



Future-proof your HCP strategy.

Robust and accurate HCP measurement is crucial throughout biologics development.

From sample preparation to data analysis, each step affects the next — and ultimately, your results.

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Four questions to help you decide if your HCP analysis data is accurate, robust, and ready for next phase approval.

Is your sample compatible?

CV between a minimum of three dilutions should be < 20%.

You are off to a good start!

Below 20% means your assay is **compatible**.



Well that was a rough start!

Above 20% means your assay is **not** compatible.

Challenge your current HCP ELISA against another manufacturer.

Pick your more compatible sample and confirm the accuracy with spike recovery.

Recovery of known HCP concentration must be within 80% to 120% to be valid.

Now you are just showing off!

Within 80% to 120% means your assay is **accurate**.



Back you go!

Outside 80% to 120% means your assay is **not** accurate.

Challenge your current HCP ELISA against another manufacturer.

Is your assay reproducible?

Inter- and intra-plate assay CV should be < 20%.



Have you done this before?

Below 20% means your sample is **reproducible**.



We all know what happens next...

Above 20% means your sample is **not** reproducible.

Challenge your current HCP ELISA against another manufacturer.

Is your HCP antibody coverage sufficient?

Over 70% coverage is optimal.



You did it! Cue inspirational montage...

Over 70% coverage using DIBE™ is optimal.

So close!

Coverage **under 70%** is **not** optimal.

Challenge your current HCP ELISA against another manufacturer.

Submit your accurate and robust data for next phase approval.

We understand that HCP control requires more than a product. It requires a strategy.

Whether your HCP detection is outsourced or managed in-house, our solution is to lead with quality, reliability, and efficiency across the entire workflow — giving you the confidence that your results are robust and reproducible.

- ELISA kits and coverage workflow
- Equipment
- 2D consumables
- Software
- Training
- Scientific support