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Inova Diagnostics' QUANTA Flash RF IgM and IgA get FDA clearance

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These chemiluminescent assays complement Inova Diagnostics previously cleared QUANTA Flash CCP3 assay that detects anti-citrullinated peptide antibodies (ACPA)

Inova Diagnostics, a world leader in autoimmune disease diagnostic systems and reagents for the clinical laboratory, is pleased to announce the 510(k) clearance of QUANTA Flash® Rheumatoid Factor (RF) IgM and QUANTA Flash RF IgA assays by the US Food and Drug Administration (FDA). These chemiluminescent assays complement Inova Diagnostics previously cleared QUANTA Flash CCP3 assay that detects anti-citrullinated peptide antibodies (ACPA) and expands the number of FDA-cleared assays available on BIO-FLASH®, a random access chemiluminescent system.

Rheumatoid arthritis (RA) affects approximately one percent of the global population and leads to progressive and permanent joint damage. The American College of Rheumatology and the European League Against Rheumatism classification criteria include both RF and ACPA. RF IgM has been reported to be the main RF isotype in confirmed RA patients with a prevalence of 70-80%.

RF IgA, while less prevalent than the IgM isotype, has been reported to be associated with more severe erosive disease and an increased likelihood for Sj?gren's Syndrome or other extra-articular manifestations. There is also value in testing for multiple RF isotypes as the specificity and predictive value for RA increases when more than one isotype is positive.