



## Poor Spike and Recovery

Spike and recovery of known amounts of analyte into your various sample types is a critical experiment to validate the accuracy of a given method. In some cases the product protein itself or certain components in the product formulation buffer may interfere in the ability of the assay to detect HCPs or other contaminants. Factors such as extremes in pH, detergents, organic solvents, high protein concentration, and high buffer salt concentrations are known to interfere. This interference is normally negative in nature and manifests itself as under recovery of the spiked analyte. It is necessary to validate by universally recognized experimental procedures (i.e. ICH & FDA guidelines) that the assay will yield accurate results. Should the end user of this kit determine there is significant product or matrix interference, it may be necessary to further process the sample by methods such as dilution or buffer exchange to render it into a more assay compatible buffer. The same diluent used to prepare the kit standards is ideally the preferred material for dilution or buffer exchange of your samples. In other cases, modification of the assay protocol can affect improved accuracy in some sample types. For each sample type to be tested, be it final product or in-process samples, you should demonstrate that the assay can recover added analyte spiked into that sample matrix. Proper dilution protocol can be found at [Spike & Recovery Studies](#). You are encouraged to contact our Technical Services Department for advice on how best to solve poor spike and recovery problems in our kits.