



**SDI Review Form 1.6**

Journal Name:	<a href="#">International Blood Research &amp; Reviews</a>
Manuscript Number:	Ms_IBRR_38371
Title of the Manuscript:	External quality assessment of transfusion-transmissible infections testing
Type of the Article	Short Research article

**General guideline for Peer Review process:**

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty**', provided the manuscript is scientifically robust and technically sound. To know the complete guideline for Peer Review process, reviewers are requested to visit this link:

(<http://www.sciencedomain.org/page.php?id=sdi-general-editorial-policy#Peer-Review-Guideline>)



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**PART 1: Review Comments**

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<b>Compulsory</b> REVISION comments	<p><b>This is a quality improvement program in blood transfusion service. The researchers were not doing an assessment but a quality improvement program. The assessment was done by the European agency.</b></p> <p><b>It will be important to know how the program was conducted ie process of documentation of non conformities, organising of the audit of processes, instruments like check lists designed for the process, problems encountered during the process, results at each step investigated, factors that assisted them in the investigation like good record keeping, cost of the investigation ie personnel and financial.</b></p> <p><b>Ethical issue:</b></p> <p>There was no ethical approval or permission by the authorities to publish the program management data.</p>	<p>As it was mentioned in the discussion the quality improvement programme was conducted to investigate the root cause of the not satisfactory results of the B-PTS study in which we participated.</p> <p>Upon the valuable suggestion of the reviewer the authors tried to present the process more systematically. It was conducted in 3 phases: 1) Look back at the laboratory documentation, 2) Retesting and additional testing if necessary, 3) Corrective and preventive measures...(see the manuscript).</p> <p>The costs of the above mentioned investigation can be measured by the cost of the reagents used to perform the retesting (in general, the price of one TTI test from a single manufacturer is well known to the people who work in the field-proximately 2.5 EUR/test for the reagents which were used) of the original B-PTS035 samples and the efforts and time of the laboratory staff which was considered as part of their daily work.</p> <p>The program management data are no confidential. The second author of this study is the Quality Manager of the Institution.</p>
<b>Minor</b> REVISION comments	<p>It will be desirable to know the sensitivity and specificity of the reagents and the permission of the transfusion service to publish their data</p>	<p>The overall sensitivity (99.10%-99.99%) and specificity (99.60%-99.95%) of the used reagents for Architect assays (anti-HCV, Syphilis, Ag/Ab HIV combo and HBsAg Qualitative II), as well as for the Enzygnost assays (anti-HCV 4.0, Syphilis, HIV Integral 4.0 and HBsAg 6.0) is shown in the each of the package insert instructions of the reagents. See for example: <a href="http://www.abbottiagnostics.com/HBSAG_2G22.pdf">www.abbottiagnostics.com/HBSAG_2G22.pdf</a> and <a href="http://www.siemens.com/diagnostics/enzygnost_hiv_integral_4_brochure">www.siemens.com/diagnostics/enzygnost_hiv_integral_4_brochure</a></p> <p>The reagents which are used, are licensed and CE marked (approved by the Council of Europe for in vitro diagnostics) which is also well known.</p> <p>The data on sensitivity and specificity are already published and well known, so there is no need of permission.</p>
<b>Optional/General</b> comments		<p>We consider the reviewer's remarks very constructive. We tried to do our best to incorporate them in the manuscript. Thank you.</p>