Announcement of the National advisory Committee 'Blood' (Arbeitskreis Blut)
of the German Federal Ministry of Health

Revision of the recommendations made in Votum 34 and 35 concerning look-back procedures (According to Paragraph 19 of the Transfusion Act) from 14 June, 2006 with regard to hepatitis B infections

The following recommendation (Votum) V 42 was adopted at the 74th session of the National Advisory Committee 'Blood' held on March 05, 2013:

The algorithm for determining whether a look-back procedure must be performed according to V34/V35 was in need of revision: The interpretation of isolated anti-HBc positive results was difficult because of ambiguous results that occur more commonly than in other serological tests. This often led to donor deferrals that were hard to explain and needless uncertainty on the part of the donor. To help alleviate this situation the Appendices B1 (Hepatitis B Virus (HBV) Assay diagram for Look-Back Procedure) and B2 (Hepatitis-B-Virus (HBV) – Laboratory diagnosis to determine the infection status of the first blood sample) have been adapted accordingly. The aim was to recognize non-specific anti-HBc results more reliably than in the past and to define the resultant prerequisites for initiation of a look-back procedure.

A new category, "Anti-HBc specificity" has been introduced in the revised assay diagram. This is of significance in situations in which a initial positive anti-HBc result together with negative HbsAG and negative ID-NAT must be clarified. Clarification can be made on the basis of a 2:1 decision using 3 different anti-HBc tests. Alternatively, clarification can be made on the basis of a CE-certified or acoording to Medicinal Products Act valdated in-house anti-HBc confirmation test if such a test is available. In case of a confirmed positive anti-HBc result it is necessary to initiate the look-back procedure.

If specificity testing of the initial positive anti-HBc result indicates the possibility of non-specificity (two further positive anti-HBc results or confirmation test negative) it will be necessary to carry out an HBV-ID-NAT with high sensitivity (≤12 IU/ml). If the NAT is negative it can be assumed that the positive anti-HBc result was the result of non-specificity and it is not necessary to initiate a look-back procedure. The donation can be released and the donor is eligible to donate again. A positive HBV-NAT result confirms infection and a look-back procedure must be initiated. Furthermore, all confirmed positive test results that lead to "HBV – suspicion of infection confirmed" as indicated in Appendix B2 will result in initiation of a look-back procedure.

According to the revised clarification of positive results it is no longer necessary to determine the anti-HBs titer. In the interim, this test served the fundamental assessment of donor eligibility in cases of repeated positive anti-HBc tests. Seven years after introduction of anti-HBc testing this test is only required for the requalification of donors 5 years after an HBV infection as described in the hemotherapy guidelines. It has therefore been removed from the diagram for the look-back procedure.

In addition, details for clarification of vaccination related test results have also been removed from the diagram. If there is reason to believe that positive confirmation results may be due to vaccination it will be necessary to retest for HbsAG, anti-HBc and HBV ID-NAT of appropriate sensitivity (≤12 IU/ml) one to three weeks after the initial donation depending on the time of vaccination. The donation is to be permanently quarantined. Before the donor can be reinstated with the result: “HBV infection not confirmed” after the second confirmational testing it will be necessary to substantiate the vaccination anamnesis (e.g. by presentation of vaccination records). If vaccination is confirmed as the source of the positive results in the first confirmation tests any of the donor’s plasma that has been stored for 4 months can be released for use.

The algorithm presented here was specifically intended for the interpretation of virological laboratory diagnosis within the framework of look-back procedures and is not to be understood as a general standard for the virological clarification of HBV infections.

This recommendation, together with Appendices B1 and B2, replace those of Votum 34 and Votum 35.

In the name of the National Advisory Committee ‘Blood’

Prof. Dr. R. Burger - Chairman

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This Votum is available in German at http://www.rki.de>Kommissionen>Arbeitskreis_Blut>Voten.