Autoimmune Disease Diagnostic Reference Panel

(Catalog No. 6405)

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Application Notes: Autoimmune disorders manifest themselves across a broad spectrum of clinical disease with varying degrees of severity and rate of disease progression. Autoimmune disease can be seen as affecting specific organs such as the adrenal or thyroid gland and causing thyroiditis, Addison's Disease and diabetes, or affecting a number of tissues and causing Lupus and Rheumatoid Arthritis. The BioClinical Partners, Inc. ***Autoimmune Disease Diagnostic Reference Panel*** is a 10 member Panel of carefully selected subjects exhibiting antibody specific markers corresponding to particular clinical disease.

Panel I.D. Number	Age	Sex	Antibody Type	Diagnostic Test Data**	Physician's Diagnosis	Clinical Symptoms	Summary and Background
AU6405-01	31	F	**RNP**	4.0 RATIO	**ACUTE THYROIDITIS AND MIXED CONNECTIVE TISSUE DISEASE (MCTO)**	Polyarthralgia, muscle weakness Chronic glandular enlargement with multiple physical expression	Autoantibodies against a series of protein components of uridine-rich RNP complexes are found in SLE and mixed collagenoses. The responsible nuclear antigens, the U-smRNP complexes, are involved the splicing of pre-mRNA. Thus, they are of central importance in information transfer from the level of transcription to that of translation on ribosomes in the cytoplasm.
AU6405-02	24	F	**Jo-1**	3.4 RATIO	**POLYMYOSITIS**	Proximal muscle weakness, tenderness, pain and frequent rash, Polyarthralgia	Within the autoimmune-related rheumatic diseases one can find an unusual set of autoantibodies which is restricted to a group of patients suffering from idiopathic inflammatory myopathies (IMM). The responsible antigens, unlike those with other disease belonging to this group (which are mostly ANA-positive systemic autoimmune diseases), are predominantly localized in the cytoplasm. All are protein and tRNA components belonging to the complex protein synthesis machinery.
AU6405-03	29	F	**CLP-IgG (ACA)**	55 U/ml	**SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND VASCULITIS**	History of malaise, fever, adenopathy Intermittent arthralgia, polyarthritis, and erythema with generalized blood vessel infraction	Anti-cardiolipin antibodies (ACA) are anti-phospholipid antibodies. Their occurrence was first demonstrated in sera of syphilis patients. More recently they have also been described as common in SLE patients and those with related autoimmune diseases. The so-called "lupus anticoagulant" is a member of this group of antiphospholipid antibodies. Over the years it became evident that in patients with lupus anticoagulant, hemorrhagic abnormalities are rare. However, a tendency to thromboses could be found in these patients.
AU6405-04	41	F	**SS-A**	4.5 RATIO	**SJOGREN'S SYNDROME, RHEUMATOID ARTHRITIS AND HASHIMOTO'S THYROIDITIS**	Multiple joint inflammation	In expression of SS-A, an autoimmunopathy of the exocrine glands, chronic inflammation, particularly of the lacrimal and salivary glands, caused by lymphocytic infiltrations, leads to swelling and progressive loss of function, together with the appearance of the symptoms of the sicca syndrome. The disease occurs primarily in women between the ages 30 and 60. Autoantibodies against the subcellular RNP particles SS-A/Ro and SS-B/La are considered to be the dominant serological markers in Sjogren's Syndrome as well as in SLE.
AU6405-05	39	F	**SS-b**	4.3 RATIO	**SJOGREN'S SYNDROME (SS) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)**	Dry eyes and mouth with intermittent arthralgia and erythema	In Sjorgren's Syndrome (SS), an autoimmunopathy of the exocrine glands, chronic inflammation, particularly of the lacrimal and salivary glands, caused by lymphocytic infiltrations, leads to swelling and progressive loss of function, together with the appearance of the symptoms of the sicca syndrome. The disease occurs primarily in women between the ages 30 and 60. Autoantibodies against the subcellular RNP particles of Ro (SS-A) and La (SS-B) are considered to be the dominant serological markers in Sjogren's Syndrome as well as in SLE.

