Association for the Advancement of Blood & Biotherapies

Toolkit: HCV Testing, Lookback and Reentry

06/21/22

AABB would like to acknowledge Jenn Vrieze of the Mayo Clinic for her assistance in developing the flowcharts.

PURPOSE:

In response to member requests, this is the second in a series of resources developed as a resource for actions following positive testing for an RTTI.

- The Flowcharts in this Toolkit have been developed to assist with compliance efforts <u>but</u> <u>not replace your review</u> of the recommendations found in FDA's Dec 2017 Guidance, <u>Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis</u> <u>C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry</u> and the regulations in <u>21 CFR 610.47</u>.
- The Flowcharts are based on the current recommendations in the Dec 2017 Guidance and include references to specific regulations and recommendations for cross-checking information.
 - \circ $\;$ The guidance includes a number of useful tables and figures to review.

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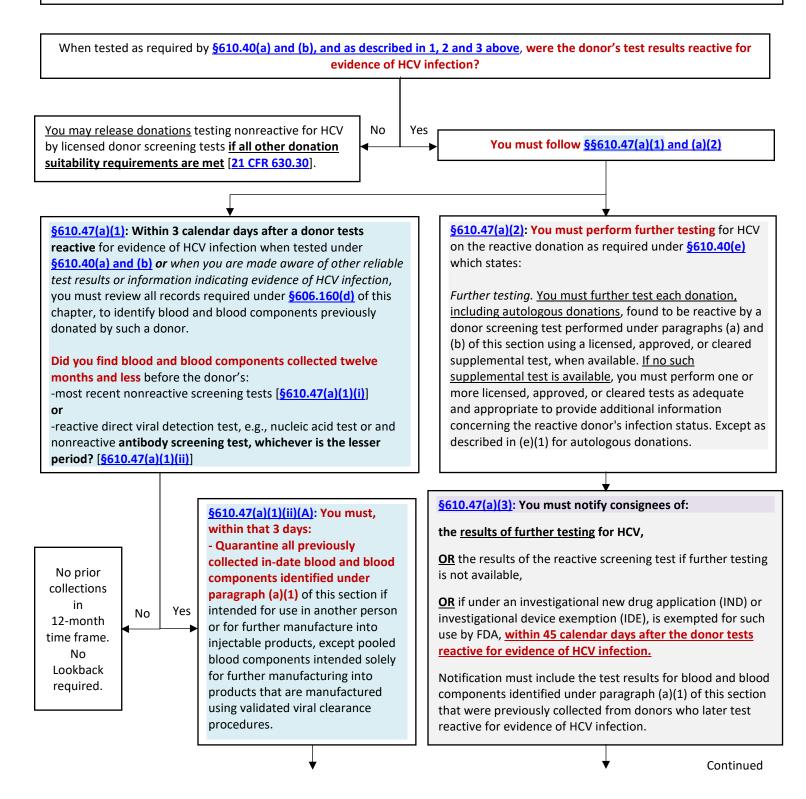
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FLOWCHART 1: HCV TESTING and LOOKBACK REQUIREMENTS, including quarantine and discard

- 1) All blood donors must be tested for RTTIs, including HCV, under <u>21 CFR 610.40</u> and HCV Lookback must be completed as required by <u>§610.47 Hepatitis C virus (HCV) "lookback" requirements</u>.
- 2) <u>21 CFR 610.40(a)(1)</u> requires you to "Test each donation for evidence of infection due to the relevant transfusion-transmitted infections described in § 630.3(h)(1)(i) through (iii) of this chapter (HIV, HBV, and HCV).
- 3) In the December 2017 Guidance, <u>Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C</u> <u>Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry</u>, Section III, Background and Discussion, A. on p. 6, FDA clarifies that: "Under 21 CFR 610.40(b) you must use screening tests that FDA has licensed, approved, or cleared for such use."





Continued

§610.47(a)(1)(ii)(B): You must, within those 3 days: -Notify consignees to quarantine all previously collected in-date blood and blood components identified under paragraph (a)(1) if intended for use in another person or for further manufacture into injectable products, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures.

NOTIFIED CONSIGNEE §610.47(b):

If you are a consignee of Whole Blood or blood components, including Source Plasma and Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions:

(1) You must quarantine all previously collected in-date blood and blood components identified under paragraph (a)(1) of this section, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures, when notified by the collecting establishment.

