

RELATIVE SENSITIVITY OF HBsAg AND HBV NAT TESTS

Committee Update

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Update: Relative Sensitivity of HBsAg and HBV NAT Tests

Data presented at the March 16, 2000 Blood Products Advisory Committee meeting indicated that HBV NAT testing of Source Plasma donations, using the format of testing minipools containing 512 donations, currently being performed under IND, might offer little improvement in sensitivity compared to HBsAg testing of individual donations using some of the more sensitive HBsAg tests.

In regard to this, FDA is organizing studies in collaboration with NIH that directly compare (1) HBsAg testing, of individual samples using various HBsAg screening assays, to (2) HBV NAT testing using the 512-sample minipool format for testing Source Plasma.

At the present time Whole Blood and components for transfusion in the United States are not tested by HBV NAT assays. HBV NAT testing of all blood donations has been implemented in Japan, and is being discussed in Europe.

FDA is also reviewing the lower limits of detection of all currently licensed HBsAg tests that are used to screen the blood supply. After completion of this review, FDA will decide whether to change the lot-release requirements of licensed HBsAg tests in regard to lower limits of detection.

We welcome the submission of any existing data on high-sensitivity tests for HBsAg. The data should contain sufficient detail, so that meaningful head-to-head comparisons between tests can be made.