

aDHQ v2.1 Crosswalk to aDHQ v4.0

- This Crosswalk has been developed as a resource to assist with compliance efforts. It should not replace the full review of DHQ v4.0 and Accompanying Materials (including the aDHQ), which comprise the system of documents formally recognized by FDA.

aDHQ v2.1 renumbered as --->	aDHQ v4.0	Question and Flowchart Revisions	Basis for the Revision of aDHQ v4.0
n/a	n/a	<ul style="list-style-type: none"> Throughout the aDHQ questions have been reordered to: <ul style="list-style-type: none"> focus attention on new content. group similar questions 	
n/a	n/a	<ul style="list-style-type: none"> Throughout the aDHQ v4.0 Flowcharts, references have been added to the CFR, FDA guidance and AABB Standards. 	
n/a	n/a	<ul style="list-style-type: none"> aDHQ v4.0 Flowcharts: “Accept Donor” boxes have been removed. 	<ul style="list-style-type: none"> Donors are not “accepted” until they have completed the entire donor screening process. Therefore, the “Accept Donor” boxes in the Flowcharts have been removed.
1. Are you feeling healthy and well today?	1. Are you feeling healthy and well today?	<ul style="list-style-type: none"> No revision. 	
Refer to aDHQ v2.1 Q26	2. Are you pregnant now?	<ul style="list-style-type: none"> The compound aDHQ v2.1 question Q26, “Female donors: Since your last donation, have you been pregnant or are you pregnant now?” was broken into 2 questions. Note: aDHQ v4.0 Q29 “Since your last donation, have you been pregnant?” assesses an individual who has been pregnant in the past 6 weeks but is no longer pregnant. 	<ul style="list-style-type: none"> Member feedback described poor donor attention to the compound aDHQ v2.1 question. Member feedback – Posing this question to all donors supports an individual donor assessment approach.

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		<ul style="list-style-type: none"> Q29 also assesses TRALI risk. 	
<p>2. Have you read the educational materials today?</p>	<p>3. Have you read the blood donor educational materials today?</p>	<ul style="list-style-type: none"> Number change. Clarification 	<ul style="list-style-type: none"> The words “blood donor” were added to clearly identify the FDA required blood donor educational material which must be presented to the donor prior to donation.
<p>3. In the past 48 hours, have you taken aspirin or anything that has aspirin in it?</p>	<p>4. In the past 48 hours, have you taken aspirin or anything that has aspirin in it?</p>	<ul style="list-style-type: none"> Number change. 	
<p>4. In the past 8 weeks, have you donated blood, platelets or plasma?</p>	<p>5. In the past 8 weeks, have you donated blood, platelets, or plasma?</p>	<ul style="list-style-type: none"> Number change. 	
<p>5. In the past 8 weeks, have you had any vaccinations or other shots?</p>	<p>6. In the past 8 weeks, have you had any vaccinations or other shots?</p>	<ul style="list-style-type: none"> Number change Information on Jynneos vaccine was added to the flowchart. 	<ul style="list-style-type: none"> AABB's Updated Information on Donation of CCP, Blood Components and HCT/Ps During the COVID-19 Pandemic
<p>6. In the past 8 weeks, have you had contact with someone who was vaccinated for smallpox in the past 8 weeks?</p>	<p>7. In the past 8 weeks, have you had contact with someone who was vaccinated for smallpox in the past 8 weeks?</p>	<ul style="list-style-type: none"> Number change. Information on Jynneos vaccine was added to the flowchart. 	
<p>aDHQ v2.1 Area for Additional Questions</p>	<p>8. In the past 3 months, have you taken any medication by mouth (oral) to prevent an HIV infection? (i.e., PrEP or PEP)</p>	<ul style="list-style-type: none"> New question added. (moved from the area for additional questions). 	<ul style="list-style-type: none"> FDA's 2023 HIV Guidance AABB Association Bulletin #22-03 Updated Recommendations on Donor Deferral for Use of Antiretroviral Medications for HIV Prevention and Treatment including Long-Acting Injectable PrEP and the Impact on Blood Safety
<p>12. Male Donors: In the past 3 months, have you had sexual contact with another male?</p>	<p>9. In the past 3 months, have you had sexual contact with a new partner? (refer to the examples of “new partner” in the Blood Donor Educational Material)</p>	<ul style="list-style-type: none"> New individual donor assessment question. Examples of “sex with a new partner” have been included in the Note section. Examples of “sex with a new partner” have been added to the Blood Donor Educational 	<ul style="list-style-type: none"> FDA's 2023 HIV Guidance

