Electronic Supplementary Material (ESI) for Analytical Methods.

Stability and Biosimilarity Assessment of Infliximab using Orthogonal Testing Protocol and Statistically-guided Interpretation of Peptide Mapping

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Keywords:

Peptide Mapping; Principal Component Analysis; Infliximab; Biosimilars

Supporting Data 2: Biosimilarity Assessment

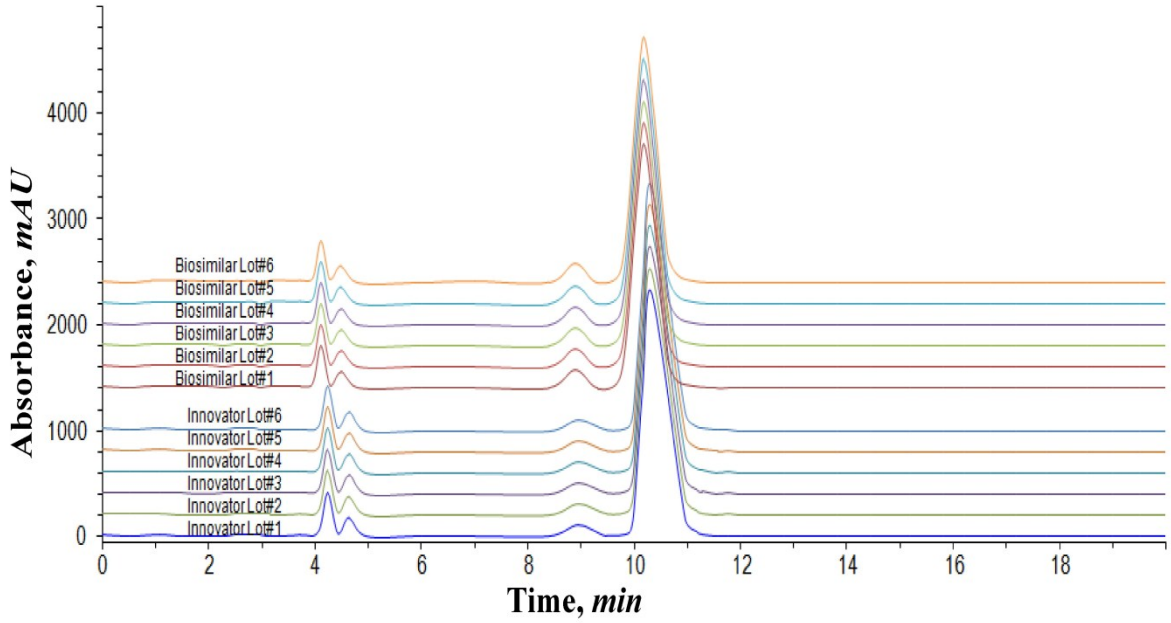

Fig. S10: Overlaid RP-HPLC chromatograms of Infliximab innovator and its biosimilar. The analysis was carried out using Zorbax SB-C8 column, a mobile phase of solvent A (0.1 % TFA in water) and solvent B (0.1 % TFA inacetonitrile), flow rate 1.0 mL $min^{-1}$and detection wavelength of 214 nm. Results of samples from six different batches from each of the innovator and the biosimilar products.

