

## nDNA IFA plus

Immunofluorescence assay (IFA) for the determination of IgG antibodies against dsDNA in human serum



CE



### Product Highlights

- Specific detection of IgG antibodies against dsDNA
- Serological marker for systemic lupus erythematosus
- High diagnostic efficiency, high sensitivity and specificity

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# Antibodies against Double-Stranded DNA (dsDNA)

## Importance in the Diagnosis of systemic Lupus erythematosus

### Systemic lupus erythematosus

Systemic lupus erythematosus (SLE) is an autoimmune disease that manifests with the formation of antinuclear antibodies (ANA), particularly antibodies against double-stranded deoxyribonucleic acid (dsDNA). The disease is rare. Women are more frequently affected than men. Depending on which organs or organ systems are affected, systemic lupus erythematosus manifests with different symptoms, which can also change over the course of the disease. Butterfly erythema occurs in a large number of patients and spreads symmetrically from the bridge of the nose to the cheeks. Furthermore, general symptoms such as fatigue, fever and weight loss are often described.

### Diagnosis

The diagnosis is made on the basis of the clinical symptoms and laboratory medical examinations. The clinical suspicion is based in particular on the detection of anti-nuclear antibodies. Antibodies against double-stranded deoxyribonucleic acid are pathognomonic for systemic lupus erythematosus. They occur in about 65 % of patients and, along with antibodies against Smith antigen (Sm) and against phospholipids, are part of the classification criteria of American and European rheumatologists (ACR: American College of Rheumatology, EULAR: European League Against Rheumatism).

### Detection of Antibodies against dsDNA

*Crithidia luciliae* is a eukaryotic, protozoan parasite of the Trypanosomatidae family. A so-called kine-

toplast in a large mitochondrion, which essentially consists of circular, double-stranded deoxyribonucleic acid, is characteristic of this micro-organism. The high concentration of DNA in this kinetoplast and the simultaneous absence of other human nuclear antigens makes *Crithidia luciliae* so valuable for the specific detection of antibodies against dsDNA in the immunofluorescence assay (IFA).

### Publications

- Conrad, K., Ittenson, A., Reinhold, D., Fischer, R., Roggenbuck, D., Büttner, T., Bosselmann, H.P., Steinbach, J., Schössler, W. (2009) High sensitive detection of double-stranded DNA autoantibodies by a modified *Crithidia luciliae* immunofluorescence test. Ann. N. Y. Acad. Sci. 1173, 180 – 5.
- Haugbro, K., Nossent, J.C., Winkler, T., Figenschau, Y., Rekvig, O.P. (2004) Anti-dsDNA antibodies and disease classification in antinuclear antibody positive patients: the role of analytical diversity. Ann. Rheum. Dis. 63, 386 – 94.
- Infantino, M., Nagy, E., Bizzaro, N., Fischer, K., Bossuyt, X., Damoiseaux, J. (2021) Anti-dsDNA antibodies in the classification criteria of systemic lupus erythematosus. J. Transl. Autoimmun. 5, 100139.
- Melegari, A., Bonaguri, C., Russo, A., Luisita, B., Trenti, T., Lippi, G. (2012) A comparative study on the reliability of an automated system for the evaluation of cell-based indirect immunofluorescence. Autoimmun. Rev. 11, 713 – 6.

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## Slides

The slides of the nDNA IFA plus immunofluorescence assay are coated with haemoflaggelates of *Crithidia luciliae*.

## Test Principle

The immunofluorescence assay (IFA) is an immunoassay for the determination of specific antibodies. Tissue sections or cells containing the antigens of interest are immobilized on slides. If specific antibodies are present in the patient's sample, they bind to the antigens. A secondary antibody conjugated with fluorescein-isothiocyanat (FITC) detects the generated immune complexes. The slides are examined using a fluorescence microscope. A specific fluorescent staining pattern based on histological distribution of the antigens in the cells or tissues demonstrates the presence of specific antibodies in the patient's sample.

## Precision

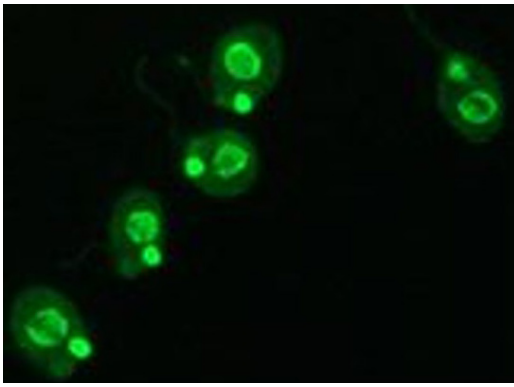
The precision of test results was assessed by the determination of the intra- and interassay variation with multiple samples of different antibody activities. No differences in the qualitative evaluation have been detected.

## Diagnostic Sensitivity and Specificity

The sensitivity and specificity of the immunofluorescence assay were assessed by the analysis 57 pretested positive samples from patients with systemic lupus erythematosus (SLE) and 96 pretested negative samples from patients with other diseases.

DIAGNOSTIC PERFORMANCE	
Sensitivity	78.2 %
Specificity	98.2 %





## Product Information

### nDNA IFA plus



## nDNA IFA plus

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### HIGH QUALITY – MADE IN GERMANY

- Slides coated with *Crithidia luciliae*
- Detection of IgG antibodies against double-stranded DNA (dsDNA)
- Support for the diagnosis of systemic lupus erythematosus (SLE)
- Qualitative and semi-quantitative determination of the IgG antibody activity
- Ready-to-use reagents (exception: PBS buffer)
- Quality assured handling in routine laboratories
- Short incubation times (30 min / 30 min) at room temperature
- Consistent processing for the parallel use of multiple immunofluorescence assays
- High diagnostic sensitivity and specificity
- CE marked

## Contact

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## Order Information

### nDNA IFA plus

(10 x 6 Determinations)

REF 81050

### nDNA IFA plus

(10 x 12 Determinations)

REF 81100