

January 5, 2020

Dear Curative Customers,

As you may be aware, FDA issued a Safety Communication on January 4, 2021, about the Curative SARS-CoV-2 Assay and the potential risk of false negative results for our test, consistent with our FDA authorized labeling. Curative's test has been validated and is being offered during the pandemic under an Emergency Use Authorization, and is labeled with specific warnings, precautions, and limitations that FDA reiterated in the Safety Communication. The test performance and labeling, however, have not changed, nor has the company observed any changes in test performance. We have been working with the agency to address their concerns and these limitations, and we will continue to work interactively with FDA through the Emergency Use Authorization process.

As part of our communication with FDA, Curative recently submitted data from a clinical study that evaluated more than 1,300 subjects and multiple different sample types and comparisons. Due to FDA questions about the study design for these additional data, FDA's Safety Communication reminds Healthcare Providers of the existing precautions and limitations that remain in place at this time. We understand that the Safety Communication seeks to ensure that Curative's test is administered and performed according to the labeling and limitations in the EUA. FDA also communicates that a negative result does not exclude the possibility of COVID-19 and that potential inaccuracies, such as increased false negatives can occur in people tested more than 14 days post infection/symptoms and in people who are not observed and directed by a healthcare worker.

Curative will continue to work actively with FDA to provide additional data required to address the limitations and precautions. Curative remains committed to following FDA and CMS regulations in the development, testing, and use of our Emergency Use Authorized test, and in providing medical devices and services that meet or exceed our customer's expectations operating in accordance with these requirements.

For additional questions on the above or related to your account please contact your account representative. For any patient inquiries related to their test they may contact support@curative.com or 888.702.9042.

Sincerely,



Amy Vandenberg
Sr. VP of Regulatory Affairs & Quality Assurance
Curative, Inc.