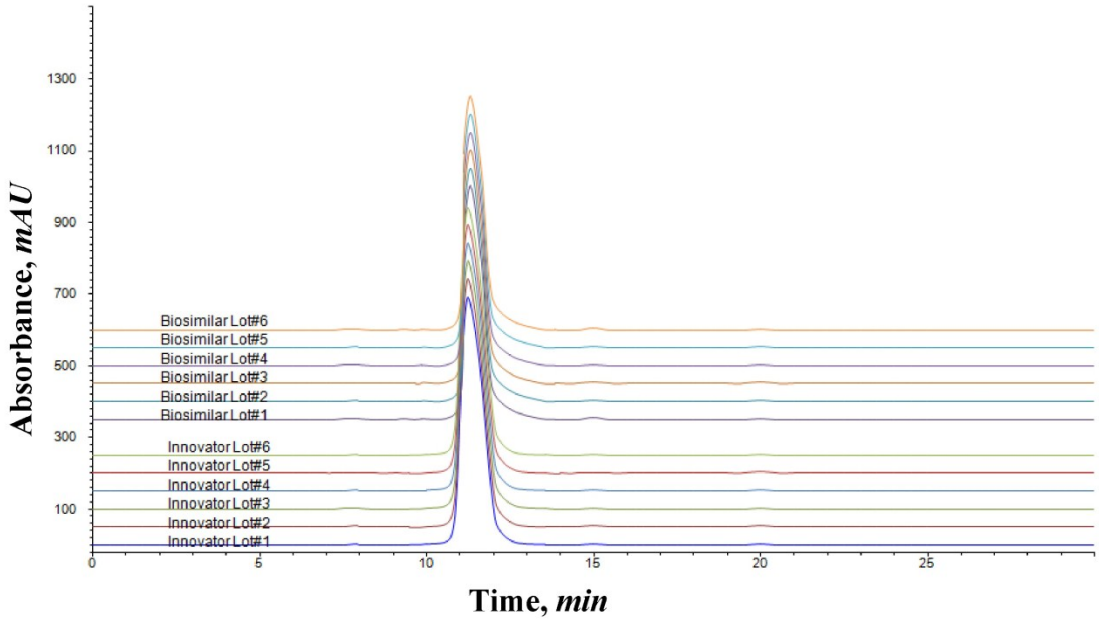

Fig. S11: Overlaid SE-HPLC chromatograms of Infliximab innovator and its biosimilar. The analysis was carried out using YMC-Pack-Diol 300analytical column, a mobile phase of 0.4M sodium perchlorate monohydrate in 40mM phosphate buffer (pH6.8 ± 0.05), flow rate 0.8 mL min^{-1} and a detection wavelength of 214 nm. Results of samples from six different batches from each of the innovator and the biosimilar products.

