

**A new kit in the block: TOSOH cardiac troponin I (cTnI) second generation test on the AIA 600 II. Clinical and analytical evaluation.**

**Topic:** Cardiac Markers

**g. printzen**, N. Berclaz, B. K. Moor;  
inselspital, Bern, SWITZERLAND.

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**Introduction**

Cardiac Troponin I is a specific as well as a sensitive marker for the diagnosis of myocardial damage.

**Objective**

In our study we evaluated the clinical and analytical performance of the new 2nd generation cardiac troponin I (cTnI) test on the TOSOH AIA 600 II . We compared the AIA 600 II cTnI method with our routine cTnI-test on the AxSYM (Abbott).

**Material and Methods**

A total of 84 consecutive patients with potential cardiac problems - 29 with a discharge diagnosis of myocardial infarction (MI) - were evaluated using both immunoassay methods. All patient samples were collected in lithium heparin tubes.

**Results**

Analytical part: The inter-day coefficient of variation (CV) was 2.5 +/- 0.29 and the intra-day CV was 1.6 +/- 0.18. We determined the functional sensitivity CV=20% corresponding to 0.04 ng/ml and CV=10% corresponding to 0.12 ng/ml. The results after dilution over the dynamic range of the assay were excellent. Method comparison with the Abbott AxSYM demonstrated very good correlation ( $r = 0.930$ ) with a proportional bias:  $AIA\ 600\ II = 0.976 + 0.190 (AxSYM)$  ; CI (95%) for intercept and slope were -0.098 to 2.050 and 0.177 to 0.204 respectively.

Clinical part: This part was carried out on 84 samples from patients of the daily routine. The TOSOH cTnI performed great in terms of 100 % clinical specificity in chronic renal disease and same-day noncardiac surgery patients. Clinical agreement between the assays was very good. The ROC-curve of the AIA 600 II demonstrated an excellent AUC of 0.957 (95% CI of area 0.917 to 0.998).

**Conclusion**

The Tosoh cTnI fulfills the most important "points" of the IFCC document: precise explanation of assay design; declared detection limit significantly lower than concentration corresponding to CV = 10% as well as good correlation and high agreement to routine analyzer analytically and in comparison with clinical interpretation. The STAT and precise performance qualify the TOSOH AIA 600 II cTnI as a reliable method for both routine and emergency use.