Gold Dot NR2 Antibody Test

For in vitro quantitative determination of antibodies to NR2 subunit of NMDA receptors in serum

Intended Use

The Gold Dot NR2 Antibody assay is a serological enzyme-linked immunosorbent assay (ELISA) for the quantitative determination of antibodies to the NR2 subunit of human NMDA glutamate receptor in serum. The test is intended to be used in conjunction with clinical evaluation and radiological methods for diagnosis of transient ischemic attack (TIA) and ischemic stroke vs stroke-like disorders. The Gold Dot NR2 Antibody ELISA indicates prior isolated or multiple ischemic stroke and increased risk of near-term cerebral ischemic events in patients with preexisting conditions (diabetes, hypertension, atherosclerosis, cardiovascular disorders). The test allows differentiation between ischemic and hemorrhagic stroke.[1-5]

Principle of the Test

Concentrations of NR2 antibodies are determined immunochemically in a serological assay. NR2 peptide, the fragment of NMDA receptors, is coated on the solid phase of a microtiter plate (MTP). In a first incubation step, antibodies in the sample react with the solid phase bound NR2 peptide. After intensive washing, the antibodies captured on the MTP react with horseradish peroxidase labeled Protein A (Protein A, HRP).

//-NR2 Peptide ← Serum Antibodies ← Protein A-HRP

The immunocomplex is formed and quantitatively determined in a third incubation step via HRP/TMB-detection reaction. An acidic stopping solution is then added. The color converts from blue to yellow. The intensity of the yellow color is directly proportional to the concentration of NR2 antibodies in the sample. A dose response curve of the absorbance measured at 450 nm or using dual wave measurement at 450 nm and 630 nm vs concentration is generated. NR2 antibody concentrations in the diluted serum samples are determined directly from this calibration curve.

Gold Dot NR2 Antibody test is available in the USA for research use only

Gold Dot NR2 Antibody Strengths

- NR2 antibody is an independent blood-borne
- marker that rules in cerebral ischemic event and rules out hemorrhage
- NR2 antibody is a marker of neurotoxicity and circulates in the blood 3-6 months after prior isolated or multiple ischemic stroke
- NR2 antibody elevation corresponds to increased risk of near-term ischemic stroke and strongly predicts risk of TIA
- NR2 antibody indicates old ischemic lesions
- NR2 antibody allows follow-up after treatment
- NR2 antibody concentration correlates with the size of prior isolated or multiple cortical ischemic stroke (for strokes with areas from 3 cc to approximately 30 cc)

Gold Dot NR2 Antibody Limitations

- NR2 antibody test has low sensitivity to small (<3 cc) and/or white matter strokes

Reference Values of Gold Dot NR2 Antibody Assay

NR2 Antibody, ng/mL		
Normal	**Preexisting conditions (risk group)**	**Disease**
0.9-1.5	**1.5-2.0**	**> 2.0** **2.0-5.0** — Prior isolated or multiple ischemic stroke **≥5.0** — TIA

Advantages

• Color-coded reagents
• The reagents in one kit are sufficient for 89 determinations
• Convenient, cost-effective ELISA
• For in vitro diagnostic use in CE marking countries
• 90-minute procedure

CE

References

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2. Bokesch PM, Izykenova GA, Justice JB, Easley KA, Dambinova SA. NMDA receptor antibodies predict adverse neurological outcome after cardiac surgery in high-risk patients. *Stroke*. 2006;37:1432-36.
3. Dambinova SA. *Brain Biomarkers for Cerebral Ischemia: NMDA Neuroreceptor Degradation and Blood Assay Development.* AACC Press. 2009. In press.
4. Dambinova SA. Biomarkers for transient ischemic attack (TIA) and ischemic stroke. *Clin Lab Int.* 2008; 32(7):7-10
5. Data on file.

This product is covered by U.S. Patent No. 6896872 and additional patents pending: 11/076074, 11/339440, 11/339452, 11/338447 and PCT/US06/002306, 11/451679 and PCT/US2006/023020, and PCT/US2007/087278.

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