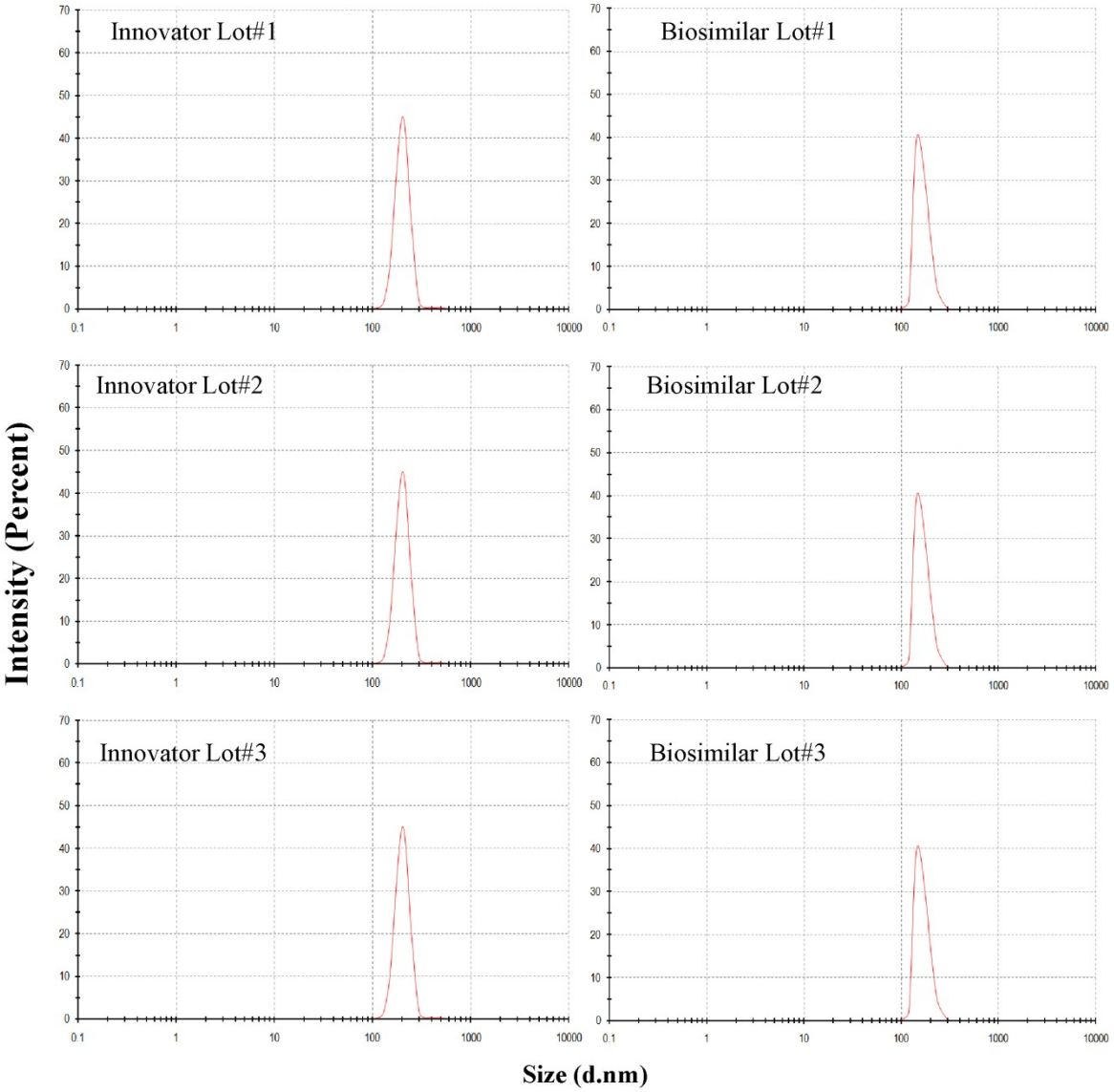

Fig. S12: Particle size distribution for Infliximab Innovator (30.00 mg $ml^{-1)}$ and its biosimilar using dynamic light scattering. Results of samples from three different batchess from each of the innovator and the biosimilar products.

