



Advancing Transfusion and
Cellular Therapies Worldwide

AABB's Resources for: FDA's Updated Information for Blood Establishments Regarding the Novel Coronavirus (COVID-19) Outbreak Updated MAY 2020

This toolkit has been updated to align with FDA's May 11th [Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak](#).

The 2019 novel coronavirus has been named "SARS-CoV-2" and causes coronavirus disease 2019 (COVID-19).

FDA has issued these precautionary measures for COVID-19 and continues to state:

"There have been no reported cases of transfusion-transmitted coronavirus, including SARS-CoV-2, worldwide.

Routine measures used to determine blood donor eligibility prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation (21 CFR 630.10)."

This toolkit highlights FDA's changes in the updated information.

AABB’s Resources Supporting: FDA’s Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak

AABB’s Regulatory Affairs is issuing this updated toolkit in response to FDA’s [May 11th communication](#).

- The following table highlights **new information** and changes to remove outdated information.
- Example flowcharts and self-deferral messaging are found on pages 5-8. [The flowcharts are not donor screening questions but clarify who should self-defer if a donor needs more information.]

MAY 11, 2020 CHANGES TO BLOOD DONATION INFORMATION FROM FDA: Updated Information for Blood Establishments Regarding the Novel Coronavirus (COVID-19) Outbreak	
FDA’s MAY 11th UPDATE	REPLACING MARCH 11th COMMUNICATION
FDA continues to work closely with CDC and other federal and international agencies to monitor the coronavirus disease 2019 (COVID-19) pandemic caused by the virus, SARS-CoV-2.	FDA is working closely with CDC and other federal and international agencies to monitor the evolving outbreak of the 2019 novel coronavirus that was first identified in Wuhan, Hubei Province, China.
	The virus has been named “SARS-CoV-2” and the disease it causes has been named coronavirus disease 2019 (abbreviated COVID-19).
	The potential for transmission of SARS-CoV-2 by blood and blood components is unknown at this time.
Respiratory viruses, in general, are not known to be transmitted by blood transfusion. There have been no reported cases of transfusion-transmitted coronavirus, including SARS-CoV-2, worldwide .	NOT changed, added “ worldwide” in May 11 th document.
Routine measures used to determine blood donor eligibility prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation (21 CFR 630.10).	NOT changed

<p>As communities are affected, it is imperative that healthy individuals continue to donate blood.</p>	<p>NOT changed</p>
<p>Considerations</p>	
<p>FDA supports the recommendations of AABB's Interorganizational Task Force encouraging healthy individuals to make plans to donate blood to maintain the adequacy of the nation's blood supply.</p> <ul style="list-style-type: none"> o Those interested in donating blood may contact the following organizations to find a local blood collection site and to schedule an appointment: <ul style="list-style-type: none"> ▪ AABB: www.aabb.org External Link Disclaimer (http://aabb.org External Link Disclaimer); +1.301.907.6977 ▪ America's Blood Centers: www.americasblood.org External Link Disclaimer (https://americasblood.org/External Link Disclaimer) ▪ American Red Cross: www.redcrossblood.org External Link Disclaimer (https://www.redcrossblood.org/External Link Disclaimer) +1.800.RED CROSS (+1.800.733.2767) ▪ Armed Services Blood Program: www.militaryblood.dod.mil External Link Disclaimer (https://www.militaryblood.dod.mil/External Link Disclaimer) +1.703.681.8024 	<p>NOT changed</p>
	<ul style="list-style-type: none"> • Blood centers should prepare and evaluate their emergency plans to address possible challenges, such as effects on the availability of blood donors and staff.
<ul style="list-style-type: none"> o FDA does not recommend using laboratory tests to screen asymptomatic blood donors. 	<ul style="list-style-type: none"> • At this time, FDA does not recommend using laboratory tests to screen asymptomatic blood donors. Based on available information, detection of SARS-CoV-2 in blood samples has only been seen in severely ill patients, not in asymptomatic individuals.
<ul style="list-style-type: none"> o FDA is aware that some blood establishments have introduced donor education and/or donor deferral measures in response to COVID-19. 	<p>NOT changed</p>

