

Clinical Diagnosis of Celiac Disease Biomarkers: Sensitivity and Specificity in a Novel 4-PLEX Planar Microarray Assay

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Simultaneous multiplex detection of recognized gluten-sensitive enteropathic Celiac disease biomarkers improves diagnosis. A novel multiplex serological assay simultaneously measured four Celiac disease auto-antibody biomarkers, Gliadin IgA, Gliadin IgG together with tTG IgA and tTG IgG, using SQI's IgX PLEX™ assay. Testing 10 microliter clinically diagnosed serum samples (n=100), the multiplex planar microarray fluorescent immunoassay offers qualitative /semi-quantitative and positive/negative results for four biomarkers in each sample well of a 96-well, Celiac assay microarray plate. Immunoglobulin 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. 2009 Dec 9. [DOI 10.1007/s12016-009-8189-z; Lea et al]. Celiac disease human serum samples and normal controls were tested and results compared with predicate and conventional immunoassays. Based on ROC analysis, the study demonstrated that the IgX-PLEX test achieved Gliadin IgA 47.6% sensitivity with 98.1% specificity; Gliadin IgG at 61.9% sensitivity with 94.6% specificity; tTG IgA 90.5% sensitivity at 100% specificity; and tTG IgG 52.4% sensitivity at 98.1% specificity. In a method comparison study, clinical truth discrepant result resolution indicated that, when compared to predicate assays, the percentage of accurate IgX-PLEX Celiac assay detection resulted in increases of 13.3% for Gliadin IgA, 57.5% for Gliadin IgG, 37.5% for tTG IgA and 8.3% for tTG IgG.