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		Material and the Flowchart.	
13. Female Donors: In the past 3 months, have you had sexual contact with a male who had sexual contact with another male in the past 3 months?	10. In the past 3 months, have you had sexual contact with more than one partner?	<ul style="list-style-type: none"> • New individual donor assessment question. • Number change. 	<ul style="list-style-type: none"> • FDA's 2023 HIV Guidance
9. In the past 3 months, have you had sexual contact with anyone who has ever had HIV/AIDS or has ever had a positive test for the HIV/AIDS virus?	11. In the past 3 months, have you had sexual contact with anyone who has ever had a positive test for HIV infection?	<ul style="list-style-type: none"> • Number change. • Revised to align with the language of the guidance. 	<ul style="list-style-type: none"> • FDA's 2023 HIV Guidance
17. In the past 3 months, have you received money, drugs, or other payment for sex?	12. In the past 3 months, have you received money, drugs, or other payment for sex?	<ul style="list-style-type: none"> • Number change. 	<ul style="list-style-type: none"> • FDA's 2023 HIV Guidance
10. In the past 3 months, have you had sexual contact with a prostitute or anyone else who has ever taken money or drugs or other payment for sex?	13. In the past 3 months, have you had sexual contact with anyone who has, in the past 3 months, received money or drugs or other payment for sex?	<ul style="list-style-type: none"> • Number change. • Revised to align with the language of the guidance. • Revised from sexual contact with anyone who has "ever" to "in the past 3 months". • Flowchart includes deferral recommendation for donors who have uncertainty about when their sexual partner exchanged sex for money or drugs. • Removed the word "prostitute". 	<ul style="list-style-type: none"> • FDA's 2023 HIV Guidance • Donor satisfaction – objection to use of the word "prostitute" in the question • FDA guidance now includes eligibility assessment for donors who are unsure of when their sexual partner exchanged sex for money or drugs.
16. In the past 3 months, have you used needles to take drugs, steroids, or anything not prescribed by your doctor?	14. In the past 3 months, have you used needles to inject drugs, steroids, or anything not prescribed by your doctor?	<ul style="list-style-type: none"> • Number change. • Revised to align with the language in the guidance. 	<ul style="list-style-type: none"> • FDA's 2023 HIV Guidance
11. In the past 3 months, have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?	15. In the past 3 months, have you had sexual contact with anyone who has used needles in the past 3 months to inject drugs,	<ul style="list-style-type: none"> • Number change. • Revised to align with the language in the guidance. 	<ul style="list-style-type: none"> • FDA's 2023 HIV Guidance • FDA guidance now includes eligibility assessment for donors who are unsure of when their

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	steroids, or anything not prescribed by their doctor?	<ul style="list-style-type: none"> Revised from sexual contact with anyone who has “ever” to “in the past 3 months”. Flowchart includes deferral recommendation for donors who have uncertainty about when their sexual partner engaged in non-prescription injection drug use. Definition of “sexual contact” has been included in the donor eligibility statement and Note section. 	sexual partner engaged in non-prescription drug use.
<p>22. Since your last donation, have you had sexual contact with a person who has hepatitis?</p>	<p>16. In the past 3 months, have you had sexual contact with a person who has hepatitis?</p>	<ul style="list-style-type: none"> Number change. Timeframe for sexual contact was changed from 12 months to 3 months. Flowchart was modified to include follow-up questions to the donor based on the recommendations of FDA's Sept 2017 Hepatitis Guidance. Definition of “sexual contact” has been included in the donor eligibility statement and Note section. 	<ul style="list-style-type: none"> Follow up questions in the flowchart, assess donors for a history of sexual contact with a person who has hepatitis B or C. Donor who has had sexual contact with a person who has had other types of viral hepatitis such as CMV and mononucleosis are not deferred.
<p>23. In the past 12 months, have you lived with a person who has hepatitis?</p>	<p>17. In the past 3 months, have you lived with a person who has hepatitis?</p>	<ul style="list-style-type: none"> Number change. Timeframe for having lived with a person who has hepatitis was 	<ul style="list-style-type: none"> Follow up questions in the flowchart, assess donors for a history of having lived with a person who has hepatitis B or C.

