



Memorial Blood
Centers

MEMBER AMERICA'S BLOOD CENTERS

It's About *Life*.

Dr. Robin Biswas
C/o Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20857

Re: 6/25/03, Guidance for Industry, **“Revised Recommendations for Donor and Product Management Based on Screening tests for Syphilis”**

Dear Dr. Biswas,

The most potentially problematic part of this revision is contained in section III.C. on page 5. It states that “We recommend that units of Whole Blood and blood components intended for transfusion be released if they tested reactive for syphilis by screening tests but have negative results by FTA or other confirmatory assay on the reactive collection. Such testing must be performed in a FDA-registered and CLIA-qualified laboratory.”

Like most blood centers we:

- Send our confirmatory testing to the state department of health (Minnesota in our case).
- Do not release units, as few hospitals will accept units labeled as reactive by a screening test for syphilis and negative by an additional confirmatory test.

There are relatively few labs that perform syphilis confirmatory testing that are also FDA registered. We interpret the above paragraph to allow us to continue sending confirmatory testing to the State Department of Health, if we are only using the information for donor counseling and eligibility status and NOT for release of the unit. Hence, if we may continue to send confirmatory testing to our state department of health, we have no objection to the revised guidance. If we must send confirmatory testing to an FDA registered lab, then we have grave concerns that this change will delay confirmatory testing and hence, donor counseling and will have no effect on the safety of the blood supply, since we don't transfuse these units anyway.

Respectfully yours,

Jed B. Gorlin MD
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