<ul style="list-style-type: none"> ○ FDA recognizes that deferral for travel to areas with cases of COVID-19 is not feasible. 	
<ul style="list-style-type: none"> ○ Blood establishments may wish to consider donor educational materials to instruct individuals to self-defer and refrain from blood donation if they have: <ul style="list-style-type: none"> ▪ been diagnosed with COVID-19 and had symptomatic disease, ▪ are suspected to have COVID-19, or ▪ had a positive diagnostic test (e.g., nasopharyngeal swab) for SARS-CoV-2 but never developed symptoms. 	<p>Blood establishments may wish to consider donor educational materials to instruct individuals to self-defer and refrain from blood donation if they have:</p> <p>-cared for, cared for, lived with, or otherwise had close contact with individuals diagnosed with or suspected of having COVID-19;</p> <p>been diagnosed with or suspected of having COVID-19.</p>
<p>You may wish to consider instructing these individuals not to donate for at least 14 days after complete resolution of symptoms or the date of the positive diagnostic test, whichever period is longer.</p>	
<p>The blood establishment's responsible physician must evaluate the prospective donor and determine eligibility (21 CFR 630.5). The responsible physician may want to consider the following:</p> <ul style="list-style-type: none"> ○ individuals diagnosed with COVID-19 or who are suspected of having COVID-19, and who had symptomatic disease, refrain from donating blood for at least 14 days after complete resolution of symptoms, ○ individuals who had a positive diagnostic test for SARS-CoV-2 (e.g., nasopharyngeal swab), but never developed symptoms, refrain from donating at least 14 days after the date of the positive test result, ○ individuals who are tested and found positive for SARS-CoV-2 antibodies, but who did not have prior diagnostic testing and never developed symptoms, can donate without a waiting period and without performing a diagnostic test (e.g., nasopharyngeal swab). 	<p>The blood establishment's responsible physician must evaluate the prospective donor and determine eligibility (21 CFR 630.5).</p> <p>Based on the limited information available at this time, we suggest individuals refrain from donating blood at least 28 days after resolution of symptoms after a diagnosis of COVID-19 or 28 days after the last possible close contact exposure to a person with COVID-19.</p>
<ul style="list-style-type: none"> • Blood establishments may wish to consider updating post-donation instructions provided to all donors of blood and blood 	<p>NOT changed</p>

<p>components to ask donors to report a subsequent diagnosis of COVID-19 as soon as possible to the blood establishment.</p>	
<p>Blood establishments may wish to consider retrieval and quarantine of blood and blood components if donors report onset of fever, symptoms or a diagnosis of COVID-19 within 48 hours after their donation.</p>	<p>Blood establishments may wish to consider retrieval and quarantine of blood and blood components collected in the 28 days prior to or after COVID-19 symptom onset; or collected in the 28 days prior to or after possible exposure to patients with COVID-19.</p>

- ✓ Refer to example for updated posted messaging regarding self-deferral on page 5.
- ✓ Refer to the updates in the flowcharts on pages 6-8.

OPTIONAL POSTER/HANDOUT *Per your policy, you:*

- *Should revise the poster/handout to reflect your current policy*
- *May revise the poster to clarify the donor messaging.*
- *Will determine when and where to use this poster/handout based on your policy.*

COVID-19 and Donation

Do Not Donate Blood Today

If

- **In the past 14 days**, you have had any symptoms of COVID-19.
- **In the past 14 days**, you had a positive diagnostic test (nasal swab test) for COVID-19 but you never developed symptoms.

