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FOUR PARAMETER NAT SCREENING BY TAQSCREEN MPX WITH COBAS S201 IN SWITZERLAND: VALIDATION, IMPLEMENTATION AND FIRST EXPERIENCES

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Background

The system cobas s201/TaqScreen MPX test (Roche Diagnostics) is a fully automated multiplex nucleic acid test for blood screening for hepatitis B virus (HBV) DNA, hepatitis C virus (HCV) RNA, HIV-1 RNA (groups M and O) and HIV-2 RNA. We implemented this test system at the ZURICH Blood Transfusion Service SRC for routine analysis in April 2008 based on a head to head comparison of alternative system. Limit of detection validated by probit analysis and first results of routine testing are presented.

Aims

To show overall performance and suitability of the system for high throughput blood donor screening aiming to improve transfusion safety.

Methods

The cobas s201 platform (Roche Diagnostics) consists of automated pooling of blood donations using Hamilton Star pipettor, automated sample preparation using cobas Ampliprep instrument and automated amplification (real time PCR) and detection using cobas TaqMan analyzer. The test cobas TaqScreen MPX for use on this platform is a CE labeled in vitro diagnostics (IVD) for detection of HBV DNA, HCV, HIV-1 and HIV-2 RNA in a multiplex assay. In reactive samples, the individual reactive parameters have to be identified using alternative testing. Routine samples were tested in pools of six. Resolution of positive pools by single donation re-testing.

Results

The 95% limit of detection (LOD) for HBV, HCV and HIV were 2.3 IU/ml, 7.4 IU/ml and 31.1 IU/ml (HIV-1), respectively.

Table: 95% LOD of TaqScreen MPX by Cobas s201

	HBV			HCV			HIV-1 Group M		
Site	95% LOD	95% Lower CI	95% Upper CI	95% LOD	95% Lower CI	95% Upper CI	95% LOD	95% Lower CI	95% Upper CI
Valencia	1.7	1.2	4.1	10.0	5.7	27.7	45.0	23.2	137.0
Rome	3.1	1.6	75.6	14.4	8.5	34.6	53.2	30.1	132.1
Edinburgh	1.9	1.2	4.4	9.7	5.7	23.4	47.3	26.4	118.5
Madrid	3.6	2.3	7.7	5.7	3.5	12.7	37.0	22.1	90.0
Porto	4.6	2.6	11.3	12.1	6.9	29.9	80.2	42.0	226.0
Verona	3.9	2.4	8.7	13.2	7.5	33.0	72.7	39.0	196.0
All sites combined	**3.8**	3.0	5.2	**10.8**	8.4	14.4	**56.7**	43.0	79.2
RMS (Development)	**3.7**	3.3	4.4	**10.7**	7.0	21.7	**49.0**	42.3	58.1
Zürich	**2.3**	1.4	5.4	**7.4**	4.7	15.5	**31.1**	18.6	71.8

These results are comparable with those of other European testing sites using the same platform and are even better than indicated in the test manual by Roche Diagnostics.
From April until middle of November 2008 we screened more than 46'000 donations. From 8 reactive donations, 4 were confirmed positive for HBV (HBsAg positive by ELISA), 2 were positive for HCV (HCV Ab positive by ELISA) and 1 was confirmed positive for HIV-1(HIV Ab and p24 Ag positive by ELISA). One donation was "isolated PCR reactive" (ELISA screening negative for all parameters tested). This sample could be identified as HBV PCR and anti-HBc positive, but negative for HBsAg. Actual data including nature and frequency of problems will be presented.

Summary/Conclusions
LOD of the cobas s201 TaqScreen MPX fulfills well the national and international requirements and proves to be most suitable for high throughput screening. Operational consistency is excellent. The first results indicate already a net safety benefit by application of this screening approach for Swiss blood donors.