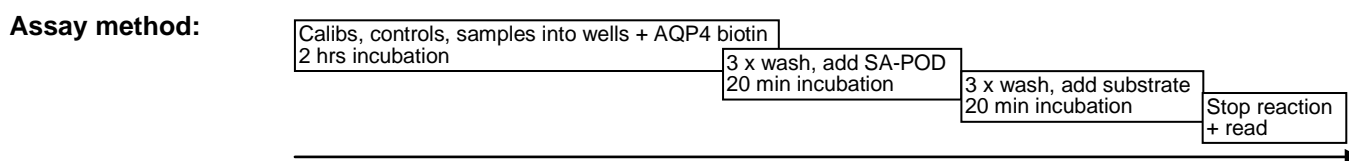


- Description:** Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to aquaporin-4 (AQP4) in serum
- Disease application:** Neuromyelitis Optica (NMO), also known as Devic's syndrome, or NMO spectrum disorder (NMOSD).
- Test samples:** Sera can be used. Do not use lipaemic or haemolysed samples. Some EDTA plasma samples may show approximately $\pm 30\%$ of results obtained with corresponding serum samples (see IFU).
No interference was observed; haemoglobin <500 mg/dL, bilirubin <20 mg/dL and intralipid < 3,000 mg/dL.

Assay volume: 50 μ L per well

Total assay time: Apprx. 3 hours



Sensitivity: 77 % n = 62 for NMO or NMOSD patients positive for NMO IgG immunofluorescence test

Specificity: 99 % n = 358 for healthy blood donors

Calibrator range: 1.5 – 80 units/mL (arbitrary RSR units)

Cut-off: Negative: < 3 unit/mL; Positive: \geq 3 unit/mL

Lower detection limit: 0.17 units/mL (mean + 2 standard deviations in assay of negative control; n = 20)

Advantages: A non-isotopic method with easy assay format for use in routine clinical laboratories and suitable for automated systems

Features: Reliable and convenient method to measure AQP4 autoantibodies, which are a specific marker for NMO or NMOSD. Measurement of AQP4 autoantibodies can be of considerable value in distinguishing NMO and/or NMOSD from Multiple Sclerosis when full clinical features may not be apparent and early intervention may prevent or delay disability.

Improvement: Sensitivity has been improved without any loss in specificity using M23-AQP4 rather than M1 (compared with ElisaRSR™ AQP4 Ab).

Kit size: 96 wells

Order code: AQP4/96/2

- Literature:**
- V A Lennon et al, Lancet 2004 **364** (9451): 2106-2112
A serum autoantibody marker of neuromyelitis optica: distinction from multiple sclerosis
 - V A Lennon et al, The Journal of Experimental Medicine 2005 **202**: 473-477
IgG marker of optic-spinal multiple sclerosis binds to the aquaporin-4 water channel
 - B G Weinschenker et al, Annals of Neurology 2006 **59**: 566-569
Neuromyelitis optica IgG predicts relapse after longitudinally extensive transverse myelitis
 - N Isobe et al, Multiple Sclerosis Journal 2012 **18**:1541-1551
Quantitative assays for anti-aquaporin-4 antibody with subclass analysis in neuromyelitis optica
 - S Jarius et al, J of the Neurological Sciences 2012 **320**: 32-37
Testing for antibodies to human aquaporin-4 by ELISA: Sensitivity, specificity and direct comparison with immunohistochemistry

This kit is intended for in-vitro use by professional persons only. The data quoted is for guidance only. Each laboratory should establish its own normal and pathological reference ranges for the assay and should include its own panel of control samples in the assay along with the controls provided as part of the kit.

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TECH/ElisaRSR AQP4 Ab Version 2 Rev0