

AOAC INTERNATIONAL Certifies Three Test Kits for Detecting Novel Coronavirus on Surfaces

Validated test kits needed in manufacturing and other situations where maintaining surfaces free of coronavirus is a public health concern

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/EINPresswire.com/ -- [AOAC INTERNATIONAL](#) announced today that it has issued Certificates of Validation for three proprietary test kits that detect SARS-CoV-2, the causative agent of COVID-19 illness, on environmental surfaces.



The three tests are the first to pass the rigorous independent evaluation required by the globally recognized AOAC [Research Institute's](#) Performance Tested MethodsSM Program, which implemented an Emergency Response Validation process to accelerate the review process.

"Food manufacturers and contract labs have stringent protocols to ensure their facilities are free of harmful pathogens and more recently, viruses," said Erin Crowley, president of AOAC INTERNATIONAL. "Now, they also have independently validated tests they can use to ensure their sanitation protocols are effective and they continue to provide a culture of safety for their essential employees."

In this initial phase of the validation process, test kits were evaluated for detection of the virus on stainless steel surfaces only. AOAC will expand validation to a broader range of environmental surfaces and food matrices in a follow-up project.

While SARS-CoV-2 is known to be susceptible to standard disinfection methods,[1] recent studies have shown that it can also be highly persistent on non-porous surfaces[2] such as stainless steel.

Certifications were issued for the VERIPRO[®] SARS-CoV-2 Environmental Assay by bioMérieux; EnviroX-Rv by PathogenDx, and COVID-19 Indoor TestTM by Phylagen.

•The bioMérieux VERIPRO SARS-CoV-2 Environmental Assay uses molecular, one-step, reverse transcription polymerase chain reaction (RT-PCR) technology for qualitative detection of SARS-CoV-2. The VERIPRO SARS-CoV-2 Environmental Assay can be performed without the need for an

optional RNA purification step. No clinical supplies or reagents are required to run the VERIPRO SARS-CoV-2 Environmental Assay, freeing up critical clinical COVID-19 testing resources. The test is commercially available and can be run on all GENE-UP® Real Time PCR systems.

- The PathogenDx EnviroX-Rv assay is a test based on end-point RT-PCR coupled to DNA microarray hybridization for the detection of multiple genes within SARS-CoV-1 and SARS-CoV-2 viruses. The advantage of the EnviroX-Rv assay is its ability to deliver a higher level of sensitivity as demonstrated by its lower limit of detection in comparison to the reported qRT-PCR assays approved by the U.S. Food and Drug Administration Emergency Use Authorization. Additionally, the DNA microarray provides unmatched multiplexing power where numerous viruses and clades can be detected off a single swab at an affordable cost. The test is already in commercial use and available.

- The COVID-19 Indoor Test™ by Phylagen is a SARS-CoV-2 qualitative detection method that extracts the SARS-CoV-2 RNA from environmental swabs and detects it utilizing RT-PCR technology. Environmental surface swabs are collected by the customer and shipped back to Phylagen, Inc. for sample processing. Sample data are analyzed, and results are reported through a tracking portal. The test is commercially available for sampling surfaces and is a single site method for the detection portion of the test method.

To perform the reviews, the AOAC Research Institute technical consultants (Patrick Bird, Sharon Brunelle Ph.D., Maria Nelson and Zerlinde Johnson) assembled a team of analytical science experts.

- Laura J. Rose is a Microbiologist at the Healthcare Environment Applied Research Team, Clinical and Environmental Microbiology Branch, Division of Healthcare Quality Promotion of the U.S. Centers for Disease Control and Prevention.

- John SantaLucia, Jr. Ph.D. is President and Co-founder of DNA Software, Inc. and a Professor at Wayne State University.

- Chengzhu Liang, Ph.D. is Director of Technical Center of Qingdao customs in the People's Republic of China as well as President of the AOAC China Section.

Sanjiv R. Shah, Ph.D. is a Senior Microbiologist in the Homeland Security Research Program of the U.S. Environmental Protection Agency's Office of Research and Development.

- Jacquelina Williams-Woods, Ph.D. is a Research Microbiologist at the U.S. Food and Drug Administration's Gulf Coast Seafood Laboratory.

- William Burkhardt, Ph.D. is the Director, Division of Seafood Science and Technology at the U.S. Food and Drug Administration's Gulf Coast Seafood Laboratory.

This validation project broke new ground by employing in silico (“in silicon”) analytical techniques that harness modern computational power to compare results against large databases of genetic information. This has a significant advantage over traditional “wet-lab” testing in that genetic sequences from tens of thousands of strains of SARS-CoV-2 and near neighbors could be analyzed for inclusivity and exclusivity. Moreover, obtaining and shipping large numbers of SARS-CoV-2 strains and variants necessary for comparison could be difficult and potentially dangerous.

AOAC received validation applications for nine test kits in this initial phase of the program. In addition to the three that have received certification, four are in the final stages of certification and two are being revised for re-submission.

“The extraordinary depth and precision of in silico analysis in this Emergency Response Validation Program are remarkable,” said Scott Coates, AOAC Research Institute Director. “Some kits are demonstrating over 97 percent perfect matches for more than 15,000 SARS-CoV-2 genomes, when traditionally we can only test against 100 species, strains or variants. This is world-class research conducted in double-time tempo.”

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About AOAC INTERNATIONAL

AOAC INTERNATIONAL is a globally recognized, 501(c)(3), independent, third party, not-for-profit association. AOAC is a voluntary consensus standards developing organization founded in 1884. When analytical needs arise within a community or industry, AOAC INTERNATIONAL is the forum for finding appropriate science-based solutions through the development of microbiological and chemical standards. The AOAC Official Methods of Analysis database is used by food scientists around the world to facilitate public health and safety and to promote trade. For more information, please visit www.aoac.org. The AOAC Research Institute’s Performance Tested Methods program provides independent third-party expert review and certification for proprietary test kit performance. The AOAC Research Institute is a division of AOAC INTERNATIONAL.

1. “Stability of SARS-CoV-2 in different environmental conditions”, The Lancet Vol. 1 Issue 1, May 1, 2020, [https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(20\)30003-3/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(20)30003-3/fulltext) (accessed December 10, 2020)
2. “The effect of temperature on persistence of SARS-CoV-2 on common surfaces”, Virology Journal, 7 October 2020 <https://virologyj.biomedcentral.com/articles/10.1186/s12985-020-01418-7> (accessed December 10, 2020)

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