

# The value of knowing

## *Connective Tissue Diseases*

Improving the diagnostics journey  
with a comprehensive solution from  
screening to confirmation

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**sebia** 

The new language of life

# Sjögren syndrome

## *the «dry-eye» disease*

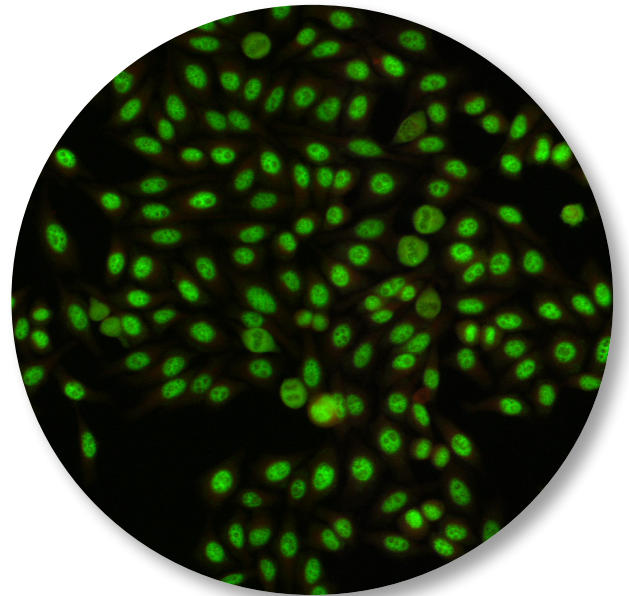
**Sjögren syndrome** (SjS) is a systemic autoimmune disease that primarily affects the exocrine glands (mainly the salivary and lacrimal glands) and results in the severe dryness of mucosal surfaces, principally in the mouth and eyes.

The clinical presentation of SjS is heterogeneous and can vary from local symptoms to systemic disease, involving the skin, joints, thyroid, liver, kidneys, lungs, and nervous system.

The mechanism underlying the development of SjS is the destruction of the epithelium of the exocrine glands, because of abnormal B cell and T cell responses to the autoantigens Ro/SSA and La/SSB, among others.

Diagnosing SjS can be challenging due to the variability of symptoms and their overlap with other conditions. The diagnostic criteria include the detection of autoantibodies in patient serum and histological analysis of biopsied salivary gland tissue.

High-resolution image on **dIFine® automated microscope** of nuclear fine-speckled pattern with **Sebia IFA ANA Test System**. The nuclear fine-speckled pattern is informative of Ro/SSA, and La/SSB antigens positivity.



Product Name	Product Code
ANA HEp-2	FA2500A
ANA Detect*	ORG 200
ENAscreen	ORG 206
Anti-SS-A*	ORG 208
Anti-SS-B*	ORG 209
ANAscreen*	ORG 238
Anti-alpha-Fodrin IgG	ORG 242G
Anti-SS-A 52*	ORG 252
Anti-SS-A 60*	ORG 260



# Systemic Lupus Erythematosus

## *the «butterfly wings» disease*

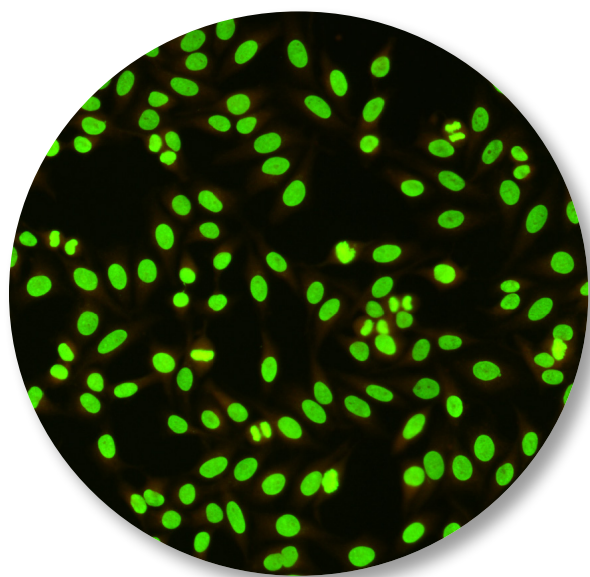
**Systemic lupus erythematosus (SLE)** is an autoimmune disorder characterized by multisystem inflammation, and a relapsing and remitting course. More than 90% of cases of SLE occur in women, frequently starting at childbearing age.

