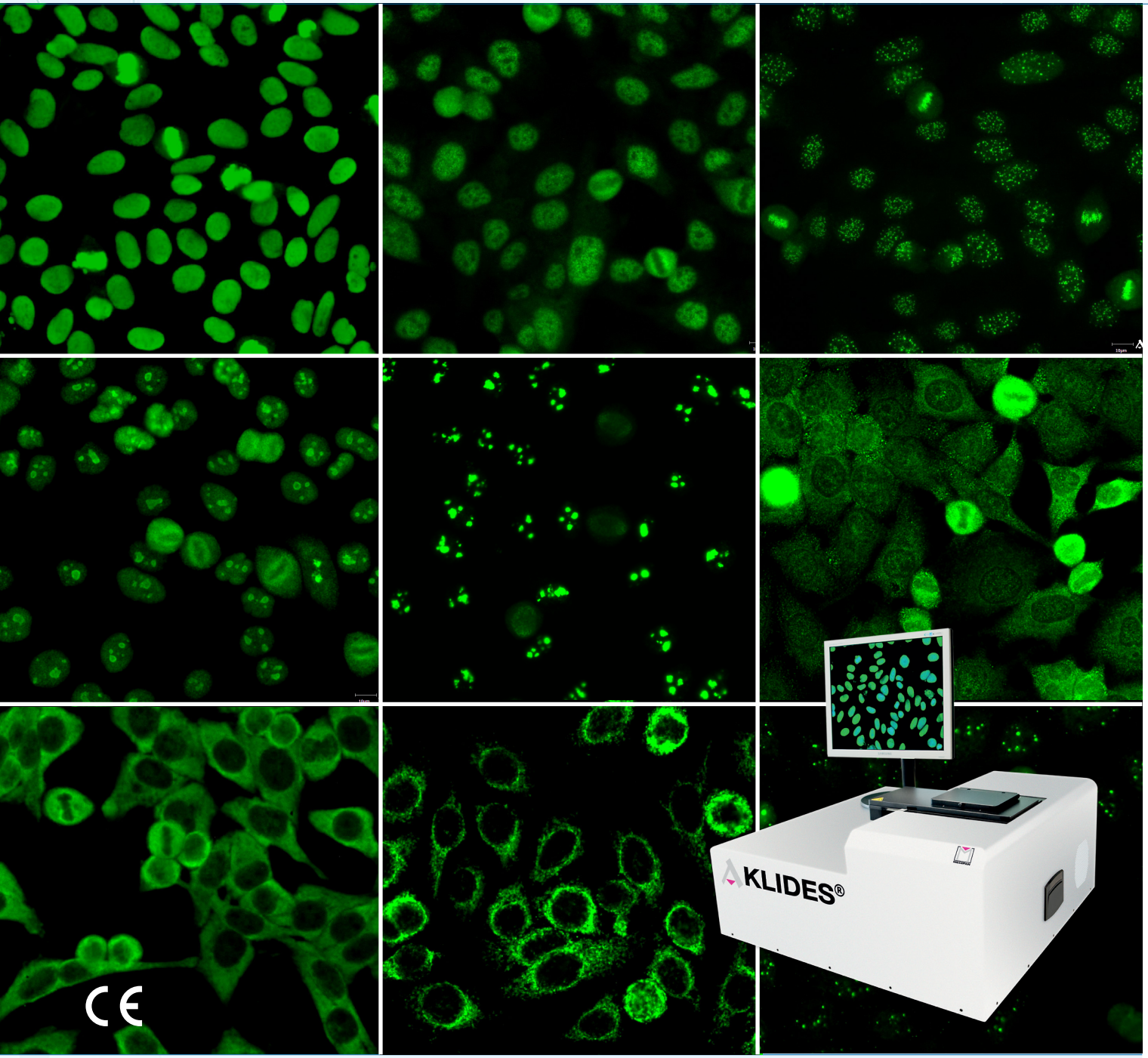
IFA

AKLIDES® ANA plus

Immunofluorescence assay (IFA) for the determination of IgG antibodies against nuclear and cytoplasmic antigens

MEDIPAN



Product Highlights

- Sensitive detection of IgG antibodies against HEp-2 cells
- Screening test for the diagnosis of systemic autoimmune diseases
- Imaging with AKLIDES® or akiron® systems

Nuclear and Cytoplasmic Antibodies (ANA)

Importance in the Diagnosis of Systemic Autoimmune Diseases

Autoimmune Diseases

Autoimmune diseases are based on disorders of the immune system. Synthesized antibodies and autoreactive T cells are directed against endogenous structures and lead to local or systemic inflammatory reactions. In principle, any organ or tissue can be affected by an autoimmune disease. Accordingly, hundreds of autoimmune diseases have been described so far, which can be roughly divided into three groups: In organ-specific autoimmune diseases, individual organs are affected. Systemic, non-organ-specific autoimmune diseases include, for example, collagenosis or other systemic, inflammatory rheumatic diseases. In these cases, antibodies against nuclear or cytoplasmic antigens, which are found in almost all cells in the body, are often detected. In addition, different mixed forms of organ-specific and systemic autoimmune diseases are described.

