

Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Additional Safety Protections Pertaining to SARS-CoV-2 and COVID-19

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The global public health community is responding to a rapidly evolving pandemic of respiratory disease caused by a novel coronavirus that was first detected in China. The virus has been named “SARS-CoV-2” and the disease it causes has been named “COVID-19.”

The Food and Drug Administration (FDA) is informing health care providers and patients of the potential risk of transmission of SARS-CoV-2 virus by the use of fecal microbiota for transplantation (FMT) and that FDA has determined that additional safety protections are needed.

Summary of the Issue

Several recent studies have documented the presence of SARS-CoV-2 ribonucleic acid (RNA) and/or SARS-CoV-2 virus in stool of infected individuals.^{1,2,3} This information suggests that SARS-CoV-2 may be transmitted by FMT, although the risk of such transmission is unknown.⁴ At this time, testing nasopharyngeal specimens from stool donors for SARS-CoV-2 may not be widely available. Furthermore, there is limited information on the availability and sensitivity of direct testing of stool for SARS-CoV-2.

Additional Protections for the Use of FMT

At this time, FDA is advising that clinical use of FMT has the potential to transmit SARS-CoV-2, whether used as part of a study under an Investigational New Drug Application (IND) on file with the FDA or under FDA’s enforcement discretion policy. To address the risk, stool used for FMT should have been donated before December 1, 2019. Due to the potential for serious adverse events to occur, FDA has determined that the following protections are needed for any use of FMT that is found to be necessary for clinical care if it involves stool donated after December 1, 2019:

- Donor screening with questions directed at identifying donors who may be currently or recently infected with SARS-CoV-2;
- Testing donors and/or donor stool for SARS-CoV-2, as feasible;
- Development of criteria for exclusion of donors and donor stool based on screening and testing; and
- Informed consent that includes information about the potential for transmission of SARS-CoV-2 via FMT, including FMT prepared from stool from donors who are asymptomatic for COVID-19.

Actions

FDA is in the process of notifying IND holders of the potential risk of transmission of SARS-CoV-2 via FMT and of FDA's determination that additional safety protections that are needed.

FDA is communicating this information with this statement to all other stakeholders to ensure that everyone is fully informed.

As the scientific community learns more about SARS-CoV-2 and COVID-19, FDA will provide further information as warranted.

Information for Health Care Providers and Patients on Enforcement Discretion

In July 2013, FDA issued a guidance (</media/86440/download>) document stating that it intends to exercise enforcement discretion under limited conditions regarding the IND requirements for the use of FMT products to treat *C. difficile* infection in patients that have not responded to standard therapies. The guidance states that FDA intends to exercise enforcement discretion provided that the treating physician obtains adequate consent for the use of FMT from the patient or his or her legally authorized representative. The consent should include, at a minimum, a statement that the use of FMT to treat *C. difficile* is investigational and a discussion of its potential risks.

Reporting Adverse Events

FDA encourages all health care providers and patients to report any suspected adverse events or side effects related to the administration of FMT products to the FDA at 1-800-FDA-1088 or <http://www.fda.gov/medwatch> (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>).

¹ Xiao F, Tang M, Zheng X, Liu Y, Li X, Shan H, Evidence for gastrointestinal infection of SARS-CoV-2, *Gastroenterology* (2020), doi: <https://doi.org/10.1053/j.gastro.2020.02.055> (<https://doi.org/10.1053/j.gastro.2020.02.055>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

² Tang A, Tong Z-d, Wang H-l, Dai Y-x, Li K-f, Liu J-n, et al. Detection of novel coronavirus by RT-PCR in stool specimen from asymptomatic child, China. *Emerg Infect Dis.* (2020), <https://doi.org/10.3201/eid2606.200301> (<https://doi.org/10.3201/eid2606.200301>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) from https://wwwnc.cdc.gov/eid/article/26/6/20-0301_article (https://wwwnc.cdc.gov/eid/article/26/6/20-0301_article)

³ Wang, W, Xu, Y, Gao, R, et al., Detection of SARS-CoV-2 in Different Types of Clinical Specimens. *JAMA* (2020), <https://doi.org/10.1001/jama.2020.3786> (<https://doi.org/10.1001/jama.2020.3786>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

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⁴ Gu J, Han B, Wang J, COVID-19: Gastrointestinal manifestations and potential fecal-oral transmission, *Gastroenterology* (2020), doi: <https://doi.org/10.1053/j.gastro.2020.02.054> (<https://doi.org/10.1053/j.gastro.2020.02.054>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)