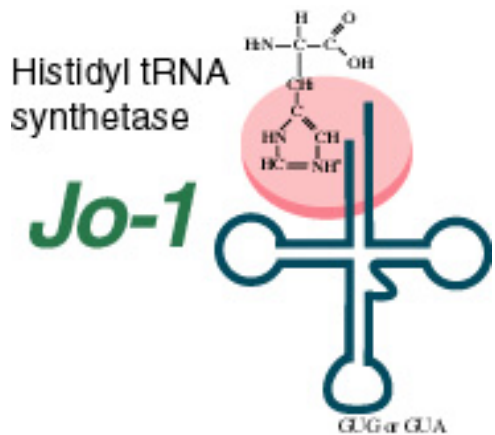


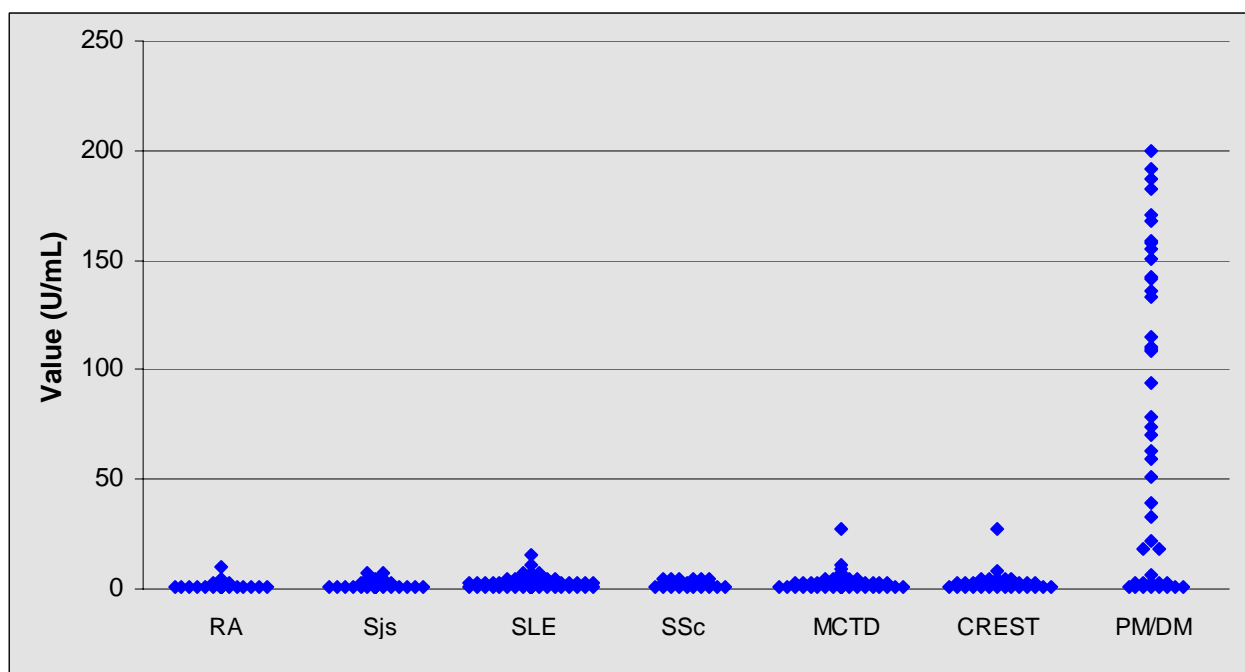
The MESACUP-2 Test Jo-1 is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of anti-Jo-1 antibodies in human serum as an aid in the diagnosis of polymyositis and/or dermatomyositis, or other related connective tissue diseases.



- Detects anti-Jo-1 antibodies using recombinant purified histidyl tRNA synthetase protein
- Highly sensitive and specific for polymyositis and dermatomyositis
- Excellent correlation compared to double immunodiffusion method (DID)
- Results are reported in semi-quantitative units, eliminating subjective interpretation required with immunodiffusion methods
- Easy to use procedure can be automated allowing for a large number of specimens to be screened in a short period of time

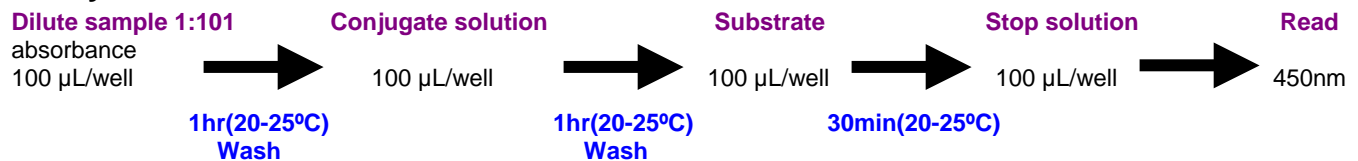
### Clinical Specificity and Sensitivity

Serum samples from various autoimmune disease groups were tested to determine clinical specificity and sensitivity of the MESACUP-2 Test Jo-1 assay. These groups included rheumatoid arthritis (RA), Sjögrens Syndrome (SjS), systemic lupus erythematosus (SLE), systemic sclerosis (SSc), mixed connective tissue disease (MCTD), CREST syndrome and polymyositis/dermatomyositis (PM/DM). Results are presented in the graph below.



Anti-Jo-1 antibodies were first reported by Nishikai et al<sup>1</sup>, and known to be detected in the serum of patients with Polymyositis (PM) and Dermatomyositis (DM). Anti-Jo-1 antibodies are one of the anti-ENA antibodies, and the corresponding antigen appeared to be histidyl-tRNA synthetase. Polymyositis and Dermatomyositis are considered to be the typical diseases which result in inflammatory myopathies and immunologic abnormalities and have been implicated in the pathogenesis of these disorders, but details have not been revealed. Since this antibody was found in 20-30% of patients with PM/DM, in 30-40% of patients with PM, and particularly in more than 60% of patients with PM combined with interstitial lung disease, and rarely found in the other collagen diseases, it is regarded as a marker for PM/DM. In recent studies, it was reported that the quantity of this antibody varied in proportion to disease activity, therefore anti-Jo-1 antibodies are also expected to indicate treatment effectiveness.

### Assay Procedure



### Correlation with double immunodiffusion (DID) method

A comparison analysis was performed on 730 collagen disease patient samples with the MESACUP-2 Test Jo-1 assay and a DID method resulting in a 99% relative agreement. A population of 265 healthy donor samples were also tested on both the ELISA and DID method resulting in a 99.6% relative specificity and agreement.

ELISA vs. DID Correlation		DID method	
		Positive	Negative
MESACUP	Positive	37	6
	Negative	0	687

### Kit Contents

96 antigen coated microwells in frame	12 x 8 strips
Calibrator-1 (0 U/mL) (ready to use)	1.5 mL
Calibrator-2 (100 U/mL) (ready to use)	1.5 mL
Positive Control	0.2 mL
Negative Control	0.2 mL
Conjugate Reagent (IgG,IgM and IgA)	15 mL
Assay Diluent	50 mL
Wash Concentrate (10x)	100 mL
Substrate (ready to use)	20 mL
Stop Solution (ready to use)	20 mL

### MESACUP-2 Test Jo-1

Product # 10756  
Quantity: 96 tests  
Storage: 2-8°C  
Stability: 18 months



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Corgenix Medical Corporation trades on the NASD (OTC BB) under the ticker symbol CONX. Corgenix, Inc. operates under FDA Quality System Regulations and is ISO 9001:1994/ISO 13485/EN 46001 certified.