

CADTH Reference List

Antinuclear Antibody Testing for Autoimmune Disorders

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Key Messages

- We found 1 non-randomized study about the clinical utility of antinuclear antibody testing for the diagnosis of systemic or organ-specific autoimmune disease.
- We found 2 evidence-based guidelines describing antinuclear antibody testing for the diagnosis of systemic or organ-specific autoimmune disease.

Research Questions

1. What is the clinical utility of antinuclear antibody testing for the diagnosis of systemic or organ-specific autoimmune disease?
2. What are the evidence-based guidelines describing antinuclear antibody testing for the diagnosis of systemic or organ-specific autoimmune disease?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the international HTA database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concept was antinuclear antibodies testing. CADTH-developed search filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, network meta-analyses, any types of clinical trials or observational studies, or guidelines. Comments, newspaper articles, editorials, and letters were excluded. Where possible, retrieval was limited to the human population. The search was also limited to English-language documents published between January 1, 2012 and October 27, 2022. Internet links were provided, where available.

Selection Criteria

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in [Table 1](#). Full texts of study publications were not reviewed. Open access full-text versions of evidence-based guidelines were reviewed when available.

Results

One non-randomized study¹ was identified regarding the clinical utility of antinuclear antibody testing for the diagnosis of systemic or organ-specific autoimmune disease. Two evidence-based guidelines^{2,3} describing antinuclear antibody testing for the diagnosis of systemic

Table 1: Selection Criteria

Criteria	Description
Population	People with suspected systemic or organ-specific autoimmune disease
Intervention	Antinuclear antibody testing using any method
Comparator	Q1: No screening Q2: Not applicable
Outcomes	Q1: Clinical utility (e.g., time to treatment, morbidity, incidence of disease, mortality, quality of life) Q2: Evidence-based recommendations and/or guidance
Study designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, evidence-based guidelines

or organ-specific autoimmune disease were identified. No relevant health technology assessments, systematic reviews, or randomized controlled trials were identified.

Additional references of potential interest that did not meet the inclusion criteria are provided in [Appendix 1](#).

References

Health Technology Assessments

No literature identified.

Systematic Reviews

No literature identified.

Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

1. Ferrari R. Evaluation of the Canadian Rheumatology Association Choosing Wisely recommendation concerning anti-nuclear antibody (ANA) testing. *Clin Rheumatol.* 2015;34(9):1551-6. [PubMed](#)

Guidelines and Recommendations

2. Trevisani VFM, Pasoto SG, Fernandes M, et al. Recommendations from the Brazilian Society of Rheumatology for the diagnosis of Sjogren's syndrome (Part I): Glandular manifestations (systematic review). *Adv Rheumatol.* 2019;59(1):58. [PubMed](#)
See Recommendation 15 on page 10
3. Pain CE, Constantin T, Toplak N, et al. Raynaud's syndrome in children: Systematic review and development of recommendations for assessment and monitoring. *Clin Exp Rheumatol.* 2016;34 Suppl 100(5):200-206. [PubMed](#)
See Recommendations 2, 3, and 5-10 on page S-202

Appendix 1: References of Potential Interest

Previous CADTH Reports

Hafizi D, Grobelna A. Antinuclear antibody testing for systemic lupus erythematosus or connective tissue disease. (*CADTH Rapid response report: reference list*). Ottawa (ON): CADTH; 2021: <https://www.cadth.ca/antinuclear-antibody-testing-systemic-lupus-erythematosus-or-connective-tissue-disease>. Accessed 2022 November 01.

Antinuclear antibody testing for systemic lupus erythematosus or connective tissue disease: Clinical effectiveness and guidelines. (CADTH Rapid response report: summary of abstracts). Ottawa (ON): CADTH; 2015: <https://www.cadth.ca/antinuclear-antibody-testing-systemic-lupus-erythematosus-or-connective-tissue-disease-clinical>. Accessed 2022 November 01.

Systematic Reviews

Unclear Comparator

Wong KO, Bond K, Homik J, et al. *Antinuclear antibody, rheumatoid factor, and cyclic-citrullinated peptide tests for evaluating musculoskeletal complaints in children. (Comparative effectiveness review no. 50)*. Rockville (MD): Agency for Healthcare Research and Quality; 2012: [PubMed](#)

Non-Randomized Studies

No Comparator

Spies MC, Gutjahr-Holland JA, Bertouch JV, Sammel AM. Prevalence of neuropsychiatric lupus in psychosis patients who have tested positive for antinuclear antibodies. *Arthritis Care Res (Hoboken)*. 2022;74(3):427-432. [PubMed](#)

Haslak F, Yildiz M, Altun I, et al. Anti-nuclear antibody testing in children: How much is really necessary?. *Pediatr Int*. 2021;63(9):1020-1025. [PubMed](#)

Koubi M, Rossi P, Arcani R, et al. Relevance of systematic anti-nuclear antibodies testing after obstetrical complications. *J Reprod Immunol*. 2021;148:103437. [PubMed](#)

Ghraiiri N, Aouadi S, Elhechmi YZ, Ben Saad S, Ben Ali I, Yalaoui S. Antinuclear antibodies in interstitial lung disease: Prevalence and clinical significance. *Tunis Med*. 2019;97(11):1240-1245. [PubMed](#)

Mantovani C, Louzada-Junior P, Nunes EA, de Figueiredo FP, Oliveira GR, Del-Ben CM. Antinuclear antibodies testing as a routine screening for systemic lupus erythematosus in patients presenting first-episode psychosis. *Early Interv Psychiatry*. 2012;6(3):322-5. [PubMed](#)

Alternative Comparator – Complement Activation Products

O'Malley T, Xie F, Su Y, et al. Complement activation products vs standard ANA testing: Treatment outcomes, diagnosis, and economic impact (CAPSTONE) in systemic lupus erythematosus. *J Manag Care Spec Pharm*. 2022;28(9):1021-1032. [PubMed](#)

Guidelines and Recommendations

Unclear Methodology

Tesija Kuna A, Derek L, Drvar V, Kozmar A, Gugo K. Assessment of antinuclear antibodies (ANA): National recommendations on behalf of the Croatian Society of Medical Biochemistry and Laboratory Medicine. *Biochem Med (Zagreb)*. 2021;31(2):020502. [PubMed](#)

See Section 1. Preanalytical Issues: Recommendations 1 and 2 for ANA Determination Indications; Recommendation 2 for Rational Algorithm.

BC Guidelines. Antinuclear antibody (ANA) testing protocol. 2013; <https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/bc-guidelines/ana-testing>. Accessed 2022 November 07. See Key Recommendations