MAYO CLINIC LABORATORIES

Test Definition: CRITH

DNA Double-Stranded (dsDNA) Antibodies by Crithidia luciliae IFA, IgG, Serum

Overview

Useful For

Confirmation testing for dsDNA IgG antibodies in patients with clinical features of systemic lupus erythematosus or at-risk for disease

This test may not be used independently for monitoring treatment response or establishing remission.

Method Name

Only available as an add-on request. For more information see ADNA1 / Double-Stranded DNA (dsDNA) Antibodies, IgG, Serum.

Indirect Immunofluorescence

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	21 days	
	Frozen	21 days	

Clinical & Interpretive

Clinical Information

Double-stranded DNA (dsDNA) antibodies are systemic lupus erythematosus (SLE)-specific antibodies and are part of the immunology domain of the 2019 European League Against Rheumatism (EULAR)/American College of Rheumatology (ACR) classification criteria for SLE (1) as well as a previous guidance on SLE diagnosis.(2) The *Crithidia luciliae* indirect immunofluorescence test (CLIFT) is widely used as a confirmatory test following a positive dsDNA IgG result obtained by a solid-phase immunoassay due to its structural or analytical specificity.(3-5)

The CLIFT (dsDNA) test is indicated in patients who are positive for anti-cellular antibody (also known as antinuclear antibody [ANA]) homogeneous pattern (6) using HEp-2 substrate by indirect immunofluorescence assay (IFA) following a

positive result for dsDNA IgG using a solid-phase immunoassay (eg, enzyme-linked immunosorbent assay or multiplex bead assay).(3,4) A positive CLIFT result is usually associated with the presence of moderate-to-high affinity dsDNA IgG antibodies. The CLIFT result may be negative and the immunoassay positive for dsDNA IgG in SLE patients with inactive (remission) disease or in patients with early disease.(3,4,7) Discordant results between CLIFT and solid-phase immunoassays may also be due to differences in the structural specificities of DNA analytes as well as the absence reliable reagents to harmonize available clinical tests.(3,5,8)

A minority of SLE patients may test negative using HEp-2 by IFA for nuclear antibodies.(9) Testing antibodies associated with the HEp-2 IFA cytoplasmic pattern such as ribosomal P IgG autoantibodies may be useful if features of neuropsychiatric disease are present.(9) Alternatively, patients may be tested for Smith, ribonuclear protein (RNP), sulfosalicylic acid (SSA)-52 and SSA-60 antibodies.(6,9)

Reference Values

Only available as an add-on request. For more information see ADNA1 / Double-Stranded DNA (dsDNA) Antibodies, IgG, Serum.

Negative

Interpretation

A positive result for double-stranded DNA (dsDNA) IgG antibodies in the appropriate clinical context is highly suggestive of systemic lupus erythematosus (SLE). The presence of dsDNA IgG antibodies detected using the *Crithidia luciliae* indirect immunofluorescence test is highly specific for SLE with moderate sensitivity. A negative result does not rule out a diagnosis of SLE.

Cautions

IgG antibodies to double-stranded DNA (dsDNA) by *Crithidia luciliae* indirect immunofluorescence test (CLIFT) is reported qualitatively (positive or negative). For semiquantitative assessment of IgG antibodies to dsDNA, see results from ADNA / Double-stranded Antibodies, IgG, Serum.

A weak positive result dsDNA IgG by enzyme-linked immunosorbent assay with a CLIFT negative result may be suggestive of early disease, inactive disease, or a false positive result.

A positive result for IgG antibodies to dsDNA by *Crithidia luciliae* may occur in patients with diseases other than systemic lupus erythematosus (SLE).

A negative result does not exclude a diagnosis of SLE.

Clinical Reference

1. Aringer M, Costenbader K, Daikh D, et al. European league against rheumatism/American College of Rheumatology Classification Criteria for systemic lupus erythematosus. Arthritis Rheumatol. 2019;71(9):1400-1412. doi:10.1002/art.40930
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3. Enocsson H, Sjowall C, Wirestam L, et al. Four anti-dsDNA antibody assays in relation to systemic lupus erythematosus

disease specificity and activity. J Rheumatol. 2015;42(5):817-825. doi:10.3899/jrheum.140677
4. Sarbu MI, Salman-Monte TC, Munoz PR, Lisbona MP, Bernabe MA, Carbonell J. Differences between clinical and laboratory findings in patients with recent diagnosis of SLE according to the positivity of anti-dsDNA by the Crithidia luciliae method. Lupus. 2015;24(11):1198-1203. doi:10.1177/0961203315573852
5. Rekvig OP. Autoimmunity and SLE: factual and semantic evidence-based critical analyses of definitions, etiology, and pathogenesis. Front Immunol. 2020;11:569234. doi:10.3389/fimmu.2020.569234
6. Damoiseaux J, Andrade LEC, Carballo OG, et al. Clinical relevance of HEp-2 indirect immunofluorescent patterns: the International Consensus on ANA patterns (ICAP) perspective. Ann Rheum Dis. 2019;78(7):879-889. doi:10.1136/annrheumdis-2018-214436
7. Bragazzi NL, Watad A, Damiani G, Adawi M, Amital H, Shoenfeld Y. Role of anti-DNA auto-antibodies as biomarkers of response to treatment in systemic lupus erythematosus patients: hypes and hopes. Insights and implications from a comprehensive review of the literature. Expert Rev Mol Diagn. 2019;19(11):969-978. doi:10.1080/14737159.2019.1665511
8. Fox BJ, Hockley J, Rigsby P, Dolman C, Meroni PL, Ronnelid J. A WHO Reference Reagent for lupus (anti-dsDNA) antibodies: international collaborative study to evaluate a candidate preparation. Ann Rheum Dis. 2019;78(12):1677-1680. doi:10.1136/annrheumdis-2019-215845
9. Choi MY, Clarke AE, St Pierre Y, et al. Antinuclear antibody-negative systemic lupus erythematosus in an international inception cohort. Arthritis Care Res (Hoboken). 2019;71(7):893-902. doi:10.1002/acr.23712

Performance

Method Description

Autoantibodies in the test specimen bind to the kinetoplast of *Crithidia luciliae*, a flagellate parasite which is bound to the slide. The kinetoplast is a complex network of interlocking circular double-stranded DNA (dsDNA) molecules and is the substrate of this test. Washing removes excess serum from the substrate. Fluorescein conjugated (FITC) antiserum added to the substrate attaches to the bound autoantibody. After a second washing step to remove excess conjugate, the substrate is cover slipped and viewed for fluorescent patterns with a fluorescent microscope. Observation of specific fluorescent patterns on the substrate indicates the presence of autoantibodies in the test sample.(Package insert: Bio-Rad Kallestad Crithidia luciliae Substrate. Bio-Rad Laboratories; 06/2015)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

2 to 4 days

Performing Laboratory Location

Rochester

Test Definition: CRITH

DNA Double-Stranded (dsDNA) Antibodies by Crithidia luciliae IFA, IgG, Serum

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

86255

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CRITH	dsDNA Ab by Crithidia IFA, IgG, S	58466-4

Result ID	Test Result Name	Result LOINC® Value
62925	dsDNA Ab by Crithidia IFA, IgG, S	In Process
37268	Crithidia Interpretation	69048-7