

# Information Pertaining to Additional Safety Protections Regarding Use of Fecal Microbiota for Transplantation - Screening Donors for COVID-19 and Exposure to SARS-CoV-2 and Testing for SARS-CoV-2

**April 9, 2020**

On March 23, 2020, the Food and Drug Administration (FDA) issued a Safety Alert ([/vaccines-blood-biologics/safety-availability-biologics/safety-alert-regarding-use-fecal-microbiota-transplantation-and-additional-safety-protections](#)) informing healthcare providers and patients of the potential risk of transmission of SARS-CoV-2 by fecal microbiota for transplantation (FMT). SARS-CoV-2 is the virus that causes the respiratory disease, COVID-19.

The rapidly evolving global pandemic of COVID-19 necessitates that FDA provide updated information to the March 23, 2020, Safety Alert.

Because of the potential risk of transmission of SARS-CoV-2 via FMT, FDA has determined that additional protections are needed for any investigational use of FMT, whether under an Investigational New Drug Application (IND) on file with the FDA or under FDA's enforcement discretion policy.

FDA has already notified all IND holders of the need for additional protections. These additional protections include:

No clinical use of FMT product manufactured from stool donated on or after December 1, 2019, until additional screening and testing procedures and changes to the informed consent process are implemented for such stool donations as described below:

1. Stool donor screening, including an assessment of whether, since December 1, 2019, the donor was diagnosed with laboratory-confirmed SARS-CoV-2 infection, experienced symptoms of COVID-19 (e.g., fever, cough, shortness of breath) not explained by another diagnosis, or was exposed to a suspected or confirmed case of COVID-19 or SARS-CoV-2 infection.
  - In any instances of suspected or confirmed SARS-CoV-2 infection or exposure as described above, exclusion of the donor from further donations and exclusion from clinical use of any FMT product manufactured from stool donated by the affected donor beginning 4 weeks prior to the suspected or confirmed SARS-CoV-2 infection or exposure.
2. Testing of the stool donation or stool donor for SARS-CoV-2 virus or RNA.

- Testing approaches might include testing upper respiratory specimens (e.g., nasal swabs) or other specimens (e.g., rectal swabs or stool donations).
  - If SARS-CoV-2 is detected, exclusion of the donor from further donations and exclusion from clinical use of any FMT product manufactured from stool donated by the affected donor beginning 4 weeks prior to the first positive test.
3. As part of the informed consent process, conveying to the FMT recipient that healthy, asymptomatic stool donors may potentially be infected with SARS-CoV-2, describing the testing approach and other strategies used to mitigate the risk of SARS-CoV-2 transmission, and advising the FMT recipient of the limitations of testing and risk mitigation strategies.

**Additional Resources:**

- Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Additional Safety Protections Pertaining to SARS-CoV-2 and COVID-19 ([/vaccines-blood-biologics/safety-availability-biologics/safety-alert-regarding-use-fecal-microbiota-transplantation-and-additional-safety-protections](#)) - March 23, 2020