

FDA issues safety alert for COVID-19 risk with fecal transplant

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(HealthDay)—The U.S. Food and Drug Administration issued a

MedWatch Safety Alert on Tuesday about the potential risk for SARS-CoV-2 transmission with the use of fecal microbiota for transplantation (FMT) to treat *Clostridioides difficile* infection.

Recent data have shown that SARS-CoV-2 RNA and/or the SARS-CoV-2 virus is present in the stool of patients with the novel [coronavirus](#) (COVID-19), suggesting that SARS-CoV-2 could be transmitted by FMT. Testing of nasopharyngeal specimens from stool donors for SARS-CoV-2 is not widely available at this time, so information on the sensitivity of directly testing stool for SARS-CoV-2 is limited.

The FDA directed [health care workers](#) to implement the following protections for any FMT with stool donated after Dec. 1, 2019: conduct [donor](#) screening to identify donors who may be or recently could have been infected with SARS-CoV-2; [test](#) donors and/or donor stool for SARS-CoV-2; develop criteria for excluding donors and donor stool based on screening and testing; and obtain informed consent from patients regarding the potential for transmission of SARS-CoV-2 via FMT, including FMT prepared from the stool of donors who are asymptomatic for COVID-19.

The FDA requests that any adverse events or side effects related to the use of FMT be reported to the MedWatch Safety Information and Adverse Event Reporting Program.

More information: [More Information](#)

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