



## **BIOFIDELITY – CUSTOMER SPOTLIGHT**

### **Premium reference materials help take innovative genomic technology into the clinic**

Biofidelity is a pioneer in the genomic technology space, and the UK-based company's mission is to unlock the benefits of precision medicine for cancer patients. Its revolutionary technologies can be used for early detection, precise diagnosis and routine monitoring applications in oncology. Barnaby Balmforth, CEO at Biofidelity, explained how working closely with LGC Clinical Diagnostics ensures the high quality, bespoke next generation sequencing (NGS) reference materials that the company needs to validate its technology for translation into clinical practice.

### **An evolution in oncology biomarkers drives demand for tumor profiling**

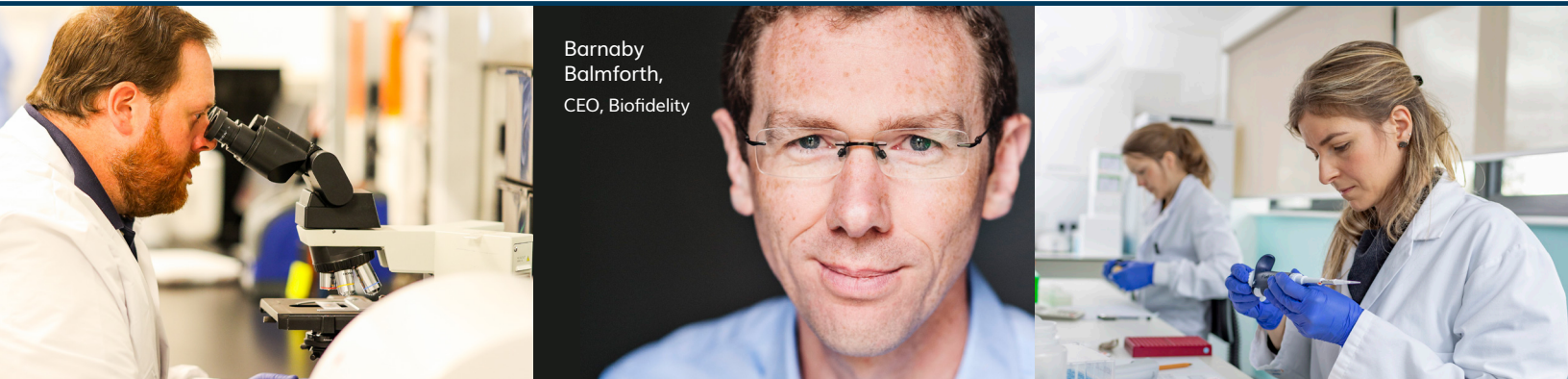
Advances in DNA sequencing have transformed oncologists' understanding of cancer over the past 20 years. Cancers are caused by a multitude of distinct genomic abnormalities characterized by mutations in DNA or RNA, and each tumor is unique. Sequencing technologies such as NGS have identified an increasing number of genomic biomarkers driving cancer formation and treatment response, and knowledge of such alterations has enabled the development of new targeted therapies. To realize the potential of this approach, physicians need to perform comprehensive biomarker testing to match cancer therapies to the tumor profile of each patient, which can lead to better patient outcomes, fewer side effects, and improved quality of life.

Unfortunately, most patients do not have access to in-depth biomarker analysis, due to high costs, slow turnaround time, and issues with both scalability and sensitivity when using conventional NGS. It typically takes two to three weeks for a result, which can be a devastating delay for terminally ill cancer patients. Consequently, fewer than half of metastatic cancer patients in the United States undergo biomarker testing, and many of those that are eligible for targeted therapy do not receive it, often due to the initiation of first-line therapy before genomic test results are available.<sup>1</sup>

### **A true expert in quality**

Validating a new technology intended for the clinical space is fraught with technical challenges. Credible validation data is mission critical to translate an innovative approach from a research setting through to the clinic for use with real patients, as regulators, investors and early adopter customers need proof that the technology works as claimed. LGC Clinical Diagnostics has supported Biofidelity since its start-up phase, providing both standard and customized Sereq<sup>®</sup> NGS reference materials to aid the development and validation of the company's unique technology. LGC Clinical Diagnostics is a well-known leader in the development and supply of high quality synthetic reference materials that closely mimic patient samples, providing invaluable credibility for its customers. Comparative data between bespoke Sereq reference materials and real patient samples therefore enabled Biofidelity to publish compelling validation data, providing the evidence the company needed to engage with investors and raise significant funding to drive further product development.

**“It's really hard to find the reference material to the standard that we need. LGC Clinical Diagnostics has worked diligently with us to refine and develop its products, tailoring them to the purpose that we need them for.”**  
Barnaby Balmforth, CEO, Biofidelity



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### A consultative approach with a growth focus

Biofidelity's unique technology has unconventional requirements for reference materials compared to typical molecular diagnostics products. LGC Clinical Diagnostics has worked closely with the company to determine optimal samples for the intended use, adapting existing products according to Biofidelity's requirements to ensure a perfect match. For example, the LGC Clinical Diagnostics team foresaw that the incredible sensitivity of the ASPYRE technology – capable of detecting one molecule with a genomic alteration in a sample – could detect the trace artifacts created during production of the ctDNA reference materials, thereby interfering with the results. The companies worked together to eliminate this issue, providing a solution that ensured the reference materials accurately represent real patient material with minimal background noise.

**“ LGC Clinical Diagnostics consistently and reliably provides the expertise in reference materials that we need for validation, allowing Biofidelity to focus on developing our core technologies.”**  
Barnaby Balmforth, CEO, Biofidelity

Biofidelity is a forerunner in the evolving field of genomic technology, and it was essential to collaborate with an organization with the expertise that allows it to truly understand its needs and the barriers faced. LGC Clinical Diagnostics' experienced team has the knowledge to see the valuable opportunity this collaboration represents, and the high level of technical and scientific expertise its sales and field science teams offer is vital to truly understand the potential of Biofidelity's mission.

### Towards a future of innovation

LGC Clinical Diagnostics is a trusted expert and supplier that understands the technical and commercial needs of Biofidelity in the rapidly evolving field of cancer diagnostics. LGC Clinical Diagnostics looks forward to supporting the cutting edge products that Biofidelity intends to develop based on this technology, which will continue to use Seraseq NGS reference materials for routine internal quality control, as well as for external controls in the future.

**“ The team at LGC Clinical Diagnostics has the scientific know-how to be able to see our vision of how Biofidelity's technology can lead to true decentralization of genomic testing. They want to support us on our journey to revolutionize cancer care, and provide us with the flexibility that we need to innovate, scale and deliver.”**  
Barnaby Balmforth, CEO, Biofidelity.

For more information on how LGC Clinical Diagnostics can help your company bring a diagnostic test to market, visit <https://lgclinicaldiagnostics.com>, or <https://seracare.com/Controls---Reference-Materials-NGS/>

For more information on Biofidelity, visit [www.biofidelity.com](http://www.biofidelity.com)

#### References

1. Hess LM, Krein PM, Haldane D, et al. Biomarker Testing for Patients With Advanced/Metastatic Nonsquamous NSCLC in the United States of America, 2015 to 2021. *JTO Clin Res Rep.* 2022;3(6):100336. doi:10.1016/j.jto.2022.100336