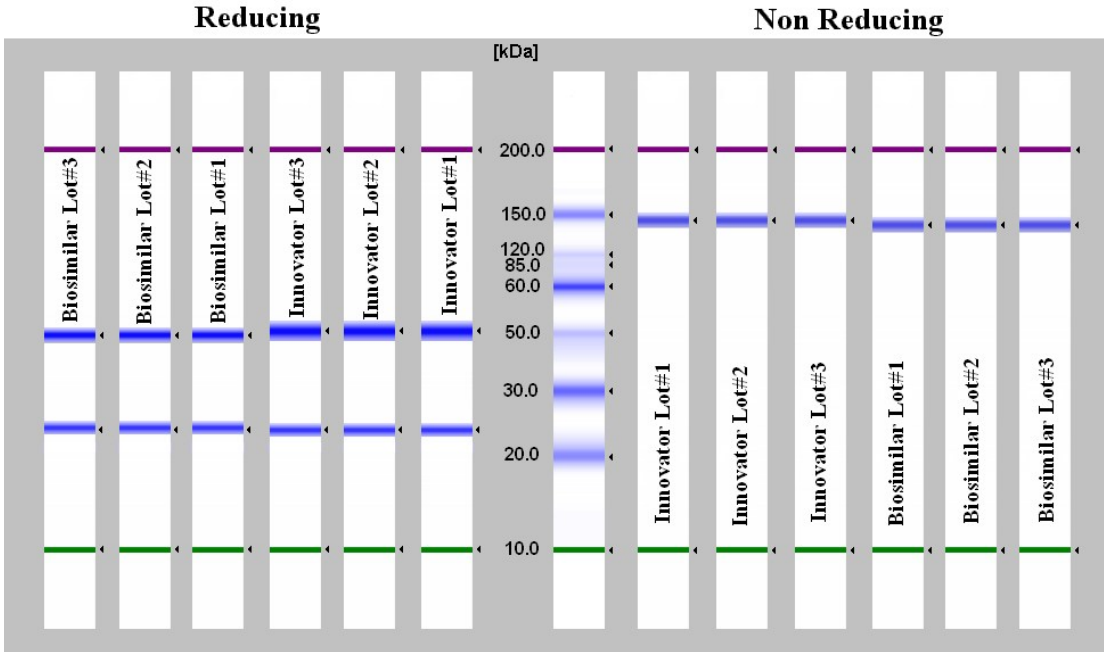

Fig. S13: SDS-PAGE analysis results of Infliximab innovator and biosimilar using Tape Station system under reducing and non-reducing conditions. Molecular weight marker: 10:200 kDa. Results of samples from three different batchess from each of the innovator and the biosimilar products.

