

FDA Resources for Florida Constituents and Health Care Providers

The Office of U.S. Senator Marco Rubio has compiled the following resources provided by the U.S. Food and Drug Administration (FDA) for constituents and health care providers with a specific COVID-19 issue.

The [FDA's COVID-19 FAQ](#) is useful in addressing questions related to vaccines, biologics, human tissue products, drugs, medical devices and tests, and food products. The FDA also has the following specific COVID-19 FAQs, which are updated as information becomes available:

- [Emergency Use Authorizations](#)
- [Diagnostic Testing](#)
- [Food Safety for Industry](#)
- [Healthcare Professionals](#)
- [Other Specific Audiences](#)

COVID-19 Diagnostic Tests: For questions about development of COVID-19 diagnostic tests, there are several important resources for Floridians:

24/7 Hotline for Diagnostics: If you are a developer, lab, manufacturer or health care provider that has questions about testing or is experiencing spot shortages of testing, personal protective equipment, or other supplies, please call the FDA's toll-free line at **1-888-463-6332 (1-888-INFO-FDA)**, then choose option (*). The line is available 24 hours a day to help address difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs, media needed for transport, and conservation of the samples – among other things. Please note, however, that the FDA does not control the production volume or distribution of medical devices.

Frequently Asked Questions about COVID-19 Diagnostic Tests: In response to questions from labs, manufacturers, health care providers, and others, the FDA has generated FAQs and posted them on their website for all who are involved in test development for COVID-19s. The FDA updates these FAQs on a rolling basis, often daily as issues arise. You can access these FAQs [here](#).

Emergency Use Authorization (EUA) for COVID-19 Diagnostic Tests: If you need additional information for completing the EUA template, would like to know how to submit Pre-EUA/EUA submissions to the FDA, or wish to consider an alternative specimen type, you should contact the Division of Microbiology Devices at **(301) 348-1778** or email CDRH-EUA-Templates@fda.hhs.gov. Please note that the FDA is unable to provide information on the status of any individual submissions.



Personal Protective Equipment: If you are a constituent or health care provider with questions or you are experiencing spot shortages of personal protective equipment or other supplies, call the FDA's toll-free line at **1-888-463-6332 (1-888-INFO-FDA)**, then choose option (*). The line is available 24 hours a day to help address difficulties obtaining supplies. Please note, however, that the FDA does not control the production volume or distribution of medical devices.

Vaccines and other biological product candidates: Biological product sponsors, including vaccine developers, wishing to develop vaccines can email industry.biologics@fda.hhs.gov or call **1-800-835-4709** for further information.

Therapeutics and other drug product candidates: Sponsors wishing to develop therapeutics are encouraged to submit information and questions via the Pre-IND Consultation program. Visit the following link [COVID-19 Therapeutics: General Information for Interested Stakeholders](#) or call **301-796-1500** for additional information on this program.

Clinical Trials: Sponsors who have questions regarding the conduct of clinical trials impacted by COVID-19 should contact clinicaltrialconduct-COVID19@fda.hhs.gov.

Drug Shortages: If you are a health care provider with questions or concerns about a drug shortage, related or unrelated to COVID-19, contact the FDA Center for Drug Evaluation and Research's (CDER) Division of Drug Information (DDI) at **855-543-3784, 301-796-3400**, or druginfo@fda.hhs.gov. The FDA's [Drug Shortage web page](#) has information related to current shortages.

Food: If you are in the food industry and have a question for the FDA, information and a list of common questions about food safety and COVID-19 are available [here](#). If you need to contact the FDA's Center for Food Safety and Applied Nutrition about a COVID-19 related question, you may do so by submitting a question [here](#).

Animal Drugs and Animal Food: If you have questions or concerns related to COVID-19 and its impact on products regulated by the FDA's Center for Veterinary Medicine, you should contact AskCVM@fda.hhs.gov and your inquiry will be routed to the appropriate subject matter expert for response. A [list of known animal drug shortages](#) is kept by the FDA's Center for Veterinary Medicine.