

NEW TEST TEST CHANGE

NOTIFICATION DATE: 03/15/2024

EFFECTIVE DATE: 04/02/2024

Double-Stranded DNA Antibody (Anti-dsDNA)

On the effective date, Northwell Health Laboratories will implement a change in the assay method used for the Double-Stranded DNA (anti-dsDNA) antibody test due to a nationwide discontinuation of reagent kits. The current Enzyme-Linked Immunosorbent Assay (QUANTA Lite dsDNA SC ELISA) will be substituted with a Multiplex Flow Immunoassay (BioPlex 2200 dsDNA).

An in-house method comparison study conducted at Northwell Health Laboratories demonstrated good, overall qualitative agreement between the two assays. These findings align with observations from other published studies (1,2,3). *However, it is important to note that due to differences in the target antigen source, direct comparison of quantitative values between the two assays is not feasible, as highlighted in the table below.* This variability is anticipated, given the heterogeneous nature of dsDNA antibodies, which may exhibit varying reactivity to specific antigenic epitope targets.

The double-stranded DNA antibody serves as a valuable serological biomarker for assessing patients with suspected systemic lupus erythematosus.

| Test Requirement | New | Previous |
|-------------------------|---|--|
| Methodology | Multiplex Flow Immunoassay | Enzyme-Linked Immunosorbent Assay |
| Manufacturer | Bio-Rad Laboratories | Inova Diagnostics (Werfen) |
| Antigen source | Synthetic dsDNA | Native calf thymus dsDNA |
| Result Interpretation | ≤ 4 IU/mL Negative $5 - 9$ IU/mL Indeterminate ≥ 10 IU/mL Positive | < 30 IU/mL Negative $30 - 75$ IU/mL Indeterminate > 75 IU/mL Positive |
| Computer Interface Code | PDM #5700071 | PDM #5700071 |
| Test Order | DNA | DNA |

If you have any questions, please contact Client Services at (800) 472-5757.

References:

1. M Infantino et al. Scand J Immunol. 2022; 96:e13220. doi: 10.1111/sji.13220
2. M Infantino et al. J Immunol Res. 2015; 2015: 902821. doi: 10.1155/2015/902821.
3. E Mummert et al. J Immunol Methods. 2018 Aug;459:11-19. doi: 10.1016/j.jim.2018.05.014.