

Information for Blood Establishments Regarding the Monkeypox Virus and Blood Donation

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FDA continues to work closely with the CDC and other federal and international agencies to monitor reports of monkeypox and populations at greatest risk of infection. We are issuing this communication to provide information regarding monkeypox virus and blood donations.

Worldwide, there have been no reports of transmission of monkeypox virus through blood transfusion and the risk of transfusion-transmission remains theoretical. The levels of virus in the blood of an infected or exposed individual have not been well characterized.

Considerations

Routine measures used to determine blood donor eligibility prevent individuals with symptomatic 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). Donors are also asked questions about risk factors for transfusion-transmitted infections and deferred when such risk factors are present. In addition, blood establishments typically request that blood donors report illnesses or symptoms that develop after blood donation so that the blood establishment can assess if the donation is safe for transfusion. These safeguards are likely to identify individuals who present to donate who are diagnosed with monkeypox virus or who are currently at the greatest risk for infection with monkeypox virus. To date, most cases of monkeypox have been diagnosed among men who have sex with other men, although the virus can spread to anyone through close, personal, often skin-to-skin contact, such as direct contact with monkeypox rash or scabs.

Given the robustness of the existing safeguards for blood safety FDA does not recommend that blood establishments ask donors additional, specific questions about possible exposure to monkeypox virus. Further, FDA does not recommend using laboratory diagnostic tests to screen blood donors for monkeypox virus.

FDA will continue to monitor cases of monkeypox in the U.S. and worldwide and the available information about potential risk of transfusion-transmitted monkeypox virus. We will provide additional information as it becomes available.

Resources:

- CDC: About Monkeypox, <https://www.cdc.gov/poxvirus/monkeypox/about.html> (<https://www.cdc.gov/poxvirus/monkeypox/about.html>)
- FDA: FDA Monkeypox Response, <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/fda-monkeypox-response> ([/emergency-preparedness-and-response/mcm-issues/fda-monkeypox-response](https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/fda-monkeypox-response))