Aquaporin-4 Autoantibody (AQP4Ab)

ELISA

NEUROIMMUNOLOGY

ASSAY CHARACTERISTICS

Semi-Quantitative

Calibration:	5 Calibrators, 1.5 – 80 U/mL (arbitrary units)
Controls (Included):	2 Positive, 1 Negative

TOTAL RUNNING TIME

2 Hours and 40 Minutes

SPECIMEN MATRIX

Human Serum

SAMPLE CALCULATION

Curve Fit Analysis

REFERENCE RANGE

< 3.0 U/mL: Negative
≥ 3.0 U/mL: Positive

PRECISION

Dose (U/mL)	Intra-Assay % CV	Inter-Assay % CV
3.5	6.5	6
32	3.4	7.8
70.2	4.1	4.6

CLINICAL STUDY

A total of 620 serum samples were included in the clinical validation for the KRONUS Aquaporin-4 Autoantibody (AQP4Ab) ELISA Assay. The validation set of samples included 85 patients diagnosed with NMO and 52 patients diagnosed with NMOSD.

CLINICAL SENSITIVITY & SPECIFICITY

Sensitivity:	69%
Specificity:	98%

ORDERING INFORMATION

KR8200 – 96 Well Kit

The KRONUS Aquaporin-4 Autoantibody (AQP4Ab) ELISA Assay is for the semi-quantitative determination of autoantibodies to Aquaporin-4 in human serum. The KRONUS Aquaporin-4 Autoantibody (AQP4Ab) ELISA Assay may be useful as an aid in the diagnosis of Neuromyelitis Optica (NMO) and Neuromyelitis Optica Spectrum Disorders (NMOSD). The KRONUS Aquaporin-4 Autoantibody (AQP4Ab) ELISA Assay is not to be used alone and is to be used in conjunction with other clinical, laboratory, and radiological (e.g. MRI) findings.

With the KRONUS Aquaporin-4 Autoantibody (AQP4Ab) ELISA Assay, AQP4 antibodies in patients' sera, calibrators and controls are allowed to interact with AQP4 coated onto ELISA plate wells. Then biotinylated AQP4 is added. AQP4 antibodies bound to the AQP4 on the well will also interact with AQP4-Biotin due to the divalent nature of antibodies. After incubation at room temperature for 2 hours with shaking, the well contents are discarded, leaving AQP4-Biotin bound to the well via an AQP4 autoantibody bridge. The amount of AQP4-Biotin bound is then determined in a second incubation step involving addition of streptavidin peroxidase (SA-POD), which binds specifically to biotin. Excess, unbound streptavidin peroxidase is then washed away and addition of a colorogenic substrate (TMB) results in formation of a blue color. This reaction is stopped by the addition of a stop solution, causing the well contents to turn yellow. The absorbance of the yellow reaction mixture at 405nm is then read using an ELISA plate reader. A higher absorbance indicates the presence of AQP4 autoantibody in the test sample.

For In Vitro Diagnostic Use. Rx Only.

KRONUS

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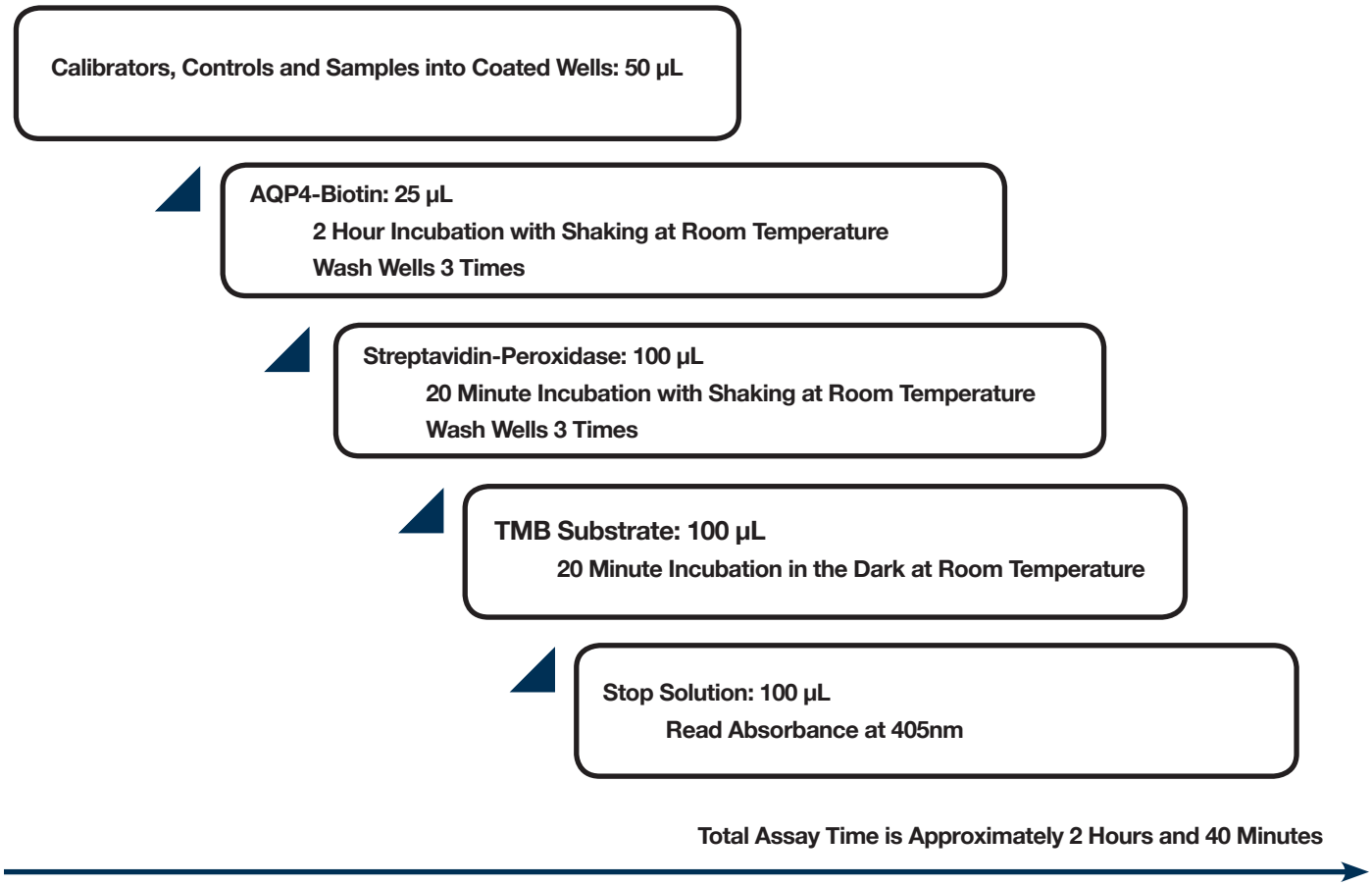
ASSAY PROCEDURE

Sample Volume: 50 µL per Well



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