SLE can affect almost any organ system, even if it mainly involves the skin (skin rashes resembling butterfly wings), swelling in the hands, feet, or around the eyes, joints, kidneys, blood cells, and nervous system.

The diagnosis of SLE is based on a combination of clinical findings and laboratory evidence.

The American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) published new criteria for the classification of SLE in 2019. These criteria represent the current gold standard of SLE diagnosis and have excellent specificity and sensitivity.

The ACR/EULAR classification requires an antinuclear antibody (ANA) titer of at least 1:80 on HEp-2 cells or an equivalent positive test at least once.



High-resolution image on **dIFine® automated microscope** of nuclear homogenous pattern with Sebia IFA ANA Test System. The homogenous pattern is informative of dsDNA, nucleosomes, and histones antigens positivity.

Product Name	Product Code
ANA HEp-2	FA2500A
dsDNA (Crithidia I.)	FAI001
ANA Detect*	ORG 200
Anti-dsDNA IgG*	ORG 204G
Anti-ssDNA*	ORG 205
ENAscreen*	ORG 206
Anti-Histone*	ORG 207
Anti-Sm*	ORG 210
Anti-Rib-P	ORG 217
Anti-Nucleosome*	ORG 228
ANAscreen*	ORG 238
Anti-C1q*	ORG 249

\*Open systems ELISA are also available

# Myositis

## *the muscle autoimmune disease*

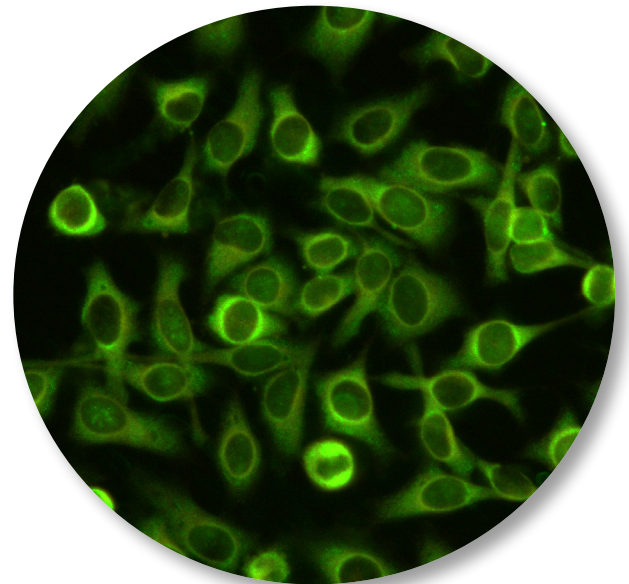
Autoimmune **myositis** is a group of inflammatory muscle disorders characterized by muscle weakness and inflammation. These conditions are part of the broader category of idiopathic inflammatory myopathies. The two main clinical manifestations of myositis are:

**Polymyositis (PM)** affects multiple muscle groups, typically those closest to the trunk, such as the hips, thighs, shoulders, and neck. The symptoms include muscle weakness, pain, and tenderness, making it difficult to perform everyday tasks.

**Dermatomyositis (DM)** with a similar muscle involvement as polymyositis, but with a characteristic skin rash. The rash is often reddish or purplish and may appear on the eyelids, knuckles, elbows, knees, and chest.

Jo-1 antibodies target histidyl-tRNA synthetase, an enzyme involved in protein synthesis, and they are a critical marker in diagnosing and managing autoimmune myositis, particularly in patients with antisynthetase syndrome.

High-resolution image on **dIFine® automated microscope** of cytoplasmic fine-speckled pattern with Sebia IFA ANA Test System. The cytoplasmic fine-speckled pattern is informative of Jo-1 antigen positivity.



Product Name	Product Code
ANA HEp-2	FA2500A
ANA Detect*	ORG 200
Anti-Jo-1*	ORG 213
ENAscreen*	ORG 206
ANAscreen*	ORG 238



# Systemic sclerosis

## *the «skin-fibrosis» disease*

**Systemic sclerosis (SSc)**, or **scleroderma**, is an immune-mediated rheumatic disease characterized by skin fibrosis, internal organs, and vasculopathy. Although systemic sclerosis is uncommon, it has a high morbidity and mortality.

