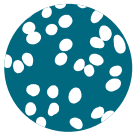




Connective tissue diseases

EliA DFS70 test – addressing the challenges in ANA HEp-2 positive results



The dense fine speckled (DFS) pattern is common in routine testing

- Found in up to 37% of samples routinely tested for anti-nuclear antibodies (ANA) by immunofluorescence assay (IFA)¹
- A common pattern in apparently healthy individuals and patients unlikely to suffer from systemic autoimmune rheumatic diseases (SARD)^{1,2}
- Included as “AC-2 – dense fine speckled” in the International Consensus on Antinuclear Antibody Patterns (ICAP)³



Confirmatory testing is recommended to differentiate anti-DFS70 antibodies from other ANA

- Identification and differentiation of the AC-2 pattern from disease associated ANA patterns (e.g. AC-1 – homogeneous, AC-4 – fine speckled, AC-5 – speckled) can be difficult^{1,3}
- Inaccurate reporting of the AC-2 pattern can lead to unnecessary additional testing and negatively impact patient management¹
- DFS pattern results from autoantibodies against the DFS70 protein, also known as lens epithelium-derived growth factor (LEDGF) or p75^{1,3}
- Testing for anti-DFS70 antibodies is recommended in routine ANA testing algorithms¹⁻³



Isolated anti-DFS70 antibodies may be an exclusionary marker for connective tissue diseases (CTD)

- Up to 22% of healthy individuals but < 1% of patients with ANA associated rheumatic diseases (AARD) show single positivity for anti-DFS70 antibodies²
- Single positivity for anti-DFS70 antibodies has a negative association with AARD²

Testing for anti-DFS70 antibodies can aid in clinical decision making



EliA™ DFS70 test – key features

- Antigen:** Recombinant full-length human DFS70 expressed in the baculovirus/insect cell system
- Controls:** EliA™ DFS70 Positive Control and EliA™ IgG/IgM/IgA Negative Control
- Automation:** Available on Phadia™ 200 and Phadia™ 250 instruments as well as on Phadia™ 2500+ and Phadia™ 5000+ series
- Flexibility:** Random access* testing with possibility of reflex testing
- Efficiency:** Easy add-on to EliA™ test portfolio by using the EliA™ IgG calibration method and ready-to-use reagents
- Cost savings:** Interchangeable reagents with other EliA tests, e.g. EliA™ CTD Screen and EliA™ dsDNA test
- Clinical performance:** In an analysis of 55 samples with the typical DFS70 pattern in IFA on HEp-2 cells and 156 samples as systemic autoimmune rheumatic disease controls, all sera with DFS70 pattern were found positive and all 156 disease controls were negative⁴

*random access testing available on Phadia 250 instrument, Phadia 2500+ and Phadia 5000+ series



Phadia™ 200 instrument



Phadia™ 250 instrument



Phadia™ 2500+ series

Phadia 2500+ comprises Phadia™ 2500, Phadia™ 2500E and Phadia™ 2500EE



Phadia™ 5000+ series

Phadia 5000+ comprises Phadia™ 5000, Phadia™ 5000E and Phadia™ 5000E+E

Technical and ordering information

Interpretation of test results

Product	Article No.	Package size	Negative	Equivocal	Positive	Short name
EliA DFS70 Well	14-5673-01	2 x 16 wells	< 7 EliA U/mL	7-10 EliA U/mL	> 10 EliA U/mL	dfs

References

1. Malyavantham K, Suresh L. (2017) Analysis of DFS70 pattern and impact on ANA screening using a novel HEp-2 ELITE/DFS70 knockout substrate. Auto Immun Highlights. 8(1):3.
2. Conrad K, Rober N, Andrade LE, Mahler M. (2017) The Clinical Relevance of Anti-DFS70 Autoantibodies. Clin Rev Allergy Immunol. 52(2):202-16.
3. Chan EKL, Damoiseaux J, Carballo OG, Conrad K, de Melo Cruvinel W, Franciscantonio PLC, et al. (2015) Report of the First International Consensus on Standardized Nomenclature of Antinuclear Antibody HEp-2 Cell Patterns 2014–2015. Frontiers in Immunology. 6(412).
4. Thermo Fisher Scientific. Internal Study.

Learn more at thermofisher.com/elia

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