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		<ul style="list-style-type: none"> changed from 12 months to 3 months. Flowchart was modified to include follow-up questions to the donor based on the recommendations of the FDA's Sept 2017 Hepatitis Guidance. 	<ul style="list-style-type: none"> A donor who has lived with a person who has had other types of viral hepatitis such as CMV and mononucleosis are not deferred.
8. In the past 3 months , have you had an accidental needle-stick?	18. In the past 3 months , have you had an accidental needle-stick?	<ul style="list-style-type: none"> Number change. 	
7. In the past 3 months , have you come into contact with someone else's blood?	19. In the past 3 months , have you come into contact with someone else's blood?	<ul style="list-style-type: none"> Number change. Flowchart was revised to differentiate types of contact. 	<ul style="list-style-type: none"> FDA's 2023 HIV Guidance
14. In the past 3 months , have you had a tattoo?	20. In the past 3 months , have you had a tattoo?	<ul style="list-style-type: none"> Number change. Information on permanent makeup was added as a Note. 	
15. In the past 3 months , have you had ear or body piercing?	21. In the past 3 months , have you had ear or body piercing?	<ul style="list-style-type: none"> Number change. Donor eligibility statement now includes a clarification from FDA. 	
18. In the past 16 weeks , have you donated a double unit of red cells using an apheresis machine?	22. In the past 16 weeks , have you donated a double unit of red blood cells using an apheresis machine?	<ul style="list-style-type: none"> Number change. The word "blood" was added for clarity. 	
New Question Added	23. Since your last donation , have you received any medication by injection to prevent HIV infection? (i.e., long-acting antiviral PrEP or PEP)	<ul style="list-style-type: none"> Question added to assess the donor for use of long-acting injectable pre-exposure prophylaxis medication to prevent an HIV infection. 	<ul style="list-style-type: none"> FDA's 2023 HIV Guidance AABB Association Bulletin #22-03 Updated Recommendations on Donor Deferral for Use of Antiretroviral Medications for HIV Prevention and Treatment including Long-Acting Injectable PrEP and the Impact on Blood Safety
19. Since your last donation , have you had any new medical problems or diagnoses?	24. Since your last donation , have you had any new medical problems or diagnoses?	<ul style="list-style-type: none"> Number change. 	

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20. Since your last donation , have you had any new medical treatments?	25. Since your last donation , have you had any new medical treatments?	<ul style="list-style-type: none"> • Number change. 	
21. Since your last donation , have you taken any medications on the Medication Deferral List in the time frames indicated? (Review the Medication Deferral List.)	26. Since your last donation , have you taken any medications on the Medication Deferral List in the time frames indicated? (Review the Medication Deferral List.)	<ul style="list-style-type: none"> • Number change. • Information from page 2 of the Medication Deferral List has been removed and relocated to Flowchart Q26 	<ul style="list-style-type: none"> • This information is intended to assist the donor historian when providing additional information to the donor about their deferral. • It is more appropriately located with the flowchart. • Additional information for PrEP/PEP/ART has been added following issue of the FDA's 2023 HIV Guidance
24. Since your last donation , have you been in juvenile detention, lockup, jail, or prison for 72 hours or more consecutively?	27. Since your last donation , have you been in juvenile detention, lockup, jail, or prison for 72 hours or more consecutively?	<ul style="list-style-type: none"> • Number change. • Flowchart updated to clarify deferral is "from date release from incarceration" 	
25. Since your last donation , have you been outside the United States or Canada?	28. Since your last donation , have you been outside the United States or Canada?	<ul style="list-style-type: none"> • Number change. 	<ul style="list-style-type: none"> • Updated guidance added, FDA's December 2022 Malaria Guidance
26. Female Donors: Since your last donation , have you been pregnant or are you pregnant now?	29. Since your last donation , have you been pregnant?	<ul style="list-style-type: none"> • Number change. • Two questions replace the aDHQ v2.1 compound question Q26. 	<ul style="list-style-type: none"> • Member feedback - Poor donor attention to this aDHQ v2.1 compound question. • Member feedback – This individual donor assessment approach assesses TRALI risk for all donors regardless of gender.
New question added to the aDHQ	30. Have you EVER had a positive test for HIV infection?		<ul style="list-style-type: none"> • Added at FDA's request • FDA's 2023 HIV Guidance • AABB's HIV Testing, Lookback and Reentry Toolkit
aDHQ v2.1 Area for Additional Questions	31. Have you EVER taken any medication to treat HIV infection?	<ul style="list-style-type: none"> • New question added (moved from the area for additional questions) • Deferral was changed from indefinite to a permanent deferral for taking medication to treat an HIV infection. 	<ul style="list-style-type: none"> • FDA's 2023 HIV Guidance • AABB Association Bulletin #22-03 Updated Recommendations on Donor Deferral for Use of Antiretroviral Medications for HIV Prevention and Treatment including Long-Acting Injectable

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			<i>PrEP and the Impact on Blood Safety</i>