

# GeneMe Receives UK MHRA Approval for SAVD Rapid RT-PCR Test for SARS-CoV-2

**February 15, 2022 (London):** GeneMe and Broadwater Health announced today that its single-step, extraction-free COVID-19 PCR assay, SAVD Rapid RT-PCR, has been successfully validated by Coronavirus Test Device Approvals (CTDA) and received UK Medicines and Healthcare products Regulatory Agency (MHRA) approval.

The SAVD Rapid RT-PCR, developed with GeneMe's proprietary enzymes, utilizes a single-step direct method (no extraction) on validated rapid RT-PCR instruments, with results in as little as 20 minutes. In clinical studies, the assay demonstrated 100% specificity and 98% sensitivity. The test exhibits class-leading Limit of Detection of only 20 copies per ml.

Dawid Nidzworski, CEO, GeneMe states "The SAVD Rapid RT-PCR is the first single-step, extraction-free Covid PCR test that is suitable for mass testing at Point-of-Care. Our testing solution has been proven to be of great benefit to natural resources operations, laboratories, nursing homes, clinics, Entertainment and Professional Sports sectors. We look forward to partnering with service providers who are committed to providing low cost, highly accurate and efficient diagnostic services to communities in a variety of settings."

Paul Reith, CEO, Broadwater Health commented "We look forward to introducing the SAVD test to the UK market, with a subsequent improvement in test processing efficiency, turn-around time and accuracy. GeneMe's pipeline of POC diagnostic tests promise to significantly benefit other test segments such as sexually transmitted diseases, women's health, respiratory diseases and other pandemics such as Tuberculosis and HIV."

## **About GeneMe**

GeneMe Ltd. is an ISO13485 certified manufacturer and developer of proprietary genetic tests and novel genetic testing procedures. GeneMe operates a network of service laboratories throughout Poland. GeneMe's unique single-step, extraction-free PCR technology allows for a range of pathogens to be tested accurately at Point-Of-Care. This platform technology allows for fast development of novel multiplex tests for any application. The entire product development and manufacturing process is performed directly by GeneMe. This allows for full control of the entire process for optimal quality and also results in a competitive price for its products and services.

## **About Broadwater Health**

Broadwater Health partners with innovative and impactful companies and technologies to bring improvements in health, wellness and nutrition to a broader audience. Broadwater Health is a unique collaboration, headed up by the company's experienced team of healthcare investors and entrepreneurs, working alongside scientific and medical advisors, supported by an international medical manufacturing and distribution network. Broadwater Health combines venture capital investment and commercial scale-up expertise to develop life sciences assets to their full potential.

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