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First fully-automated TSH receptor antibody assay launched by Roche Diagnostics

Roche Diagnostics announced today the launch of the first fully-automated immunoassay for the determination of autoantibodies to the thyroid stimulating hormone (TSH) receptor for the differential diagnosis of Graves' disease. The assay has been CE approved for use on the Elecsys / cobas e electrochemiluminescence immunoassay systems.

Graves' disease, which is also known as Basedow's disease, represents the leading type of autoimmune thyroid disease and is associated with hyperthyroidism and ophthalmopathy. The incidence is about 40 cases per 100.000 population per year. The TSH receptor antibody (TRAb) is the major pathogenic factor in Graves' disease, which, like TSH, binds the receptor and has a stimulatory effect with resulting hyperthyroidism. Measurement of the TSH receptor antibody is recommended in the diagnosis of Graves' disease and differentiation from diffuse thyroid autonomy. Additionally, TRAb measurement can be useful to monitor antithyroid drug treatment.

"The new TRAb assay provides the opportunity to perform differential diagnosis of thyroid autoimmune diseases with new levels of accuracy, speed and degree of automation", said Dirk Ehlers, Head of Roche Professional Diagnostics. "This assay will further strengthen Roche's comprehensive test menu in thyroid diseases and endocrinology."

The Elecsys TSH receptor antibody assay is based on intellectual property owned by RSR Limited, UK. Roche has concluded a license agreement with RSR in this field. RSR Limited is a developer and manufacturer of medical diagnostics with particular emphasis on research activities in the field of autoimmune diseases (www.rsrltd.com).

About the test

The newly developed third-generation Elecsys Anti-TSHR assay has been shown to meet the diagnostic requirements with excellent sensitivity and specificity. A further advantage of the assay is the short total test time of 27 minutes which is significantly faster than existing methods. The Anti-TSHR assay complements Roche Diagnostics broad immunoassay menu on Elecsys and cobas e platforms which permit the use of both routine and special assays.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totalled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 79,000 people. Additional information is available on the Internet at www.roche.com.

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