

Clinical Utility to Monitor Anti-TNF Antibodies using Novel IgXPLEX Planar Microarray Diagnostics.

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A sensitive microarray assay has been tested for measurement of anti-TNF- α using SQI's IgX-PLEX™ assay. Testing 10 microliter serum samples, the multiplex planar microarray fluorescent immunoassay offers quantitative measurement for anti-TNF- α drug concentration, such as Infliximab, in each sample well of a 96-well, test microarray plate. Immuno globulin specific fluorescent tagged markers captured on microarray spots are read in a microarray scanner. Each microarray is processed with reference to quality control and calibration incorporated into every sample well, e.g. (Clin Rev Allergy Immunol. DOI 10.1007/s12016-009-8189-z; Lea et al). The TNF blocker drug assay measures the concentration of e.g. Infliximab in patient serum when binding with TNF- α in a microarray spot. The performance criteria for this assay were set to be for >90% specificity and >80% agreement with comparative, predicate test values. Standard curves were developed at preset drug concentrations to measure the unknown amount of free drug present in patient's sera. The IgX-PLEX Infliximab assay provided 100% specificity by not reporting the drug in healthy serum samples, but reporting drug levels when expected to be present, e.g. patients responding to treatment. The assay is confirmed for non interference by Bilirubin, hemoglobin, triglycerides, and human IgG. This novel microarray assay system detects and measures TNF- α blocker drug concentrations at high sensitivity and specificity.