

## **REGULATORY UPDATE: FDA Updates Information for Blood Establishments Regarding COVID-19**

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The Food and Drug Administration issued updated considerations for blood establishments in response to the ongoing coronavirus disease 2019 (COVID-19) pandemic. The [May 11 update](#) replaces the agency's March 2020 communication. In its update, the agency said that "there have been no reported cases of transfusion-transmitted coronavirus, including SARS-CoV-2, worldwide" and continues to confirm that "routine measures used to determine blood donor eligibility prevent individuals with clinical respiratory infections from donating blood."

The May 11 communication supports the use of blood donor educational materials that instruct individuals to refrain from donation for 14 days based a short list of risk criteria. Self-deferral is encouraged for those with symptoms who have been diagnosed with or suspected of having COVID-19 and individuals with a positive diagnostic test for SARS-CoV-2, even if they never developed symptoms.

FDA clarified that individuals who have tested positive for SARS-CoV-2 antibodies but never developed symptoms and never had diagnostic testing can donate without a waiting period and without performing a diagnostic test.

AABB has updated the [COVID-19 Toolkit](#) to identify and incorporate all of the changes in the May 11 communication. Individuals with questions or concerns may contact [regulatory@aabb.org](mailto:regulatory@aabb.org).