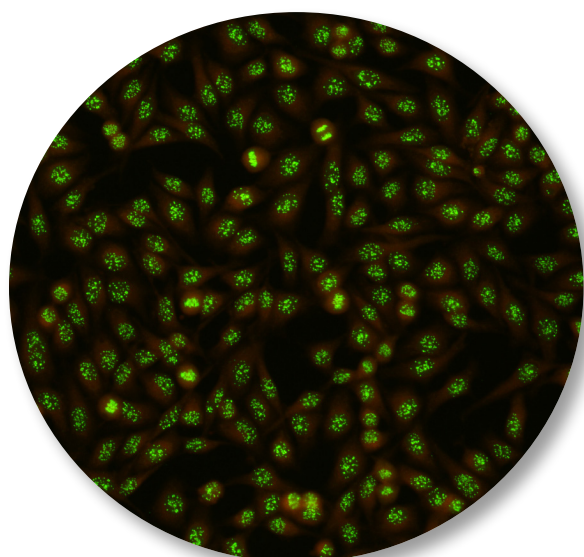
It can be categorized into two main types, each with distinct characteristics:

### Limited Cutaneous Systemic Sclerosis:

- Also known as CREST syndrome, stands for Calcinosis, Raynaud's phenomenon, Esophageal dysfunction, Sclerodactyly, and Telangiectasia.
- Skin thickening is generally limited to the fingers, hands, face, and forearms.
- Internal organ involvement is usually less severe than in diffuse systemic sclerosis but may develop gradually over time.

### Diffuse Cutaneous Systemic Sclerosis:

- Characterized by widespread skin thickening, including areas such as the trunk, arms, and legs.
- More likely to involve internal organs such as the lungs, heart, kidneys, and gastrointestinal tract early in the disease course.
- Associated with a more aggressive disease progression and a higher risk of organ complications.



High-resolution image on **dIFine® automated microscope** of centromere pattern with Sebia IFA ANA Test System. The centromere pattern is informative of CENP A/B (C) antigens positivity.

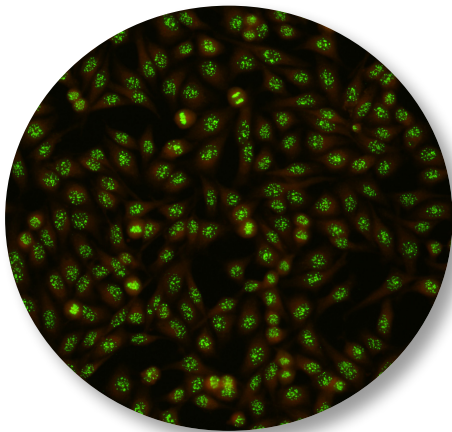
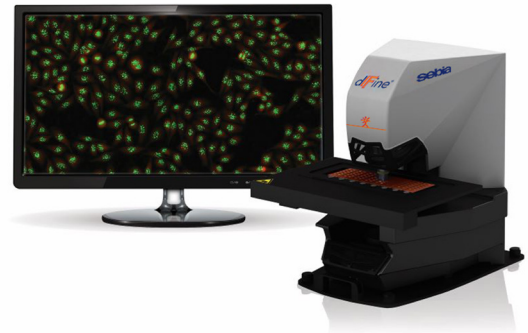
Product Name	Product Code
ANA HEp-2	FA2500A
ANA Detect*	ORG 200
ENAscreen*	ORG 206
Anti-Scl-70*	ORG 212
Anti-Centromere B*	ORG 233
ANAscreen*	ORG 238

# Sebia IFA systems *screening and differentiation of CTD*

**Easy handling** due to automated acquisition, analysis, display and storage of images

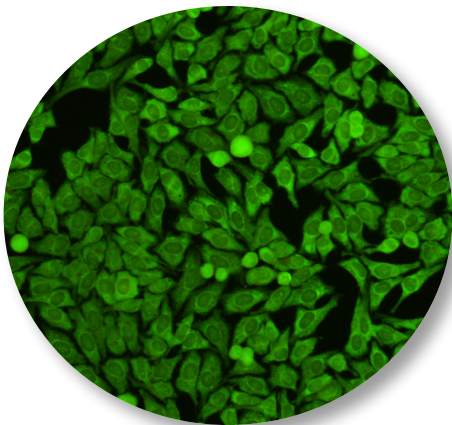
Time saving with **batch releases of negative samples**