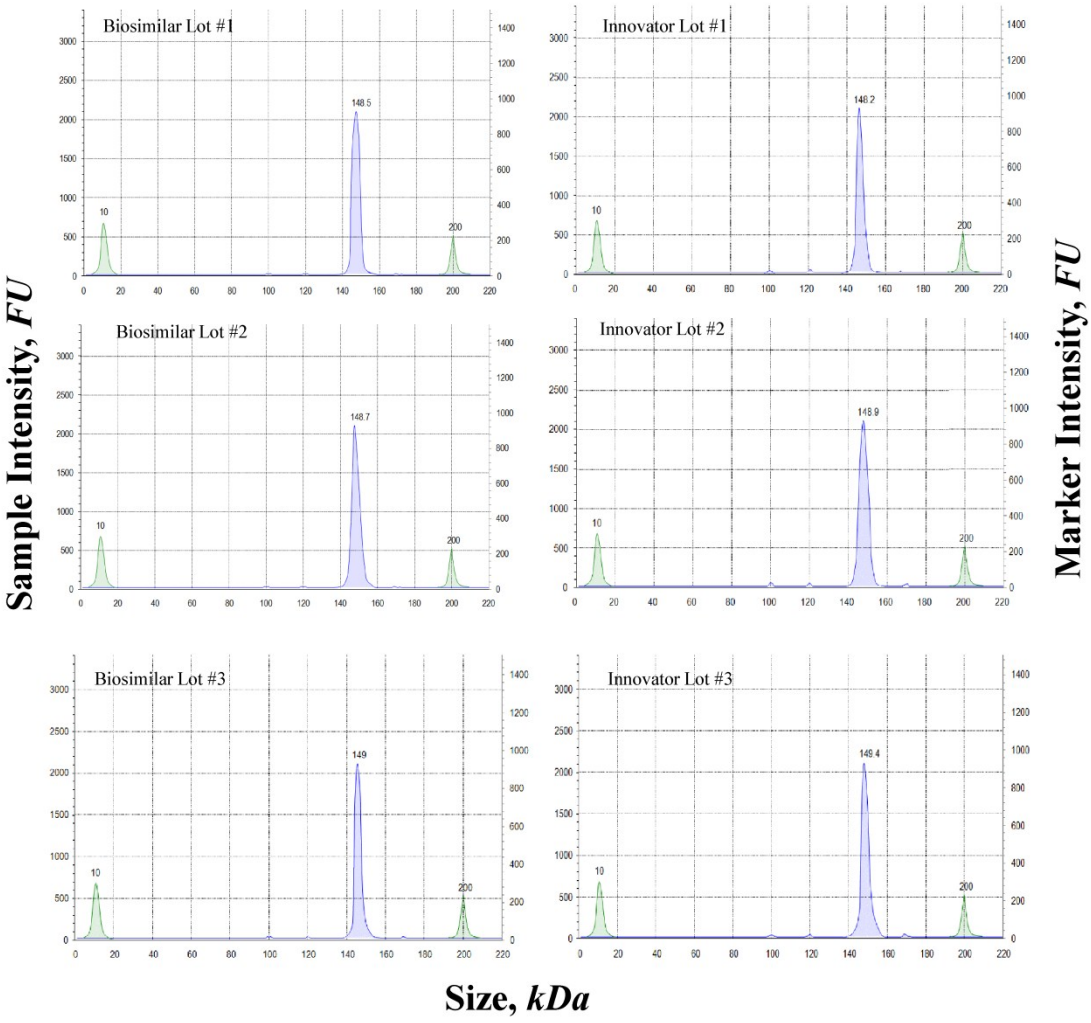

Fig. S14: Electropherograms of Infliximab innovator and biosimilar using Tape Station system under non-reducing conditions. Results of samples from three different batches from each of the innovator and the biosimilar products. Molecular weight marker: 10:200 kDa.

