

Cerca Biotech Releases New White Paper on Ki-67 Testing in Breast Cancer

MammaTyper® Establishes Benchmark Reproducibility & Reliability for Ki-67 and Core Breast Cancer Biomarkers

BERLIN, GERMANY, July 16, 2026 /EINPresswire.com/ -- [Cerca Biotech](#) has officially published a

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Rich Hughes, Commercial Director of Cerca Biotech

dedicated White Paper focused on [Ki-67](#) detection, demonstrating the superior performance in reproducibility and analytical reliability of [MammaTyper®](#) for Ki-67 alongside other key breast cancer biomarkers including ER, PR, and HER2, addressing long-standing variability pain points of traditional IHC testing.

The Ki-67 proliferation index is critical for guiding breast cancer prognosis and treatment stratification. Nonetheless, conventional IHC testing is plagued by subjective pathologist judgment, inconsistent hotspot protocols and poor inter-laboratory concordance, which frequently leads to ambiguous biomarker outcomes and

interferes with standardized clinical decision-making.

Drawing on multi-center international validation data and real-world laboratory performance evidence, the White Paper systematically validates the strengths of MammaTyper® RT-qPCR molecular detection. Its objective quantitative measurement effectively removes human subjectivity inherent to IHC and CISH detection.

Core conclusions from the White Paper include:

1. Outstanding inter- and intra-laboratory reproducibility across Ki-67, ER, PR and HER2; kappa coefficients for categorical classification reach 0.90–1.00, far surpassing the consistency level of conventional detection methods.
2. Stable quantitative readouts for MKI67 and other target genes ensure consistent results across different laboratories, testing equipment and operators.
3. High clinical concordance with reference standards: optimized Ki-67 agreement rates, together with robust matching performance on ER, PR and HER2, supporting accurate molecular

subtyping of breast cancer.

"Inconsistent Ki-67 results have remained a prominent clinical bottleneck in global breast cancer management for years," said Rich Hughes, the Commercial Director of Cerca Biotech. "Our newly issued White Paper consolidates substantial clinical evidence to demonstrate that MammaTyper® standardizes biomarker detection via molecular quantification. By drastically reducing variability in Ki-67 and core biomarker testing, we provide pathologists and clinical oncologists with highly stable, replicable data, laying a solid foundation for standardized diagnosis and precise personalized therapy."

The document also underscores the engineering design advantages for laboratory stability of MammaTyper®: compatibility with multiple mainstream testing platforms, automated standardized reporting workflows and minimized manual errors. Supported by dozens of peer-reviewed studies, the assay effectively resolves equivocal biomarker results, lowers repeated retesting rates, and facilitates unified implementation of clinical guidelines worldwide. The full version of the Ki-67 themed White Paper is now available for download for clinical laboratories, pathologists, oncologists and medical research institutions.

About Cerca Biotech

Cerca Biotech is a diagnostic company based in Germany focused on bringing novel and innovative diagnostic products to the oncology and women's health market. We strive to introduce the best tests to meet the unmet clinical needs at an affordable cost, with clinical accuracy and rapid results as our focus. Utilising a combination of experienced distributors and direct sales Cerca Biotech has a commercial reach from Germany through the Nordics and Eastern Europe to the Middle East, Africa, and beyond. Our team comprises of highly experienced commercial, technical and clinical experts in the field of IVD, allowing rapid deployment of novel technologies with a "get it right first time" strategy.

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