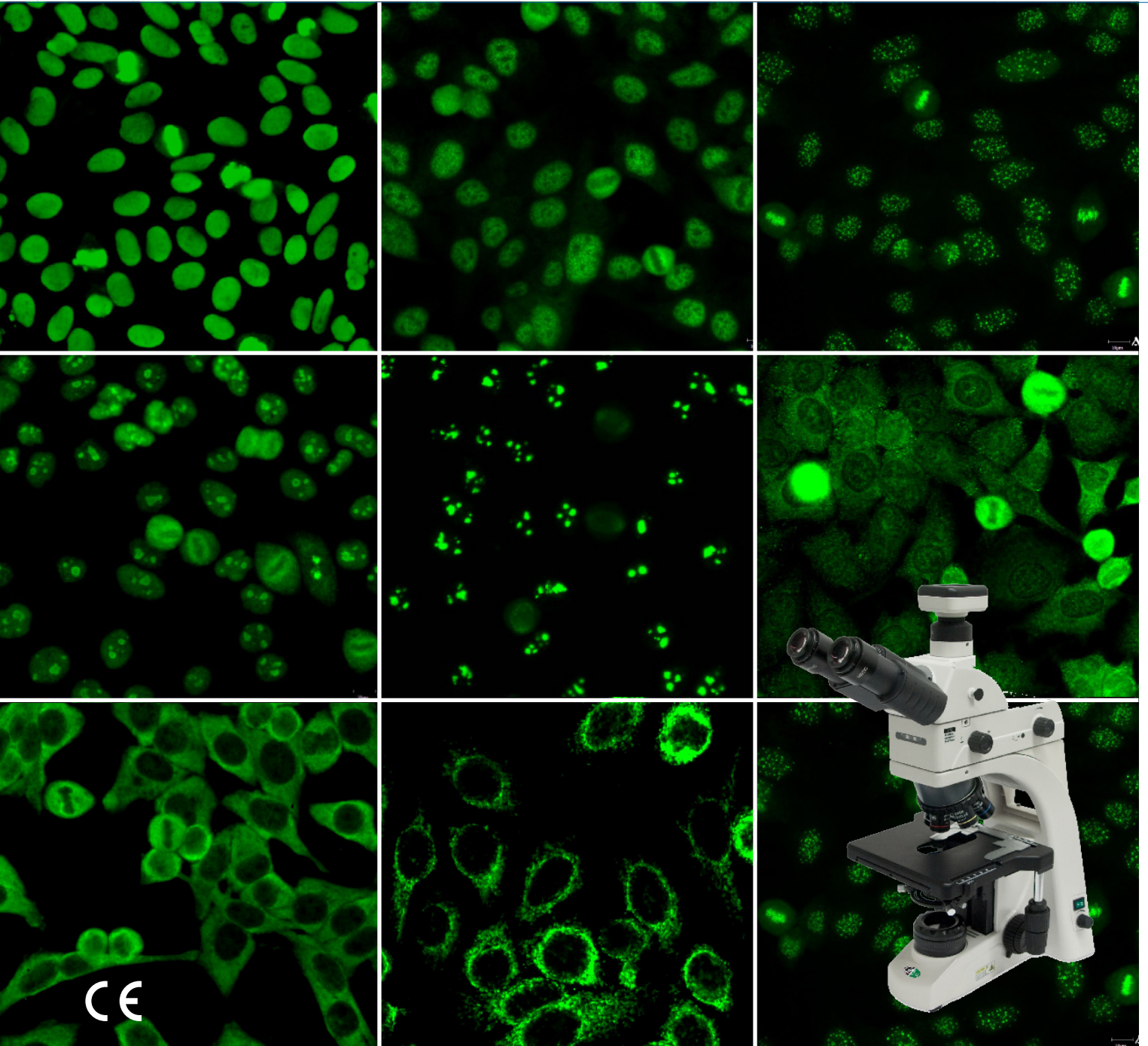


ANA HEp-2 plus

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



Product Highlights

- Sensitive detection of IgG antibodies against HEp-2 cells
- Screening test for the diagnosis of systemic autoimmune diseases
- High diagnostic efficiency, high sensitivity and specificity

YOUR RELIABLE PARTNER IN AUTOIMMUNE DIAGNOSTICS

30 Years of Experience, 150 Partners in more than 100 Countries

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 auto-reactive 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 auto-

immune 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.

ANA HEp-2 plus – Immunofluorescence Assay for the Determination of IgG Antibodies against Nuclear and Cytoplasmic Antigens (ANA)

Slides

The slides of the ANA HEp-2 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.

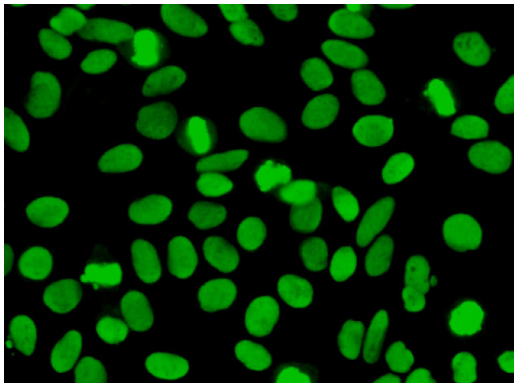
Precision

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

Sensitivity and specificity were assessed by the analysis of 391 samples from patients with systemic autoimmune diseases (103 systemic sclerosis SSc, 45 Sjögren's syndrome SjS, 174 systemic lupus erythematosus SLE, 36 rheumatoid arthritis RA, 13 mixed connective tissue disease MCTD, 20 myositis MYO) and 304 samples from patients with other diseases (21 infectious diseases ID, 11 paraproteinemia PPA, 93 autoimmune liver disease ALD, 78 inflammatory bowel diseases IBD) and unselected blood donors (101 blood donors BD).

	Disease	Diagnostic Performance
Sensitivity	SSc	> 99 %
	SjS	97.8 %
	SLE	98.9 %
	RA	86.1 %
	MCTD	> 99 %
	MYO	95.2 %
Specificity	ID	84.9 %
	PPA	90.1 %
	ALD	86.9 %
	IBD	> 99 %
	BD	83.2 %



Product Information

ANA HEp-2 plus



ANA HEp-2 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
- 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

ANA HEp-2 plus

(10 x 12 Determinations)

REF 8101

ANA HEp-2 plus

(40 x 12 Determinations)

REF 81040