NIDS® Rapid Assays for the Detection of Anti-Drug Antibodies to Various Polyethylene Glycol (PEG) Polymers

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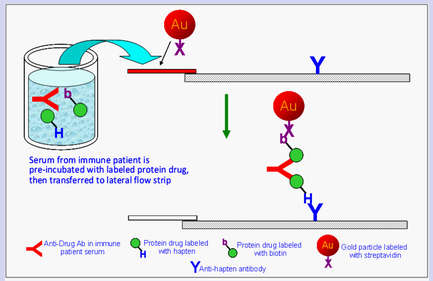
INTRODUCTION

Rapid double antigen bridging immunonogenicity assays for the detection of anti-drug antibodies (ADA) to 40 kDa and 20 kDa Polyethylene Glycol (PEG) in human serum have been successfully developed.

The assays require no sample dilution and no washing steps which can perturb fragile complexes formed by low-affinity ADAs. No dilution improves the detection of low titer ADAs.

Principle of the Rapid Immunogenicity Assay

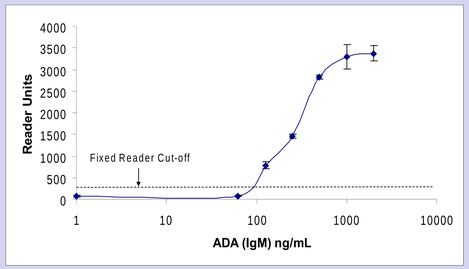


Handheld Readers and Rapid Assay Test Tickets

The NIDS® handheld reader (left) is for on-site rapid testing, and the medical reader (right) is for quantitative Point of Care testing (POCT).

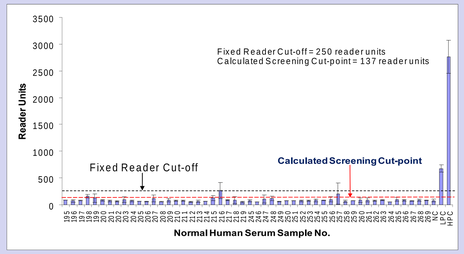
40 kDa PEG Rapid Immunogenicity Assay

Rapid Bridging Immunogenicity Assay dose response curve with anti-PEG antibody (IgM) spiked into human serum pool



Assay Sensitivity = 125 ng/mL ADA

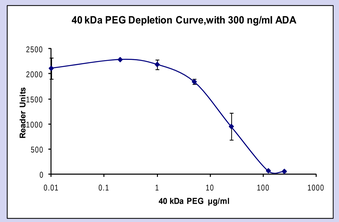
Evaluation of Normal Human Serum Samples in the 40 kDa PEG Rapid Immunogenicity Assay

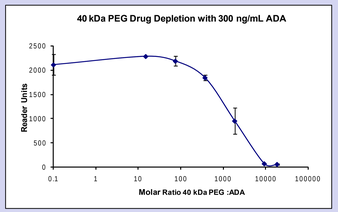


NC = Negative Control, LPC = 125 ng/mL ADA, HPC = 500 ng/mL ADA

50 normal human serum samples were tested in the 40 kDa PEG Rapid Immunogenicity Assay. Using the calculated screening cut-point, a 6% false positive rate was determined for the limited population tested. Using the fixed reader cut-off, two possible positive samples (no. 216 and 257) were identified and subsequently tested in a drug depletion assay.

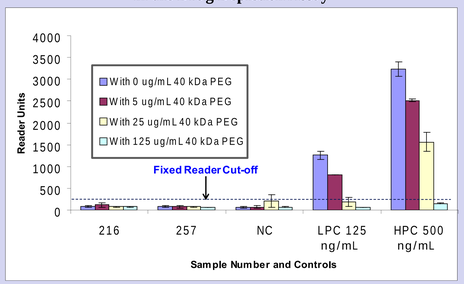
40 kDa PEG Depletion Assay in neat human serum





300 ng/mL of anti-PEG antibody (IgM) and increasing amounts of free 40 kDa PEG were spiked in a human serum pool and incubated at RT for 1 hour before testing

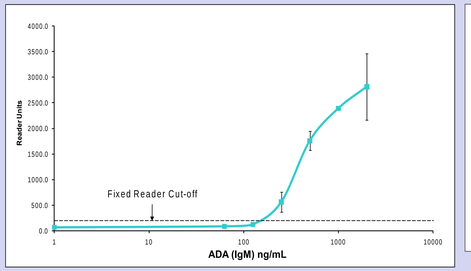
Evaluation of Positive Samples in the Drug Depletion Assay



After repeat testing and running the depletion assay, Samples 216 and 257 were confirmed to be negative.

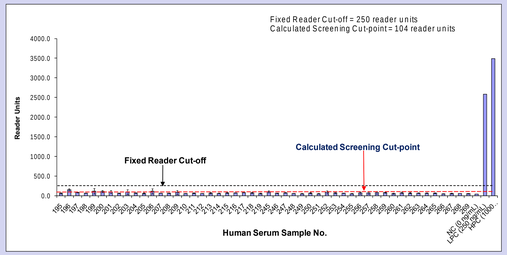
20 kDa PEG Rapid Immunogenicity Assay

Rapid Bridging Immunogenicity Assay dose response curve with anti-PEG antibody (IgM) spiked into human serum pool



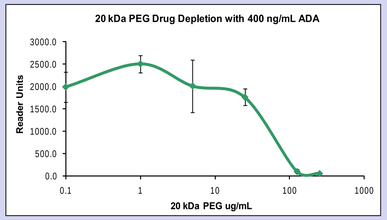
Assay Sensitivity = 250 ng/mL ADA

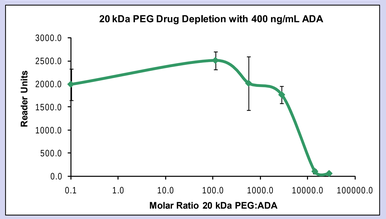
Evaluation of Normal Human Serum Samples in the 20 kDa PEG Rapid Immunogenicity Assay



50 normal human serum samples were tested in the 20 kDa PEG Rapid Immunogenicity Assay. Using the calculated screening cut-point a 6% false positive rate was determined for the limited population tested.

20 kDa PEG Depletion Assay in neat human serum





400 ng/mL of anti-PEG antibody (IgM) and increasing amounts of free 20 kDa PEG were spiked in a human serum pool and incubated at RT for 1 hour before testing

Advantages of the NIDS® Rapid Immunogenicity Assay

1. No sample dilution
2. No wash steps
3. Fixed Screening Cut-point
4. Fast
5. Accurate
6. Easy to use
7. Affordable