

IN HOUSE VALIDATION AND FIRST EXPERIENCE USING THE COBAS® TAQSCREEN MPX TEST, V.2.0 FOR NAT SCREENING

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Background: The cobas® TaqScreen MPX Test (Roche Diagnostics), a multiplex nucleic acid test for blood screening on the cobas s201 system, was used at the ZURICH Blood Transfusion Service SRC since April 2008. The new MPX Test, version 2.0 (MPX v2.0) enables a direct discrimination of HIV, HCV RNA and HBV DNA. After extensive in house validation, the v2.0 test was implemented in our lab by beginning of the year 2014. Results of the validation studies are shown and compared to the former test version as well as to the results of other laboratories. 6 month of experience in routine testing is presented.

Methods: The validation focused on the determination of the robustness, specificity and sensitivity of the assay. Analytical test sensitivity (limit of detection, LOD 95%) was determined by probit analysis for all 4 parameters (HIV-1, HIV-2, HCV and HBV). Robustness of the assay was evaluated by cross-contamination studies using samples with high viral titre and reproducibility assays were performed by repetitive testing of samples containing low viral concentrations. A comparison of the old versus the new test version was performed by parallel testing of more than 3500 routine samples. These routine samples were tested in pools of six.

Results: The analytical sensitivity (limit of detection, LOD 95%) of the MPX v2.0 was determined in our lab as 2.0; 6.8; 35.2 and 7.8 IU/ml for HBV, HCV, HIV-1 and HIV-2, respectively. These values are equal or below those determined by the former test version and also below the 95% LODs indicated in the MPX 2.0 package insert. Analytical sensitivities are comparable to those of other laboratories (Vox Sanguinis, 2013, 104, 19-29) and by far comply with the legal requirements. No cross contamination has been observed and reproducibility and robustness of the test are very satisfying. During parallel testing of routine samples, no discrepancies to the old test version have been observed. The results of first 6 month of routine testing confirm all these findings.

Conclusion: The new MPX v2.0 fulfilled all legal requirements and all acceptance criteria of the in house validation. The test turned out to be very robust and is therefore well suitable for NAT screening of blood donations. Analytical sensitivity is slightly improved. Test failures or false reactive results are rarely observed. The main advantage of the new test v2.0 is the ability of direct parameter discrimination facilitating the workflow of positive test results.