

American Red Cross

National Headquarters

BSL #86-42

To Responsible Heads Date September 4, 1986
Compliance Officers


From Dr. AuBuchon Subject ALT Cutoff Values

In designing the unit quarantine and donor deferral protocols for ALT testing, the Blood Services program was patterned according to the report of the ALT study performed at NIH by Dr. Harvey Alter.[1] This study suggested that using the calculated cutoff of 2.25 standard deviations above the mean log for normal subjects would result in discarding about 1.6% of collected units in order to reduce the risk of posttransfusion non-A, non-B hepatitis by the predicted amount. Initial reports from regions, however, indicate that the proportion discarded using this cutoff would significantly exceed 1.6%. Thus, more units would be discarded than necessary to achieve the intended effect. The reason for this discrepancy is not yet clear; regions will be asked to provide further information about their ALT activity distributions in the next several weeks to explore the reasons for these unexpected results.

During the phase-in period, which extends to October 1, 1986, regions may continue to utilize an interim ALT cutoff of not more than twice the upper limit of normal as defined by the manufacturer of the reagents. Before October 1, National Headquarters will communicate with the regions regarding the cutoff criteria to be used after that date.

The lower cutoff value selected with the approval of a region's responsible head during the interim period should be utilized as the criterion for quarantine of a unit and entry of a donor into Category 1 of the DDR (Proposed BSD 4.9). If the lower cutoff value is later changed, either through a change in the criterion or in the population base used to calculate the cutoff, the new lower cutoff should be used only in a prospective manner for units tested subsequent to that change. This represents a modification of the approach to donor management outlined in proposed BSD 6.53, Attachment I, Section I.C. The final form of BSD 6.53 will reflect the procedure stated in this memorandum.

As stated in proposed BSD 6.53, the upper cutoff value should continue to be based on the lower cutoff value in use in the region.


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Reference

1. Alter HJ, Purcell RH, Holland FV, Alling DW, Koziol DE. Donor transaminase and recipient hepatitis. Impact on blood transfusion services. JAMA 1981;246:630-4.