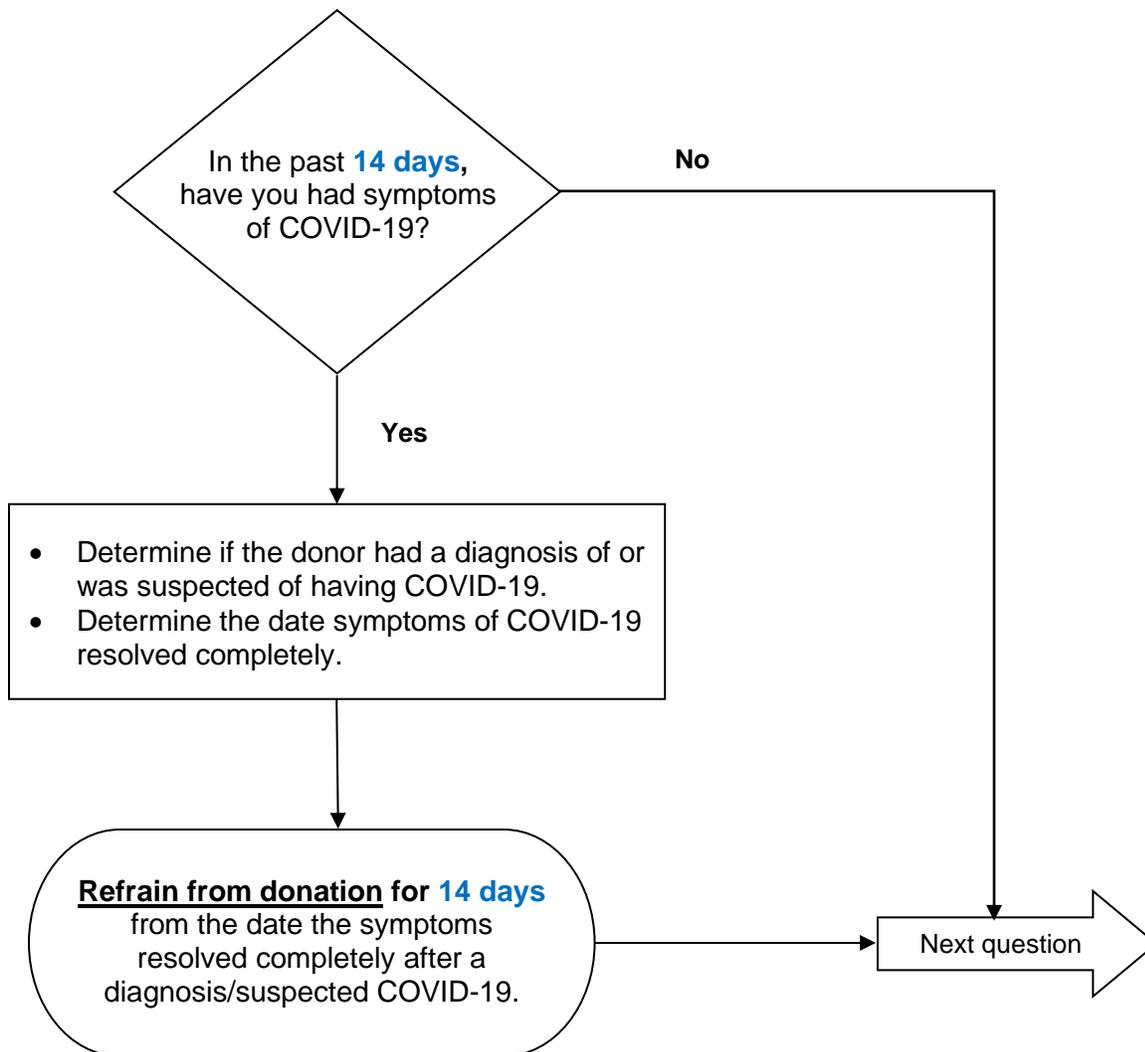
If you think you should not donate based on the information above, you may leave at this time.

If you have questions, please let us know!

Example 1 – FLOWCHART – SELF DEFERRAL FOR DIAGNOSIS/SUSPECTED INFECTION WITH SYMPTOMS.

Follow Up Question: In the past **14 days**, have you had symptoms of COVID-19?

