EUROLINE Systemic Sclerosis (Nucleoli) Profile (IgG)

Indication: Test system for the in vitro determination of antibodies against systemic sclerosis-associated antigens in human serum or plasma for the diagnosis of the following diseases: progressive systemic sclerosis (limited and diffuse form), overlapping syndromes.

Clinical significance: Systemic sclerosis (SSc) belongs to the collagenoses, a group of autoimmune connective tissue diseases. It affects the skin and internal organs. Around 2 to 50 out of 100,000 people suffer from SSc worldwide (USA: 25 out of 100,000). The incidence amounts to 12 new cases per 100,000 people per year. The disease occurs mainly in middle adulthood. Women are affected three to four times more often than men. Black people have a greater risk of acquiring the disease. A higher frequency among members of one family is rare. Early symptoms of SSc are shortening of the lingual frenum and Raynaud’s syndrome (stage 1): ischemia of the hands and feet with numbness and pain, stage 2: local cyanosis caused by hypoxia, stage 3: reactive hyperaemia with redness, pricking and throbbing). In the following phase oedema of the hands and feet develops. The skin becomes stiff and in later stages atrophic, waxy and thin. Finally, deformation of the hands occurs. The fingers become fixed in a bent position (claw hand) and are highly tapered at the ends (Madonna fingers). Furthermore, the characteristic masklike face with rigid mimic develops, leading to microstomia (reduced opening of the mouth) and problems in closing the eyelids. Finally, callousity of the inner organs, particularly of the digestive tract, lungs, heart and kidneys occurs.

SSc is divided into limited and diffuse forms, depending on the cutaneous distribution. In the limited form, skin involvement is limited to the distal extremities. In the diffuse form (also proximal systemic sclerosis) the symptoms are diffusely distributed over the trunk, the proximal and distal extremities and the face. The so-called CREST syndrome with calcinosis, Raynaud’s phenomenon, esophageal dysfunction, limited form, skin involvement is limited to the distal extremities. In the diffuse form (also proximal systemic sclerosis), the symptoms are diffusely distributed over the trunk, the proximal and distal extremities and the face. The so-called CREST syndrome with calcinosis, Raynaud’s phenomenon, esophageal dysfunction, sclerodactyly (thin, pale, thickened and hairless skin on and distal extremities and the face. The so-called CREST syndrome with calcinosis, Raynaud’s phenomenon, esophageal dysfunction, sclerodactyly (thin, pale, thickened and hairless skin on and distal extremities and the face.

Application of the EUROMEYLINE Systemic Sclerosis (Nucleoli) Profile (IgG): The newly developed EUROMEYLINE Systemic Sclerosis (Nucleoli) Profile (IgG) is the first membrane-based test system to provide such a wide range of 12 systemic sclerosis-associated antigens. The test thus allows differentiation of antibodies with nucleolar patterns obtained in indirect immunofluorescence. The assay surpasses all existing test methods with respect to sensitivity and specificity and provides an effective and accurate determination of autoantibodies in systemic sclerosis and overlapping syndrome. It supplements the wide range of EUROMEYLINE products, for which user-friendly automatic solutions and evaluation software are available.
Test Characteristics

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**Test principle:** The EUROLINE is a qualitative in vitro immunoassay, in which membrane strips printed with lines of purified, biochemically characterised antigens are used as solid phase. Each antigen is coated onto a separate membrane fragment, enabling the production process and thereby the efficiency of antibody detection to be optimized for each antigen. Since antigen bands are located at defined positions, results can be evaluated visually without the need for additional equipment. Correct performance of all test steps is confirmed by staining of the control band.

**Computer-based evaluation:** The EUROLine-Scan programme from EUROIMMUN provides automated evaluation of EUROLINE analyses and detailed documentation of results. The incubated membrane strips are either scanned onto a protocol sheet using a flatbed scanner (EUROBlotCamera) or photographed directly in the incubation tray using a camera system (EUROBlotCamera). EUROLineScan recognises the position of the strips, even if they have been laid inexacty. It then identifies the bands and measures their intensity. The EUROLINE programme facilitates data management and eliminates the need to archive potentially infectious material. A separate results sheet can be produced for each patient. Online connection to other programmes is possible, e.g. laboratory management systems (LIMS).

**Correlation with indirect immunofluorescence:** 129 sera from patients with clinically characterised SSc (limited and diffuse forms) and 142 sera from control patients (50 PM/DM, 50 SLE, 42 RA) had been tested using the indirect immunofluorescence test (IIFT) based on HEp-2 cells (EUROIMMUN AG). 92.8% (90/97) of the SSc sera with a nucleolar pattern reacted positively in the EUROLINE Systemic Sclerosis (Nucleoli) Profile (IgG). But only 17.7% (3/17) of the nucleolar pattern sera from the control panels showed a positive reaction. This shows that identification and differentiation of a high number of SSc-specific and -associated antibodies is possible.

**Technical data:**

**Antigens**

- **Native:** Scl-70: Scl-70 antigen purified by affinity chromatography; Recombinant: CENP A: centromere protein A; CENP B: centromere protein B; RP11: subunit POLR3K of human RNA polymerase III; RP155: subunit POLR3A of human RNA polymerase III; fibrillarin; N0R-90; Th/To; PM-Scl100: PM-Scl protein (100 kDa); PM-Scl75: PM-Scl protein (75 kDa); Ku: Ku protein; PDGF: PDGF receptor; Ro-52: Ro-52 protein (52 kDa).

- **Sample dilution:** Serum or plasma; 1:101 in sample buffer.

- **Test procedure:** 30 min / 30 min / 10 min. Room temperature.

- **Test kit format:** 16 membrane strips. Kit includes all necessary reagents.

- **Automation:** Compatible with all commercial blot processing systems, e.g. the EUROBlotMaster from EUROIMMUN.

**Order number:** DL 1532-1601 G