

# FDA clears Immuno Concepts IgG Anti-nDNA test system

July 2023—Immuno Concepts announced FDA 510(k) clearance of its IgG Anti-nDNA fluorescent test system for use with the company's Image Navigator system. The test is for in vitro diagnostic use for qualitative detection and semiquantitation of anti-nDNA antibodies of the IgG class in human serum to aid in diagnosing systemic lupus erythematosus in conjunction with other clinical and laboratory findings.

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