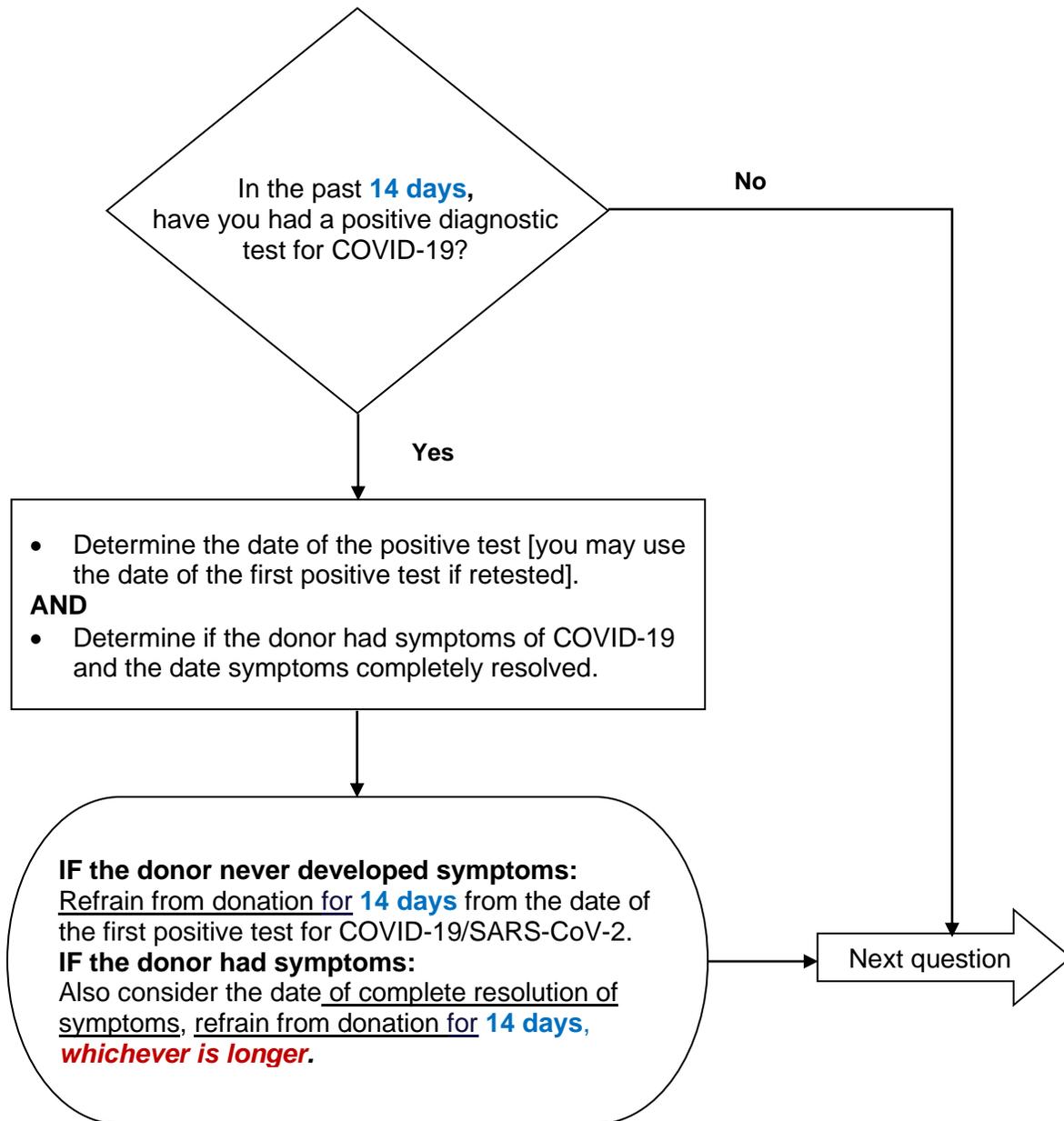
Donor Eligibility: FDA suggests that an individual diagnosed with COVID-19 or who is suspected of having COVID-19, and who had symptomatic disease, refrain from donating blood for at least **14 days** after complete resolution of symptoms.



Example 2 – FLOWCHART SELF DEFERRAL FOR POSITIVE TEST, WITHOUT SYMPTOMS OF COVID-19

Follow Up Question: In the past **14 days**, have you had a positive diagnostic test for COVID-19?

Donor Eligibility: FDA suggests that an individual who had a positive diagnostic test for SARS-CoV-2 (e.g., nasopharyngeal swab), but never developed symptoms, refrain from donating at least **14 days** after the date of the positive test result.



**Example 3 – FLOWCHART FOR POSITIVE TEST FOR ANTIBODIES
WITHOUT SYMPTOMS OR PRIOR DIAGNOSIS → NO WAIT NEEDED**

Follow Up Question: Have you tested positive for antibodies to the virus that causes COVID-19?

Donor Eligibility: This information does not impact the self-deferral process, nor donor eligibility. **IF a donor shares information regarding a positive test for antibodies to COVID-19, you may consider:**

FDA suggests that an individual who is “tested and found positive for SARS-CoV-2 antibodies, but who did not have prior diagnostic testing and never developed symptoms, can donate without a waiting period and without performing a diagnostic test (e.g., nasopharyngeal swab).”

