Sona Nanotech Updates on Timing of Clinical In-Field Validation Studies for Its COVID-19 Antigen Test

2020-08-15
Sona Nanotech, a developer of rapid, point-of-care diagnostic tests, announces that its previously announced clinical, in-field evaluation studies for its rapid detection, COVID-19 antigen test that commenced in July continue and are now expected to return their full results within two weeks.

The delays have been due to ethics review board approvals and a need to make study modifications to accommodate regulatory updates, including for study enrolment criteria and assessment at point of care settings, as well as for test handling procedures.

The evaluation protocol for these studies incorporates aspects of the revised guidance released by the FDA on July 29, 2020. The FDA's new template for commercial developers of non-lab COVID-19 tests included updated guidance on performance evaluation studies, comparator methodology, flex studies, human usability studies, and clinical evaluation, amongst other study components.

The Company is committed to the robust evaluation of its COVID-19 antigen test and to submitting a comprehensive data set in its submissions to the FDA and Health Canada that adheres to its recommended guidance. For more information on the new FDA guidance, please click here.

The data from these studies will be used to support the Company's analytical and clinical data as part of the submission it will make to Health Canada and the FDA for emergency use authorization (EUA) approval for its COVID-19 antigen test.

In addition to its in-field clinical evaluation studies, the Company has also provided prototype tests to several potential customers, under 'research use only' labelling, with whom it has entered into letters of intent for larger purchases of its tests. These smaller studies are part of the Company's commitment to maintaining ongoing evaluations of its test in order to

understand its performance in a wide range use case scenarios.

Rapid, point-of-care, antigen tests can make a significant contribution to reducing the spread of COVID-19 by detecting the presence of the virus in individuals, potentially before the onset of symptoms. As previously announced, the Company's rapid detection, COVID-19 antigen test's laboratory validation of performance levels resulted in a test sensitivity of 96%, test specificity of 96% and a Limit of Detection (LOD) of 2.1 x 102 TCID50. One of the purposes of the in-field evaluation testing is to determine, what, if any, effect environmental or containment factors or human errors in sample collection have on test performance.

The Company cautions that its COVID-19 rapid antigen test is not yet approved by the FDA or other regulatory bodies and will update the market as appropriate.

Read the original article on Sona Nanotech.