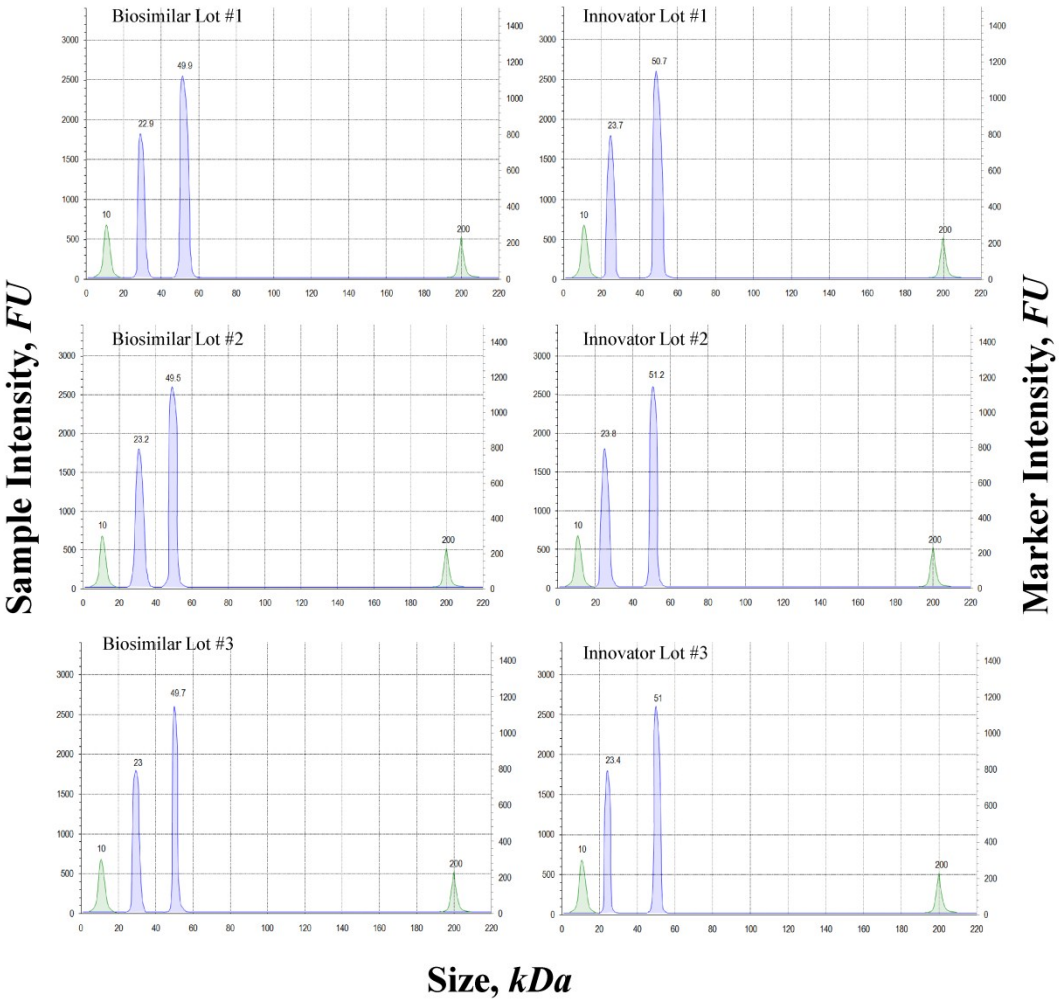

Fig. S15: Electropherograms of Infliximab innovator and biosimilar using Tape Station system under reducing conditions. Results of samples from three different batches from each of the innovator and the biosimilar products. Molecular weight marker: 10:200 kDa.

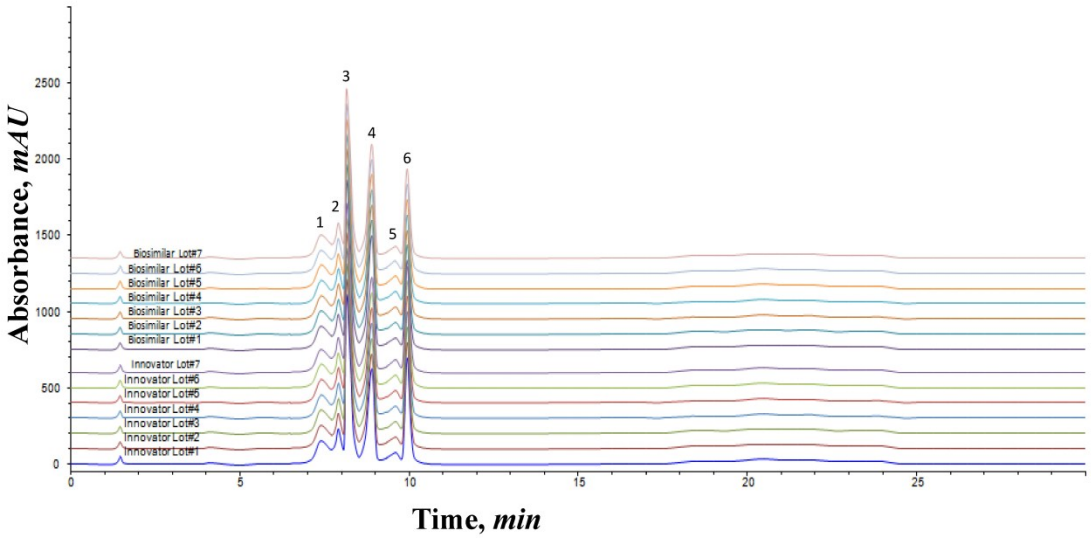

Fig. S16: Comparison of charge profiles between Innovator and biosimilar using Cation Exchange Chromatography. Peak 1, 2: acidic isoforms, peak3: Infliximab isoform, peak 4, 5&6: basic isoforms. The analysis was carried out using Pro Pac WCX-10 analytical column, gradient elution using mobile phase of solvent A 10mM sodium phosphate, (pH 7.25±0.05) and solvent B 10 mM sodium phosphate, 1M sodium chloride, (pH7.25±0.05)., flow rate 0.8 mL min^{-1} and a detection wavelength of 214 nm. Results of samples from six different batches from each of the innovator and the biosimilar products.

