



# **REF** 25009

# Background

Circulating antibodies intra-cellular to structures especially to nuclear antigens represent a characteristic feature of systemic autoimmune diseases. One of antigens, Jo-1 (Aminoacyl-tRNA those Synthetase), was first described in the serum of a myositis patient. A large number of patients with anti-synthetase syndrome suffer from interstitial lung disease. Raynaud's Phenomenon, mechanic's hands arthritis. Anti-Jo-1 and antibodies are strongly associated with isolated anti-Ro52 antibodies. More than 70% of all anti-Jo-1 positive sera in myositis also show anti-Ro52 reactivity. Apart from Jo-1, other tRNA synthetases (e.g. PL-7, PL-12, OJ) can be the target of autoantibodies, but with lower frequency.

### Intended use

The Jo-1 ELISA is intended for the semiquantitative determination of antibodies specific for the Jo-1 protein. The results of the Jo-1 ELISA aid to the diagnosis of myositis and related autoimmune disorders and should be used as prognostic marker for the disease progression.

ELISA (Dr.Fooke)	Jo1(-)	Jo1(+)	ALBIA	Jo1(-)	Jo1(+)
Ro52(-)	19	6	Ro52(-)	17	7
Ro52(+)	2	16	Ro52(+)	2	17

ALBIA = Addressable laser bead assay

#### Figure 1

Results of two independent assay systems for anti-Ro52 and anti-Jo-1 reactivity in myositis sera (n=43) showing strong association of the two reactivities (p=0.0002, kappa= 0.54). More than 70% of anti-Jo-1 positive sera show reactivity against Ro52.

### **General features**

- Recombinant antigen
- CE marked
- User-friendly
- · Colored reagents
- Ready to use reagents (except washing buffer)
- Breakapart microtiter strips

# **Technical information**

- Assay time: < 1.5 h at RT (30 min /30 min /15 min)
- 3 µL serum or plasma per test
- Detection System: HRP/TMB (OD<sub>450 nm /620 nm</sub>)
- Wide measuring range
- Low detection limit

Table 1: Precision (intra-assay variation) of the Jo-1 ELISA.

Serum	Mean RU	<b>CV %</b>
Jo-1/1 (n=4)	2.7	1.4
Jo-1/2 (n=4)	2.1	1.1
Jo-1/3 (n=4)	3.9	2.2

 Table 2 Precision (inter-assay variation) of the Jo-1 ELISA.

Serum	Mean RU	<b>CV</b> %
Jo-1/1 (n=5)	3.2	2.0
Jo-1/2 (n=5)	2.0	7.8
Jo-1/3 (n=5)	4.2	3.8





# Assay performance

- Good correlation to reference assay (LIA) systems
- Excellent "lot to lot" correlation R<sup>2</sup> > 0.98
- Low intra- and inter-assay variation CV% < 8</li>
- Excellent linearity over the entire range

ID	Target	ELISA (RU)	Interpretation
CDC 1	DNA	0.3	negative
CDC 2	SS-B/La	0.3	negative
CDC 3	RNP/Sm, SS-A/Ro, SS-B (La)	0.3	negative
CDC 4	U-1 RNP	0.3	negative
CDC 5	Sm	0.3	negative
CDC 6	Fibrillarin	0.2	negative
CDC 7	SS-A/Ro	0.2	negative
CDC 8	Centromere	0.2	negative
CDC 9	ScI-70	0.2	negative
CDC 10	Jo-1	5.0	positive
CDC 11	PM/Scl (PM 1)	0.4	negative
CDC 12	Rib-P	0.2	negative

### Figure 2

Results of the CDC ANA reference sera. 12 reference serum samples, available from the "Center for Disease Control and Prevention (CDC)" were tested in the Jo-1 ELISA (REF: 25009). Only the anti Jo-1 positive sample was found to be positive.

Jo-1 ELISA (25009)				
e		neg	pos	
enc	neg	391	5	396
Reference	pos	2	22	24
Ř		393	27	420

#### Figure 3

420 samples were tested in a reference assay (LIA) and in the Jo-1 ELISA (REF: 25009). The agreement of the results was found at 98% (kappa = 0.85, p < 0.0001).

ID	Diagnosis	RU	Interpretation	No. of competitors with positive result for Jo-1
AMLI 1	HD	0.1	negative	0
AMLI 2	SLE	0.0	negative	0
AMLI 3	MCTD	0.0	negative	0
AMLI 4	SjS	0.0	negative	0
AMLI 5	SjS	0.2	negative	0
AMLI 6	Scl	0.0	negative	0
AMLI 7	PM	3.2	positive	17/17
AMLI 8	CREST	0.1	negative	1/?
AMLI 9	SLE	0.2	negative	0
AMLI 10	HD	0.1	negative	0

HD = healthy donor; SLE = systemic lupus erythematosus; MCTD = mixed connective tissue disease; SjS = Sjögren Syndrome; ScI = systemic sclerosis; CREST = (calcinosis, Raynaud phenomenon, esophageal dysmotility, sclerodactyly and telangiectasia); PM = Polymoysitis

#### Figure 4

Results of the AMLI reference sera. 10 reference serum samples, available from the Association of Medical Laboratory Immunologists (AMLI) were tested in the Jo-1 ELISA (REF: 25009). Sample AMLI 7 was tested positive in concordance to the findings of 17 reference laboratories.

### Literature

1. Tan EM: Antinuclear antibodies: diagnostic markers for autoimmune diseases and probes for cell biology. *Adv Immunol* 1989, **44**:93-151.

2. Mielnik P, Wiesik-Szewczyk E, Olesinska M, Chwalinska-Sadowska H, Zabek J: Clinical features and prognosis of patients with idiopathic inflammatory myopathies and anti-Jo-1 antibodies. *Autoimmunity* 2006, **39**:243-7.

3. Schulte-Pelkum J, Fritzler M, Mahler M: Latest update on the Ro/SS-A autoantibody system. *Autoimmun Rev* 2009, **8**:632-637.