



CPAL

Central Pennsylvania Alliance
Laboratory

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Jo-1 - New Test Introduction -

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Ordering Information:

Mnemonics:	Jo-1 IgG Ab
Test Name:	Jo-1 IgG Ab
Test Number:	3000824
Specimen:	1 ml serum, refrigerated up to 48 hours, frozen up to 30 days

Effective Date: Testing will begin on Monday, April 6, 2015.

Performed: Monday, Wednesday, and Friday

Reference Range: Negative

Background:

The determination of antinuclear antibodies (ANA) is of central importance for the clinical diagnosis of connective tissue diseases. Jo-1 antibodies can be found as markers in dermatomyositis/ polymyositis (prevalence of about 25%), but also in patients with polymyositis overlap syndrome. They are associated with interstitial pneumonitis (in the context of myositis) and occur in a far smaller proportion of children with myositis than of adults. Patients with Jo-1 antibodies tend to have a severe form of the disease with a tendency to relapse and a poorer prognosis.

EliA Jo-1 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Jo-1 in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of polymyositis / dermatomyositis in conjunction with other laboratory and clinical findings. EliA Jo-1 uses the EliA IgG method on the instrument Phadia 250.

Principle of Test:

The EliA Jo-1 Wells are coated with human recombinant Jo-1 protein. If present in the patient's specimen, antibodies to Jo-1 bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG antibodies (EliA IgG Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away and the bound complex is incubated with a Development Solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The higher the response value, the more specific IgG is present in the specimen. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

Results Interpretation:

Phadia 250 measures specific IgG concentrations in µg/L. By using a conversion factor given by the lot-specific code of the EliA Jo-1 Well, the results are automatically converted to EliA U/ml. There are no international standards for the Jo-1 antibodies. The manufacturer’s unit of EliA U/ml is arbitrary and will be reported as U/ml.

- Negative:** <7 U/ml
- Equivocal:** 7-10 U/ml
- Positive:** >10 U/ml

The measuring range (detection limit, upper limit) for EliA Jo-1 is from 0.3 to ≥ 240 U/ml. Results less than 0.3 will be reported as <0.3 and results greater than 240 will be reported as ≥ 240.

Limitations:

A definitive clinical diagnosis should not be based on the results of a single diagnostic method, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Validation Data:

Precision:

To assess within-run precision, EliA Negative and EliA ANA Positive controls were run in the same run ten times each. To assess between-run precision, EliA Negative and EliA ANA Positive controls were run ten times each on two different days. Performance was within manufacturer’s precision claims of <10% CV. (Table 1)

Table 1: Jo-1 Precision

Phadia SN	Within Run Precision				Between Run Precision			
	Mean	CV	Mean	CV	Mean	CV	Mean	CV
N01926	< 0.3 U/mL	0%	38.5 U/mL	1.7%	< 0.3 U/mL	0%	37.4 U/mL	2.87%
N01778	< 0.3 U/mL	0%	34.6 U/mL	6.2%	< 0.3 U/mL	0%	38.0 U/mL	2.48%

Method Comparison

A total of 42 specimens were split and processed utilizing Phadia 250 EliA Jo-1 assay. The specimens were run on both Phadia 250 instruments. There was 100% interpretive agreement between the two methods and between both instruments. (Figures 1 & 2)

Figure 1: Phadia 250 A vs Quest

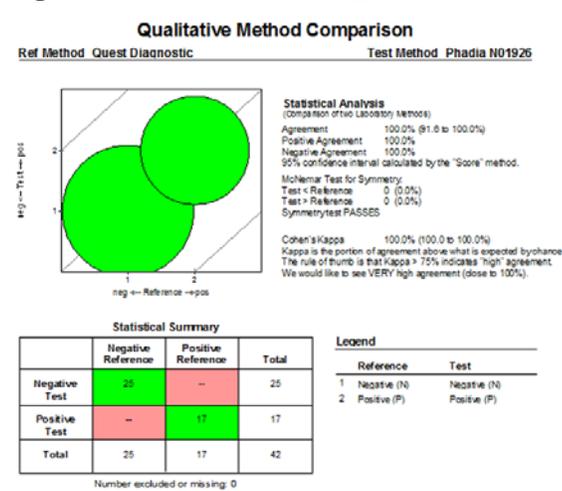
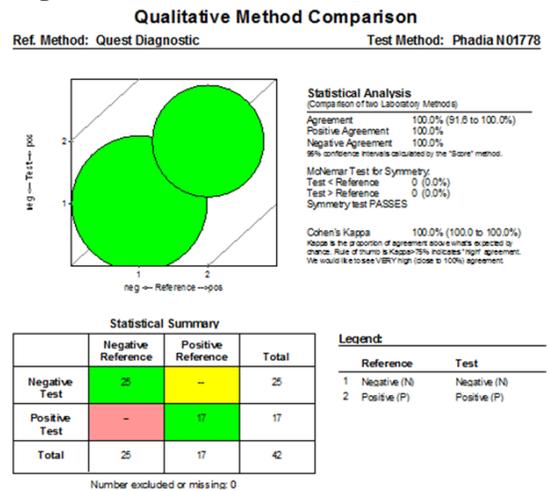


Figure 2: Phadia 250 B vs Quest



References:

- EliA Jo-1 package insert, December 10, 2011.