

ECAT survey results for HIT

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In 2008 ECAT introduced the heparin-induced thrombocytopenia (HIT) testing EQA programme. In the first three years the functional as well as the immunological testing were included. Because of some difficulties with the use of lyophilised samples the programme for functional testing was stopped and the programme continued with only qualitative tests and quantitative immunological assays. Currently approximately 300 laboratories worldwide participate in this programme.

The results of ECAT quality assurance programme for the diagnosis of HIT from the last three years 2011 – 2013 will be presented and discussed.

The samples used are prepared from citrated plasma. HIT-positive samples were only prepared from plasma of patients with a confirmed HIT type II. Plasma with a high titre of anti-Platelet Factor 4 / heparin antibodies was diluted with normal citrated plasma to obtain sufficient plasma material. Negative control samples were prepared from normal citrated pooled plasma. The response rate in each survey is about 80%.

Approximately two-thirds of the reported test results come from quantitative testing, of which $\pm 60\%$ is from IgG-specific methods.

For the qualitative tests the participants classified the sample as negative, borderline or positive. The result 'borderline' was considered correct for positive samples but incorrect for negative samples.

For the quantitative assays the participants reported the measured Optical Density (OD) as well as the cut-off level for positivity and classified the sample as negative, borderline or positive. The ratio between the measured OD and the local cut-off value was calculated, to "harmonize" the OD results.

Enzyme-immunoassays and latex-immunoassays in general show a good negative predictive value but have a moderate specificity, resulting in a substantial number of false positive test results.

The most important clinical application of HIT tests/assays is to rule out the diagnosis HIT. On the basis of the classification results in the ECAT surveys it has been shown that most laboratories give a correct interpretation of a positive HIT sample (97%). For negative samples the percentage of correct interpretation varied between 88% and 97%.

From the data of the ECAT HIT surveys may be concluded that the classification of the samples is in general acceptable, but that there is a need for standardisation of the quantitative measurement of anti-Platelet Factor 4/heparin antibodies.