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ArcDia launches a quick and automated COVID-19 antigen test with superior performance

Turku, Finland, March 3rd, 2021 – the Finnish medical device manufacturer ArcDia International Ltd has launched a range of exceptionally sensitive point-of-care rapid tests for COVID-19. The mariPOC[®] analyser is fully automated, easy to operate and enables high-throughput testing. The product is CE marked and conforms to the requirements of EU IVD directive and ISO 13485 quality standard. ArcDia's diagnostic solutions can be instrumental for improving the way the pandemic is managed.

In spring 2020, ArcDia was among the first companies to launch CE marked products for rapid antigen testing of COVID-19. The new 2nd generation COVID-19 tests bring a ten-fold improvement to the limit of detection. Contagiousness is detected in 20 minutes. The mariPOC[®] COVID-19 tests are already widely used globally in decentralized testing and laboratory testing as well as in occupational surveillance. According to recent scientific evidence, the phenotypic methodology is ideal and more accurate than PCR gene testing for catching infectious individuals.

The first clinical studies show sensitivities of 92% and 100% compared to central laboratory PCR (Ct ≤30), and specificity of 100%. The tests are designed to detect the conserved nucleoprotein of the virus which makes them robust against strain variation. Affordable mariPOC[®] tests are ideal for decentralized rapid and syndromic testing of acute infections in primary care and emergency clinics. The updated test is now available for customers. Regulatory approval in USA is pending.

“Our new mariPOC tests for COVID-19 challenge the slow central lab testing both in sensitivity and in specificity. mariPOC can be operated in the field and the test results are available straight away – at travel hubs, at harbours, and in factories for occupational health and safety testing. This is a breakthrough which allows the health authorities to set a new standard in the containment of the pandemic.”

– Mr. Vesa Kempainen the CEO of ArcDia –

“The lowest limit of detection of the new test corresponds to an amazing qPCR Ct 33 units, thus approaching the central laboratory PCR test sensitivity. Higher sensitivity than this is not needed in efficient containment of the COVID-19 pandemic, as individuals with higher Cts are non-contagious.”

– Dr. Janne Koskinen, Head of R&D at ArcDia –

mariPOC[®] test is based on the direct detection of infectious virus from a nasopharyngeal swab sample. The test is available as high-capacity, single analyte mariPOC[®] SARS-CoV-2 test format where one benchtop test system can analyse 300 samples a day. The capacity is high enough for most outpatient and emergency care units to efficiently test all COVID-19 suspected patients. Furthermore, the single analyte test allows automated and rapid COVID-19 on-site testing at airports, factories and workplaces. The COVID-19 test is also available as a part of syndromic panels which detect up to 11 common respiratory pathogens, such as influenza and RSV, simultaneously from one sample. These tests are the most appropriate and cost-efficient tool on the market to extensively diagnose and monitor respiratory infections during the Flu season.

“The mariPOC[®] tests are very easy to perform at the site of sampling by health care personnel without laboratory training. mariPOC provides swift results without delay. The extremely high sensitivity of the new improved COVID-19 tests also enables most health care providers to reduce the use of time-consuming central lab services.”

– Jenna Mäkilä, Product Manager at ArcDia –

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PRESS RELEASE

ArcDia International Oy Ltd

ArcDia International Oy Ltd develops, manufactures and markets mariPOC® worldwide. The company based in Turku, Finland, was founded in 2008 and employs 30 professionals. ArcDia is the developer and manufacturer of the mariPOC® IVD platform – an automated system designed for rapid multianalyte identification of pathogens, and detection of inflammation markers and antimicrobial resistance. **mariPOC®** products enable central laboratory level quality, performance and pathogen coverage for primary health and emergency care units. The current mariPOC® applications cover respiratory tract infections, including COVID-19, pharyngitis and gastrointestinal infections. More information about ArcDia, including **mariAST®** developed for rapid phenotypic antibiotic resistance testing, and **mariCloud™** for real-time epidemiological surveillance, is available at

www.arcdia.com

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