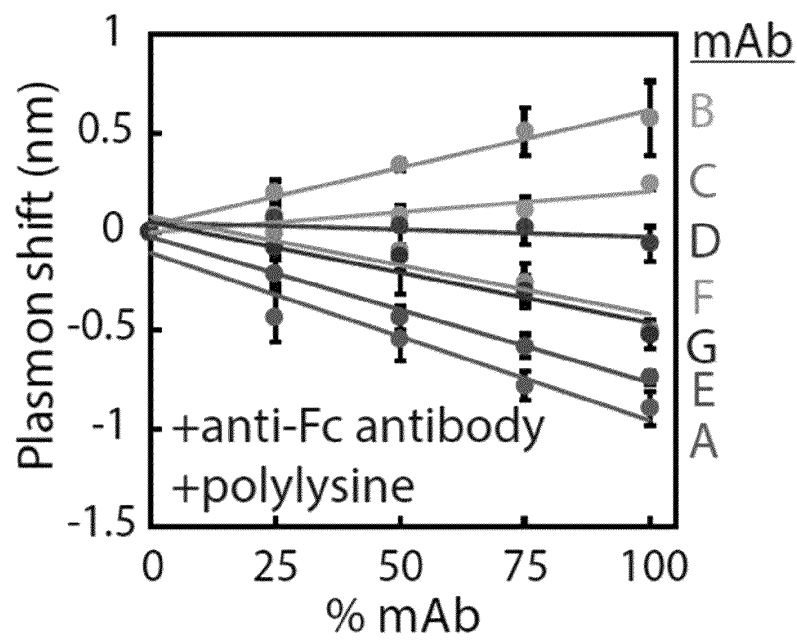


FIG. 8A

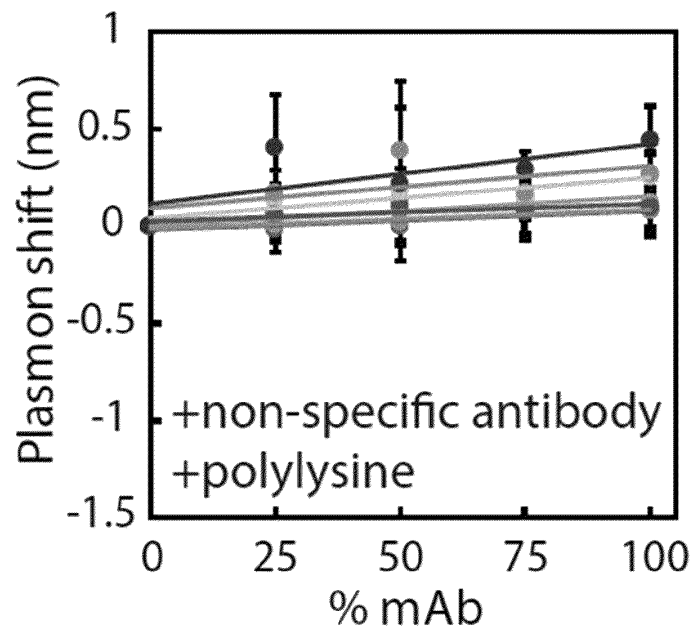


FIG. 8B

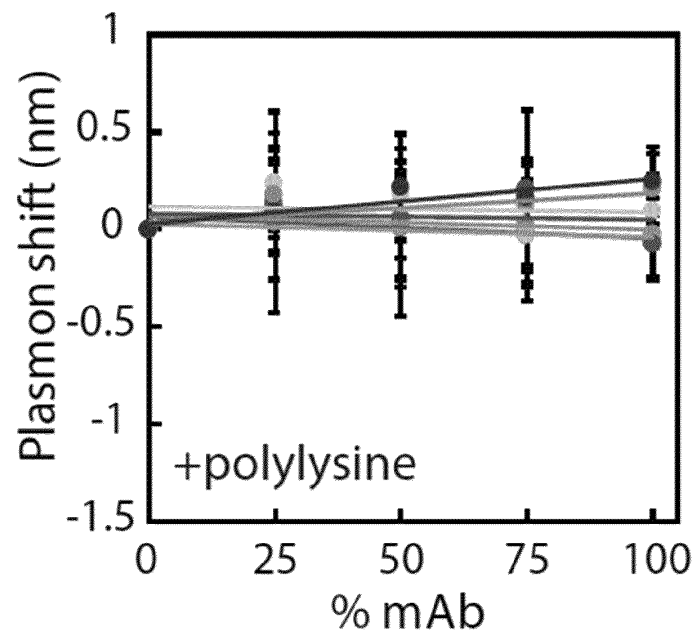


FIG. 8C

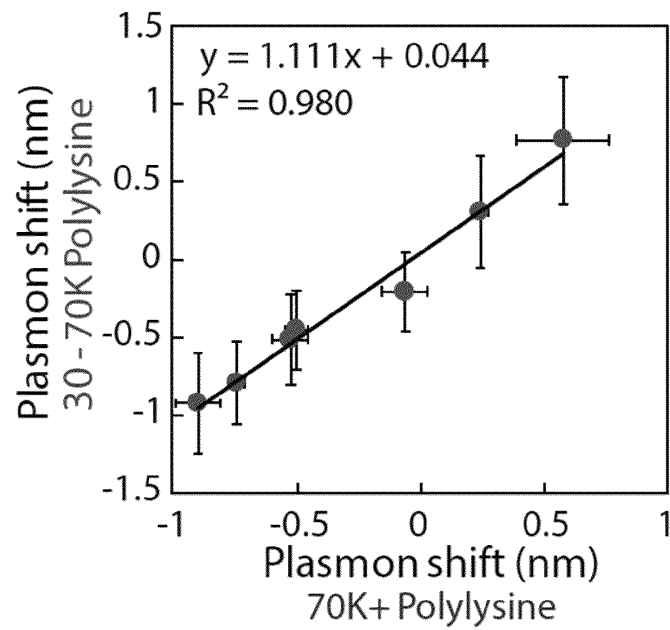


FIG. 9A

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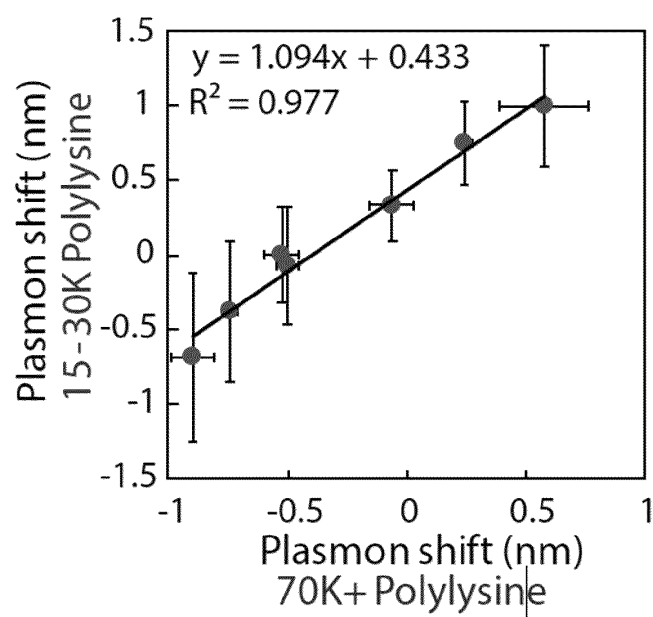


FIG. 9B