

Asuragen Launches New Kit to Enable Broader Coverage of Gene Variants Linked to Cystic Fibrosis

CFTR testing kit with streamlined workflow delivers reliable results in less than five hours

MINNEAPOLIS, Nov. 8, 2021 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ:TECH) today announced that Asuragen, Inc., a Bio-Techne brand, has launched a new kit to detect pathogenic variants in the *CFTR* gene. The AmpliDeX[®] PCR/CE *CFTR* Kit, intended for research use only, provides broader coverage of the diverse U.S. population^{1,2} than any other commercially available, targeted *CFTR* testing assay.

Cystic fibrosis is a life-limiting, autosomal recessive disease caused by variants in the *CFTR* gene. Many people with cystic fibrosis experience problems with their lungs, including serious infections, limited function, and long-term damage.

While much is known about variants associated with cystic fibrosis, the vast majority of that information came from studies of people of European descent. As a result, screening and diagnostic tests, as well as research-use assays, are more likely to detect pathogenic variants in individuals of European descent and less likely to detect them in individuals with non-European ancestry³.

"We are committed to ensuring that our Asuragen kits consistently deliver the most reliable information across all populations. To that end, we are proud to launch the new AmpliDeX PCR/CE *CFTR* Kit, which incorporates variants from the latest large-scale studies of diverse populations to provide significantly broader coverage," said Kim Kelderman, President, Diagnostics and Genomics Segment.

Because it includes variants identified in recent population genomics studies, the AmpliDeX PCR/CE *CFTR* Kit is designed to detect approximately 93% of *CFTR* pathogenic variants⁴ observed in the U.S. population, providing more reliable variant detection regardless of ancestry. It can identify a broad range of variant types, including copy number variants, single tandem repeats, single nucleotide polymorphisms, insertions, and deletions. The kit can also resolve variant zygosity.

The assay uses a simple, streamlined, and scalable approach to deliver results in less than five hours with fewer hands-on steps than other *CFTR* assays. It is optimized for use on commonly used PCR and capillary electrophoresis laboratory equipment. The assay also includes push-button data analysis software and shares a common workflow with other assays in the AmpliDeX product portfolio for easy implementation. Finally, the AmpliDeX PCR/CE *CFTR* Kit can also combine with Asuragen's AmpliDeX[®] PCR/CE *FMR1* Kit and

AmplideX® PCR/CE *SMN1/2* Plus Kit to provide the first-ever same-platform assay solution for this trio of the most prevalent and commonly analyzed carrier genes.

To learn more about this latest addition to the AmplideX portfolio, please visit www.asuragen.com/CFTR.

References

1. Beauchamp KA, Johansen Taber KA, Grauman PV, Spurka L, et al. Sequencing as a first-line methodology for cystic fibrosis carrier screening. *Genet Med*. 2019 Nov;21(11):2569-2576. doi: 10.1038/s41436-019-0525-y.
2. Westemeyer, M., Saucier, J., Wallace, J. et al. Clinical experience with carrier screening in a general population: support for a comprehensive pan-ethnic approach. *Genet Med* 22, 1320–1328 (2020). <https://doi.org/10.1038/s41436-020-0807-4>
3. Schrijver I, Pique L, Graham S, Pearl M, et al. The spectrum of CFTR variants in nonwhite cystic fibrosis patients: implications for molecular diagnostic testing. *J Mol Diagn*. 2016 Jan;18(1):39-50. doi: 10.1016/j.jmoldx.2015.07.005.
4. Parker C, Kelnar K, Hallmark E, Hall B, et al. "Verification of a Targeted PCR/CE *CFTR* Assay and Companion Software that Addresses 93% Mutation Prevalence Across Diverse Ethnic Groups." Association for Molecular Pathology (AMP) 2021 Annual Meeting Scientific Poster.

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