§610.47(a)(4)

When results of further testing required in <u>§610.47(a)(2)</u> are negative \rightarrow <u>Release</u> from quarantine

OR

When the results of further testing required in §610.47(a)(2) are positive for evidence of HCV \rightarrow destroy or relabel quarantined in-date blood and blood components consistent with the results of the further testing performed under paragraph (a)(2) of this section, or the results of the reactive screening test if further testing is not available, or if under an IND or IDE, exempted for such use by FDA.

CONSIGNEE is notified of results of further testing based on §610.47(b)(2)

IF NEGATIVE: When notified that further testing required in <u>§610.47(a)(2)</u> was negative \rightarrow <u>Release</u> from quarantine

OR

IF POSITIVE: When notified that further testing required in <u>§610.47(a)(2)</u> is **positive for evidence** of HCV \rightarrow <u>destroy or relabel</u> quarantined in-date blood and blood components consistent with the results of the further testing performed under paragraph (a)(2) of this section, or the results of the reactive screening test if further testing is not available, or if under an IND or IDE, is exempted for such use by FDA.

> If result of Further Testing is POSITIVE or not done, §610.47(b)(3) applies.

CONSIGNEE must notify transfusion recipient /physician of record /legal representative - §610.47(b)(3)

When further testing for HCV is positive <u>or</u> when the screening test is reactive and further testing is not available, <u>or</u> if under an IND OR IDE is exempted for such use by FDA, you must notify transfusion recipients of previous collections of blood and blood components at increased risk of transmitting HCV infection, <u>or</u> the recipient's physician of record, of the need for recipient HCV testing and counseling.

You must notify the recipient's physician of record or a legal representative or relative if the recipient is a minor, adjudged incompetent by a State court, or if the recipient is competent but State law permits a legal representative or relative to receive information on behalf of the recipient.

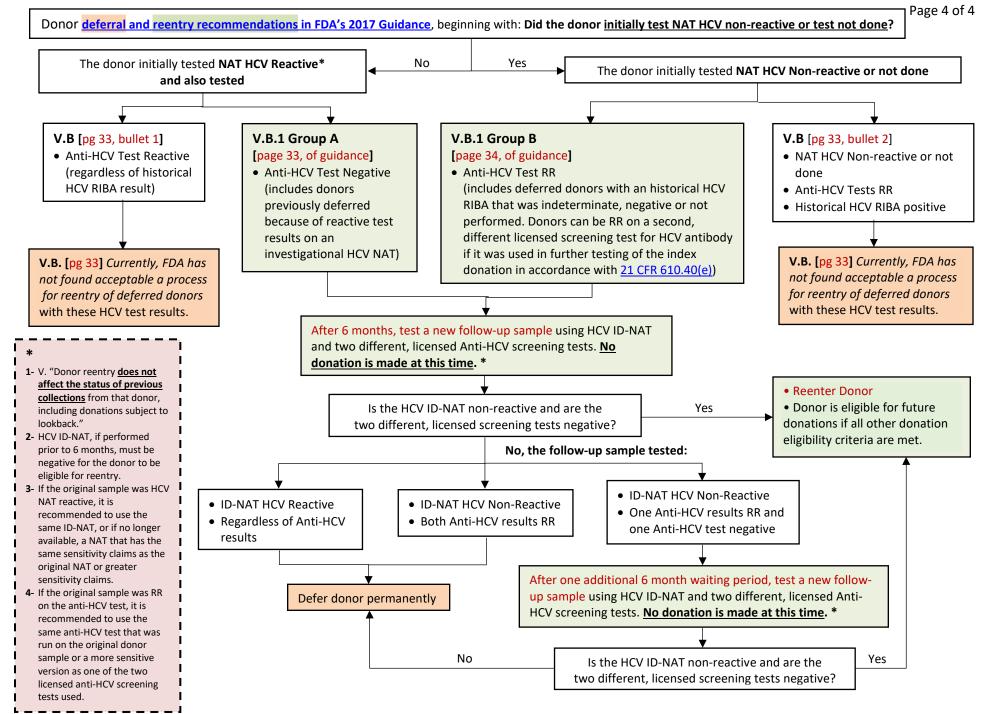
You must make reasonable attempts to perform the notification within 12 weeks:

- after receiving the results of further testing for evidence of HCV infection from the collecting establishment, OR

- after receiving the donor's reactive screening test result for HCV if further testing is not available, or if under an IND or IDE is exempted for such use by FDA.

FLOWCHART 2: DONOR DEFERRAL/REENTRY- Based on the Dec 2017 Guidance, Nucleic Acid Testing (NAT) for Human

Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry



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