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Instruction for use  
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## ORG 660 Anti-SS-A 60

Immunometric Enzyme Immunoassay for the quantitative determination of IgG autoantibodies to SS-A 60

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### NAME AND INTENDED USE

Anti-SS-A 60 is an indirect solid phase enzyme immunoassay (ELISA) for the quantitative measurement of IgG class autoantibodies to SS-A 60 in human serum or plasma. The assay is intended for in vitro diagnostic use only as an aid in the diagnosis of Sjögren's syndrome.

### SUMMARY AND EXPLANATION OF THE TEST

Rheumatoid autoimmune diseases are often associated with the occurrence of autoantibodies against several nuclear or cytoplasmic antigens. These so-called anti nuclear antigens (ANA) can be divided into three groups:

1. true anti nuclear antigens (ANA): dsDNA, ssDNA, histones, nucleolic RNA and DNP
2. extractable nuclears antigens: Sm (Smith), n-RNP, Scl 70 and PM-1
3. cytoplasmatic antigens: SS-A (Ro)\*, SS-B (La)\* and Jo-1  
*\* SS-A (Ro) and SS-B (La) are co-localized in cytoplasm and nucleus*

In patients with Sjögren-Syndrome antibodies against SS-A and SS-B often occur in combination. Due to the strong association of SS-A and SS-B antibodies to the HLA-DR3 and DR2 phenotypes a genetic predisposition is suspected. The anti SS-A protein passes the placenta and may cause the development of SLE in neonates. Immunoreactive proteins may occur in various combinations and bind also to 'host proteins' of viral origin. They induce synthesis of polyclonal autoantibodies, of the IgG, IgM and IgA class. Especially for mixed connective tissue diseases a relation to viral infections by EBV (Eppstein-Barr-Virus) is indicated. Each class of immunoglobulins causes a specific immunofluorescent pattern. Basically immunofluorescence titers correlate with the quantitation of IgG antibodies but the concentrations may vary considerably within each titer. Quantitation of IgG class antibodies extensively correlates with the diseases' activity. This makes it superior to immuno-fluorescence using Hep2 cells. The IF with Crithidia lucilliae sometimes results in deviating values.

Today the best investigated immunoreactive antigens are double-stranded DNA (dsDNA), single stranded DNA (ssDNA), Sm (Smith), sn-RNP (small nuclear ribonucleoprotein particles), the complex RNP/Sm which is stabilized by ribonucleic acid as well as SS-A (Ro) and SS-B (La). The antigen Scl 70, a 70 kD molecular weight protein is associated with scleroderma.

In rheumatoid autoimmune diseases various profiles of autoantibodies to these antigens can be detected. In a high incidence they are related to active and inactive systemic Lupus erythematodes, mixed connective tissue diseases (Sharp Syndrome), rheumatoid arthritis, Sjögren-Syndrome, Scleroderma, photosensitive dermatitis and drug-induced lupus.

In Lupus patients typically anti-dsDNA antibodies can be detected. Patients without these antibodies very often show anti-ssDNA antibodies and anti-SS-A and anti-SS-B are present. A strong correlation between antibody concentration and severity of the disease has been observed with higher antibody concentrations in active phases of the disease. Thus quantitation is more informative compared to simple titering by immunofluorescence.

Measurement of anti-ssDNA provides additional information regarding antibody specificity and activity. Except in chronic inflammatory processes anti-ssDNA antibodies are not found in healthy subjects.

Most of these parameters are not specific for just one disease but they occur in various com-