Result recommendations by means of advanced **artificial intelligence**



## **Better and easier reading**

- All phases of the cell cycle clearly visible
- Homogeneous cell distribution



## **Perfect discrimination** of all cytoplasmic patterns

- Even distribution, virtually cluster-free
- Excellent ratio of cell nuclei to cytoplasm
- Clean, clear, crisp images

## *Main benefits*

Improving the diagnostic journey

**1**  
Easy-to-use IFA screening tests and Alegria Monotest technology

**2**  
Wide measuring range



# Trusted automation *integrated, reliable, and traceable workflow*

Automated and standardized workflow with **dIFine® P30 processor**

- Processes up to 240 samples and 30 IFA slides
- Complete traceability and barcode reading of samples, reagents, and slides, reducing the risk of errors
- Precise dispensation of mounting media and automated coverslipping, decreasing slide handling, and risk of artifacts



## Fully automated testing

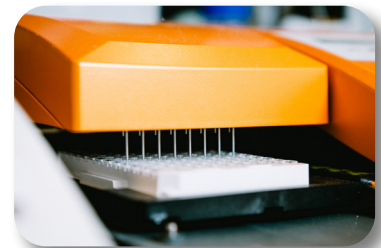
Flexible, reliable and efficient utilizing the **Alegria Monotest technology**.  
Customized full patient profiles within one run



**Unique** and broad autoimmune disease panel to confirm and follow up testing

## Open systems

Complete portfolio also available as ELISA plates



**3**  
Easy results interpretation:  
aid in diagnosis

**4**  
Reliable,  
simplified and random  
access workflow

## Proven *medical value*

- Increased sensitivity
- Affordable screening approach
- Correlation with disease activity
- Reliable results to guide the therapy



# Ordering information

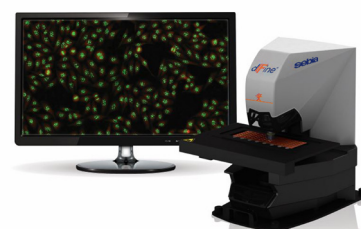
## Reagents

Alegria Monotest random access solutions, and easy-to-read IFA products for Connective Tissue Diseases Diagnostic

• ANA HEp-2 .....	<b>FA2500A</b>
• dsDNA (Crithidia I.) .....	<b>FA1001</b>
• ANA Detect* .....	<b>ORG 200</b>
• Anti-dsDNA IgG* .....	<b>ORG 204G</b>
• Anti-ssDNA* .....	<b>ORG 205</b>
• ENAscreen* .....	<b>ORG 206</b>
• Anti-Histone* .....	<b>ORG 207</b>
• Anti-SS-A* .....	<b>ORG 208</b>
• Anti-SS-B* .....	<b>ORG 209</b>
• Anti-Sm* .....	<b>ORG 210</b>
• Anti-RNP/Sm* .....	<b>ORG 211</b>
• Anti-Scl-70* .....	<b>ORG 212</b>
• Anti-Jo-1* .....	<b>ORG 213</b>
• Anti-Rib-P .....	<b>ORG 217</b>
• Anti-Nucleosome* .....	<b>ORG 228</b>
• Anti-RNP-70* .....	<b>ORG 232</b>
• Anti-Centromere B* .....	<b>ORG 233</b>
• ANAscreen* .....	<b>ORG 238</b>
• Anti-alpha-Fodrin IgG .....	<b>ORG 242G</b>
• Anti-Clq* .....	<b>ORG 249</b>
• Anti-SS-A 52* .....	<b>ORG 252</b>
• Anti-SS-A 60* .....	<b>ORG 260</b>

## Instrument

- dIFine® automated microscope ..... **FA08IMG**
- dIFine® P30 processor ..... **FA30SP**
- Alegria 2 ..... **ORG 320**
- dIFine® M1 Manual Microscope  
(with camera) ..... **FA01C**  
(w/o camera) ..... **FA01NC**



\*Products available also in ELISA open system platforms



Scan here  
for more information  
about CTD

For further information, please find your Sebia local representative to contact on our Website [www.sebia.com/sebia/worldwide-presence/](http://www.sebia.com/sebia/worldwide-presence/).



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