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Panel I.D. Number	Age	Sex	Antibody Type	Diagnostic Test Data**	Physician's Diagnosis	Clinical Symptoms	Summary and Background
AU6405-06	29	F	**SM**	2.4 RATIO	**SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)**	History of malaise, fever, adenopathy Intermittent arthralgia, polyarthritis, and erythema	Autoantibodies against a series of protein components of uridine-rich RNP complexes are found in SLE and mixed collagenoses. The responsible nuclear antigens , the U-smRNP complexes, are involved in the splicing of pre-mRNA. Thus, they are of central importance in information transfer from the level of transcription to that of translation on ribosomes in the cytoplasm.
AU6405-07	39	M	**Scl-70**	2.4 RATIO	**CALCINOSIS AND RAYNAUD'S PHENOMENON AND ESOPHAGEAL DYSMOTILITY AND SCLERODACTYLY AND VELANGIECTASIA (CREST)**	Swelling of extremities, polyarthralgia Swelling of joints	Like systemic lupus erythematosus (SLE), progressive systemic sclerosis (PSS) is a multisystemic disease. With scleroderma, however, in contrast to SLE, one rarely finds pathogenetic symptoms caused by immune processes, such as lymphocytic infiltration, massive appearance of circulating immunocomplexes and the typical signs of hypocomplementemia. Mostly, the vascularized connective tissues are affected. The characteristic signs which gave the disease its name are the thickening and hardening of the skin. This leads to a slowly progressive fibrosis and, in later stages of the disease, to sclerosis.
AU6405-08	39	F	**dsDNA**	310 IU/ml	**SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)**	History of malaise, fever, adenopathy Intermittent arthralgia, polyarthritis, and erythema	Antibodies directed against various components of the cell nucleus are found in serum of many patients suffering from rheumatoid diseases such as lupus erythematosus and discoides, progressive systemic sclerosis, polymyositis, and others. Anti-nuclear antibodies (ANA) comprise antibodies against nucleic acids (ssDNA, dsDNA), nucleoprotein complexes (DNA, RNP) and histories, as well as the so-called extractable nuclear antigens (ENA).
AU6405-09	31	F	**TPO**	575 IU/ml	**ACUTE THYROIDITIS AND SYSTEMIC LUPUS ERYTHEMATOSUS**	Chronic glandular enlargement with multiple physical expression	Scherbaum and Berg distinguish the following principal groups of thyroid autoimmune disease: Hashimoto's thyroiditis, Primary myxedema, Grave's disease, Asymptomatic autoimmune thyroiditis.
AU6405-10	66	M	**CENP**	4.9 RATIO	**PROGRESSIVE SYSTEMIC SCLEROSIS (SCLERODERMA) (PSS)**	Generalized cutaneous thickening progressing to visceral involvement	Like systemic lupus erythematosus (SLE), progressive systemic sclerosis (PSS) is a multisystemic disease. With scleroderma, however, in contrast to SLE, one rarely finds pathogenetic symptoms caused by immune processes, such as lymphocytic infiltration, massive appearance of circulating immunocomplexes and the typical signs of hypocomplementemia. Connective tissue accompanying blood vessels is the most commonly affected. The name-giving characteristics are the thickening and hardening of the skin. A slowly progressive fibrosis ensues, leading in later stages of the disease to sclerosis.

*Matrix for this Panel is SERUM
**Values for TPO and dsDNA are expressed in IU/mL and Cardiolipin IgG in U/mL
All other values are expressed in Ratio's whereby: Negative Ratio <1.0 Equivocal Ratio 1.0 - 1.4 Positive Ratio >1.4

All sera tested and found to be nonreactive for Anti-HIV 1, Anti-HCV and HBsAg