Detecting Low-Level Polyethylene Glycol (PEG)–Specific IgE by the FocalTuning™ Platform

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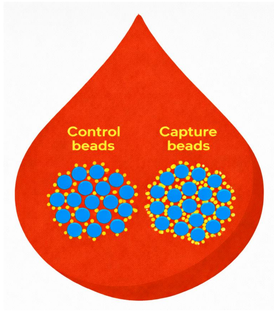
Rationale: The role of PEG-specific IgE in anaphylaxis induced by PEG-containing products remains controversial. Key bottlenecks include the low abundance of IgE antibodies and substantial background interference.

Methods: An intra-sample background control was incorporated into a bead-based flow cytometric assay. Phosphate-buffered saline (PBS) containing 5% BSA was used as the negative control; an official international standard calibrated PEG-specific IgE was served as the positive control. Healthy human plasma/serum samples were obtained from multiple commercial sources.

Control beads:
For background signal

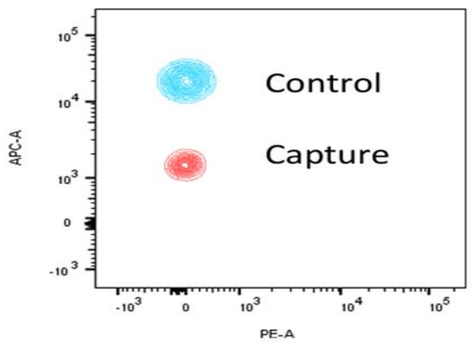
Capture beads:
For analyte signal
and
background signal



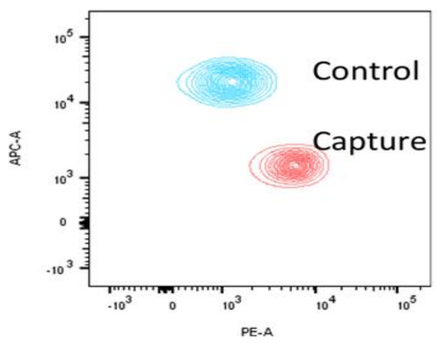
Two-level background correction
Patient-specific background
Matrix-specific background

LOD: <0.1ng/mL =0.04kU/L

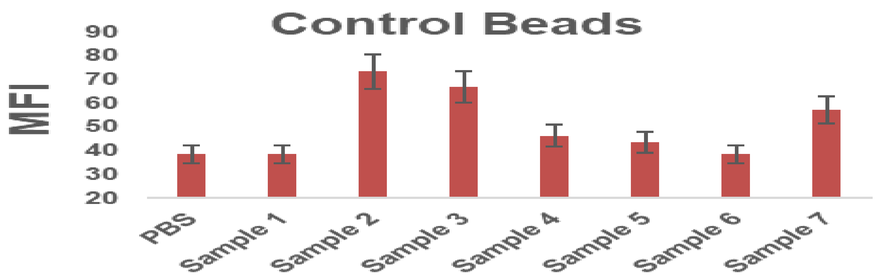
Results:



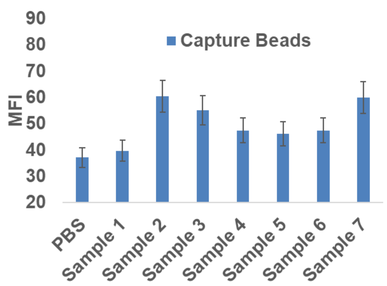
PBS Negative control

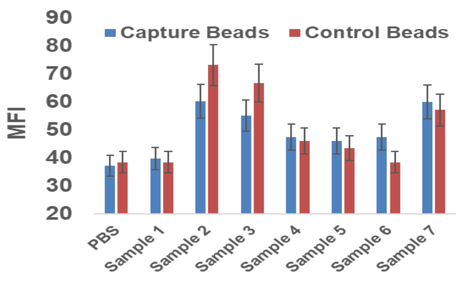


PEG IgE positive control

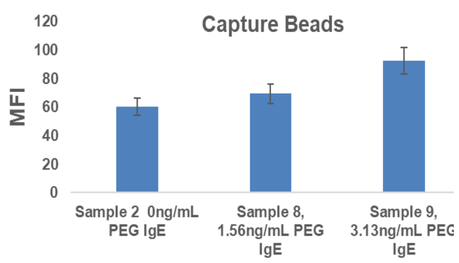


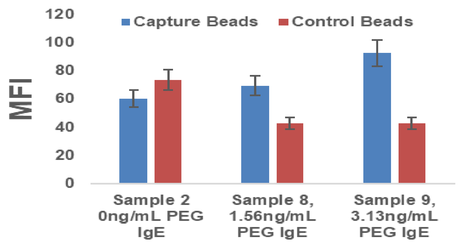
Different samples have different background signals
(Samples 1-4: human plasma; Samples 5-7: human serum)





Pseudo-positive data by capture beads alone (left panel, samples 2 and 3, compared with PBS) **are avoided** by introducing paired control beads (right panel, samples 2, 3, 7).





Pseudo-negative data by capture beads alone (left panel, low-level PEG-IgE sample 8, compared with sample 2**)** **are avoided** by introducing paired control beads (right panel, sample 8)

Conclusions: Patient-specific and matrix-specific background interference may contribute to false-positive or false-negative results, particularly when the target signal is present at low levels. The FocalTuning platform enhances the accuracy of PEG-specific IgE detection, which enables intra-sample normalization and matrix-matched control.