The Blood Connection
Your Community Blood Donation Center

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TECHNICAL SERVICES BULLETIN

HCV RIBA Supply Shortage

The HCV RIBA 3 strip immunoblot used to confirm results generated on the serological donor screening platforms will not be available for an indeterminate amount of time. The current supplies are exhausted (nation-wide). This presents two sets of issues for collection facilities, hospitals and donors/patients:

- Information normally relied on to develop donor counseling messages will not be available. This will not be an issue for NAT-reactive discriminated donors who are HCV screen repeat reactive, but will impact those with nonreactive NAT.

- Hospitals will continue to need notification regarding prior donations within 45 days of the reactive screening test results, in accordance with FDA guidance.

The FDA is aware of the problem and are developing a guidance, and as of this time they are willing to accept variance applications from the facilities to use an alternate, second licensed screening test to be used as a substitute for a RIBA-positive test result. For example, a donor sample which tests positive using either Ortho or Abbott testing platform, and negative on NAT testing can be tested by using the alternate vendor to use as a supplemental test.

How does this affect the Lookback procedure: TBC will screen our donors using our normal testing platforms. If a donor is serologically positive and NAT positive, OR if the donor is serologically positive using both manufacturer's testing methods (and NAT negative), the donor would be considered to be confirmed positive. Discordant screening tests with a negative NAT would be treated as a false positive test-of-record result. TBC will freeze samples during this process so that when the RIBA test is made available again, these samples can be tested.

User Group Meeting

The next TBC user Group Meeting will be held November 28- please make plans to attend

- Lunch will be provided beginning at 12 noon
- Meeting will start around 12:30.
- AABB audioconference to be presented (starts at 2pm): Changes in Standards
- Tentative agenda items:
  - AABB Association Bulletin #12-04 (Bacterial contamination of platelets)
  - AIM Module 1 and Module 2- demo and impact on your organization
  - HCV Lookback

Please feel free to contact me with any agenda items you would like discussed.
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