Inova announces FDA 510(k) clearance for its Aptiva system

June 29, 2021–Inova Diagnostics announced FDA 510(k) clearance of its Aptiva system and Aptiva Celiac Disease IgA assay. Aptiva is a fully automated digital multi-analyte system for the clinical laboratory.

Aptiva uses a particle-based multi-analyte technology (PMAT) that processes multiple analytes simultaneously from a patient sample. PMAT enables Aptiva to deliver up to 720 results per hour using a 12-analyte test cartridge and allows the laboratory to complete its workflow in a single shift. The system offers a 6.5-hour consumable walkaway time, and its 150-sample rack capacity reduces the number of daily interventions.

Beyond the celiac assay, Aptiva will include seven additional autoimmune disease states and has more than 60 analytes in various stages of advanced development. The system received CE marking in August 2020.