Performance of Elecsys® Toxoplasma IgG and IgM Immunoassays
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Introduction
Roche has developed two new rapid and fully automated assays for the detection of anti-Toxoplasma-specific IgG and IgM antibodies from human serum and plasma. Results of a performance evaluation study done under routine clinical laboratory conditions in Germany are presented. In general, the procedure of testing for T. gondii infection is starting with the Anti-Toxo IgG test as a screening assay. In case of a positive or indeterminate Toxo IgG result additionally an Anti-Toxo IgM test is performed. If the Toxo IgM test is also positive a T. gondii avidity test is done to exclude recent Toxoplasma infection. The new Elecsys® Toxo IgG and IgM tests were compared to the assays ADVIA Centaur® Toxo IgG and ADVIA Centaur® Toxo IgM (Siemens Healthcare Diagnostics, Tarrytown, USA).

Materials and Methods
2936 routine samples were tested in parallel with the Elecsys® Toxo IgG and ADVIA Centaur® Toxo IgG test. Discordant results were repeated with both methods and a further test, the AxSYM® Toxo IgG (Abbott Diagnostics) assay was performed for resolution. 2244 samples were tested in parallel with the Elecsys® Toxo IgM and ADVIA Centaur® Toxo IgM test systems. All samples with a positive Toxo IgM result were further examined by an anti-Toxo IgG avidity test (Avidity Anti-Toxo gondii ELISA IgG, EUROIMMUN AG, Lübeck, Germany) to exclude recent Toxoplasma infection.

Results
Performance Results of the Elecsys® Toxo IgG Assay
Figure 1 gives the value distribution which was found for Elecsys® Toxo IgG in N=2936 samples from clinical routine examined in this study. 2260 samples were found negative (76.97%). The majority of positive samples were found within the measuring range, 142 samples above the measuring range and only 25 samples (0.85%) had values within the grey zone.

Interpretation of Elecsys® Toxo IgG results:
Non reactive < 1 IU/ml, indeterminate: ≥ 1 IU/ml - < 3 IU/ml, reactive: ≥ 3 IU/ml.
Elecsys® Toxo IgG is standardized against the 3rd International Standard for ANTITOXOPLASMA SERUM, HUMAN Code TOXIM from NIBSC, UK

Sensitivity and Specificity of the Elecsys® Toxo IgG Assay
2244 samples were tested negative and 593 samples positive with both methods, 53 samples were found within the grey-zone in one of the two methods: N=27: positive by Elecsys® Toxo IgG, indeterminate by ADVIA Centaur® Toxo IgG; N=24: indeterminate by Elecsys® Toxo IgG and negative by ADVIA Centaur® Toxo IgG. Based on primary findings a sensitivity of 593/598 = 99.11% after resolution. After resolution a sensitivity of 56/87 = 64.37% was found for the Elecsys® Toxo IgM assay. After resolution a sensitivity of 56/56 = 100% was calculated. The specificity based on primary findings was 2123/2143 = 99.07% and 2123/2143 = 99.11% after resolution. Figure 3 shows the comparison study between the Elecsys® Toxo IgM and the ADVIA Centaur® Toxo IgM assay

Sensitivity and Specificity of the Elecsys® Toxo IgM Assay
2244 samples were tested in parallel with the Elecsys® Toxo IgM and ADVIA Centaur® Toxo IgM test systems. Positive or indeterminate sample results in one of both Toxo IgM tests were further examined by Toxoplasma Avidity testing or further resolved based on the results of follow-up or previous samples. 2254 samples were tested negative and 593 samples positive with both methods. All samples with a result constellation ADVIA Centaur® Toxo IgM positive/Elecsys® Toxo IgM negative were identified as samples with persistent IgM antibodies indicating a past Toxoplasma infection > 3 - 4 months. Based on primary findings a sensitivity of 56/87 = 64.37% was found for the Elecsys® Toxo IgM assay. After resolution a sensitivity of 56/56 = 100% was calculated. The specificity based on primary findings was 2123/2143 = 99.07% and 2123/2143 = 99.11% after resolution.

Conclusion:
The performance evaluation of the Elecsys® Toxo IgG assay resulted in a sensitivity of 100% and a specificity of 99.91% showing that this assay allows a very sensitive and specific detection of Toxo IgG antibodies with an excellent discrimination of positive and negative results. The performance evaluation of the Elecsys® Toxo IgM assay revealed a sensitivity of 100% and a specificity of 99.11% after resolution. Less reactivity towards persistent Toxo IgM antibodies in samples from Toxoplasma infections > 3-4 months was found with Elecsys® Toxo IgM. The performance evaluation data demonstrate that the Elecsys® Toxo IgG and Elecsys® Toxo IgM assays are reliable tools in routine diagnosis of Toxoplasma infections with the additional advantage of a high throughput on fully automated analyzers.