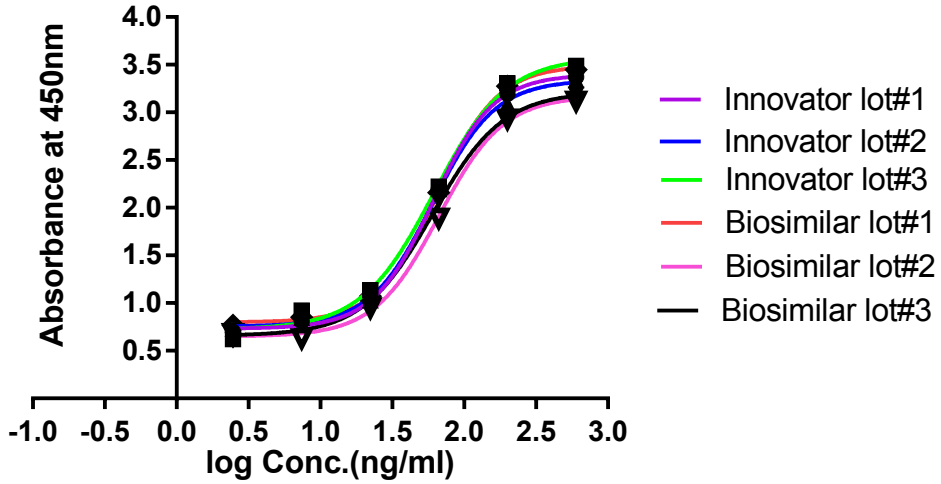

Fig. S17: 4-PL regression plot of Infliximab innovator and biosimilar using the receptor binding assay in ELISA format. Results of samples from three different batches from each of the innovator and the biosimilar products.

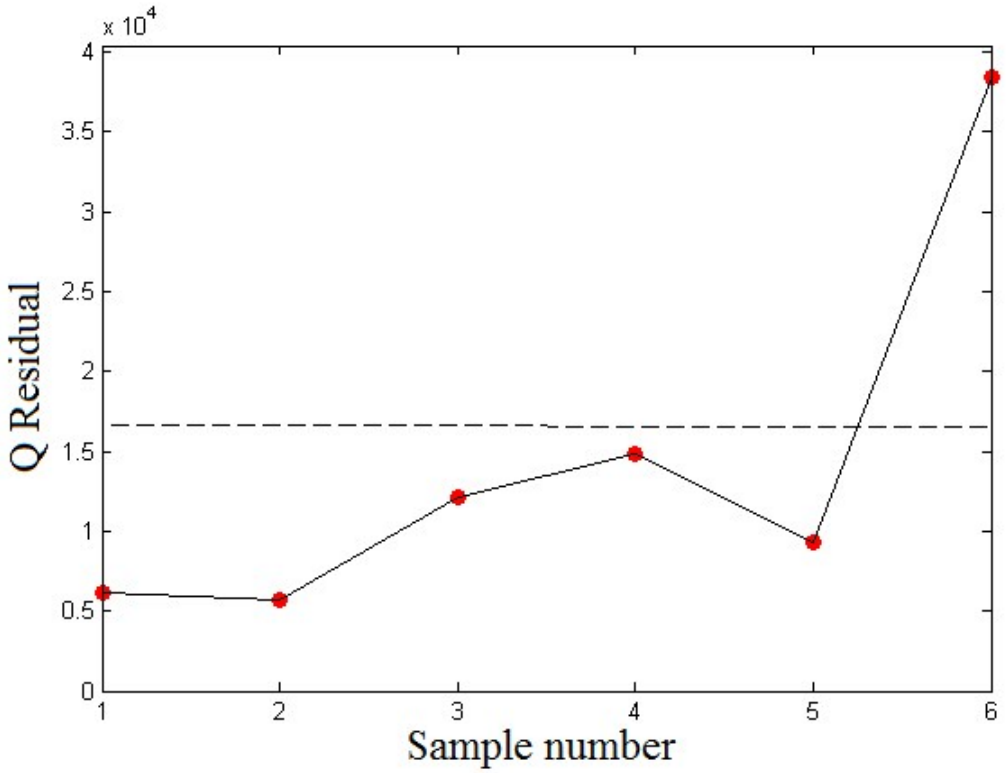

Fig. S18: Q statistic on 2 PC model showing the specificity of the created model. The dashed line shows 95% confidence limit.