Epidemiology

About 5 to 10 % of the population are affected by an autoimmune disease. The most common are psoriasis, rheumatoid arthritis (RA), diabetes mellitus type 1, multiple sclerosis, Crohn's disease and autoimmune thyroid diseases such as Hashimoto's thyroiditis and Graves' disease. In general, autoimmune diseases are more common in women than in men.

Diagnosis

The diagnosis of autoimmune diseases is made on the basis of the clinical symptoms and laboratory medical examinations. The clinical suspicion is confirmed in particular by the detection of antibodies against nuclear or cytoplasmic antigens (ANA) as a characteristic feature in systemic autoimmune diseases such as systemic lupus erythematosus (SLE), Sjögren's syndrome, progressive systemic sclerosis (PSS), mixed collagenosis (MCTD), rheumatoid arthritis (RA) or dermatomyositis. The use of HEp-2 cells fixed on slides for use in immunofluorescence assays (IFA) has proven to be particularly effective for the determination of antibodies. These immunoassays offer the possibility for a very sensitive detection of antibodies against nuclear or cytoplasmic antigens (ANA). The observed fluorescence pattern also gives an indication of the antigen specificity of the detected antibodies and thus of the autoimmune disease to be diagnosed.

Publication

Damoiseaux, J., Andrade, L.E.C., Carballo, O.G., Conrad, K., Francescantonio, P.L.C., Fritzler, M.J., Garcia de la Torre. I., Herold, M., Klotz, W., Cruvinel, W.M., Mimori, T., von Muhlen, C., Satoh, M., Chan, E.K. (2019) Clinical relevance of HEp-2 indirect immunofluorescent patterns: the International Consensus on ANA patterns (ICAP) perspective. Ann. Rheum. Dis. 78, 879 - 89.

AKLIDES® ANA plus – IFA for the Determination of IgG Antibodies against Nuclear and Cytoplasmic Antigens (ANA)

Slides

The slides of the AKLIDES® ANA plus immunofluorescence assay are coated with HEp-2 cells.

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.

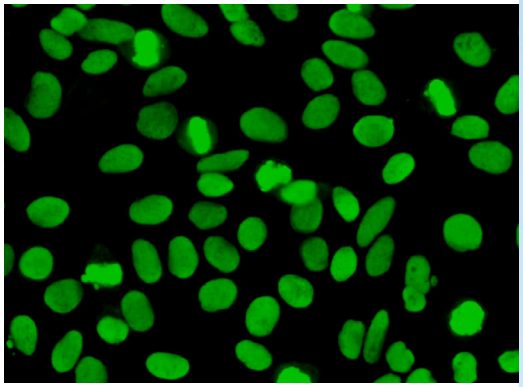
Precision

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 of 159 samples from patients with defined antibody specificities and 263 samples from unselected blood donors.

	DIAGNOSTIC PERFORMANCE
Sensitivity	98.1 %
Specificity	91.2 %

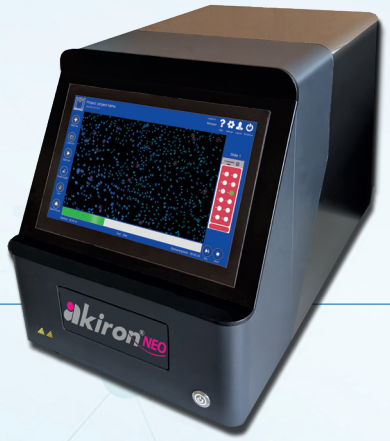


AKLIDES® ANA plus

Immunofluorescence assay (IFA) for the determination of IgG antibodies against nuclear and cytoplasmic antigens (ANA) in human serum

HIGH QUALITY – MADE IN GERMANY

- Slides coated with HEp-2 cells
- Screening test to support for the diagnosis of systemic autoimmune diseases
- Ready-to-use reagents (exception: wash 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 AKLIDES® immunofluorescence assays
- Excellent diagnostic sensitivity and specificity
- Imaging by use of AKLIDES® or akiron® systems
- CE marked



Product Information

AKLIDES® ANA plus

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Order Information

AKLIDES® ANA plus (40 x 12 Determinations)	**REF 4063**
AKLIDES® ANA plus (10 x 12 Determinations)	**REF 4065**