

CHIRON

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Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

To Whom It May Concern:

Chiron Corporation has the following comments regarding DRAFT Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV.

Section III: Availability of Licensed NAT System for Screening of Whole Blood Donors. Sentence 3 states that "The assay meets the current FDA sensitivity standards of 100 copies/mL for the analytical sensitivity of the pool test and 5,000 IU/mL for the original donation when tested in pools."

The analytical sensitivity of the test meets the 100 copies/mL claim when tested neat, not in a pool of up to 16 donations. For clarity, we suggest the following modification to this sentence:

"The assay meets the current FDA sensitivity standards of 100 copies/mL for the analytical sensitivity and 5,000 IU/mL for the original donation when tested in pools."

Section IV: Implementation. Section A. Reporting Requirements for Licensed Blood Establishments (21 CFR 610.12)

In all parts of Section A, when referring to NAT, all statements should be changed to indicate "licensed NAT". It should also clearly state that sites (licensed establishments or contract labs) who currently perform infectious disease NAT testing for blood products, using the current test under IND may submit an annual report. Those sites that are licensed to perform NAT

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testing but have not previously performed NAT testing using the recently approved method notify the agency of a change to *licensed NAT* testing, using the CBE 30 mechanism. Those sites that have not performed licensed infectious disease testing previously should file a prior approval supplement.

Section IV: Implementation. Section B. Labeling Requirements (21 CFR 606/122) The current labeling recommendation for Circular of Information requires separate labeling of blood tested by Pooled NAT vs. Individual Sample. However, the indications for use in the licensed Procleix HIV-1/HCV Assay states that the product “is intended for use in screening individual donor samples or pools of human plasma comprised of equal aliquots of not more than 16 individual donations.” Adequate data was provided to CBER supporting the safety and efficacy of this assay for “up to 16 donations.”

We recommend the following labeling change for the Circular of Information:

“Licensed Nucleic Acid Testing (NAT) for HCV RNA and HIV-1 RNA has been performed and found to be non-reactive.”

Other Comments:

Since many sites are anxiously awaiting the instructions for the Donor Management Guidelines, it is requested that these be issued as a draft as soon as possible.

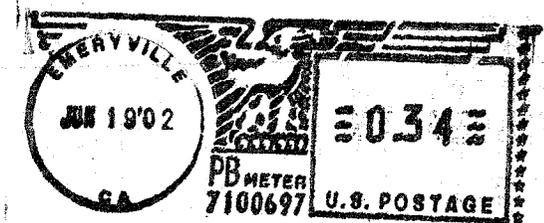
Sincerely,



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