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Commencement and optimization of HER2 DISH method for accurate breast cancer diagnosis

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Introduction and objectives: HER2 (Human epidermal growth factor receptor 2) is a crucial biomarker in breast cancer, influencing prognosis and treatment. Dual in situ hybridization (DISH) is a robust method for detecting HER2 gene amplification, providing an alternative to immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH). The objective is to describe the commencement of the HER2 DISH method in our laboratory, outline key technical aspects, and share strategies for achieving reliable and reproducible results.

Methodology: The test was performed on a BenchMark IHC/ISH instrument using the Ventana HER2 Dual ISH DNA Probe Cocktail and VENTANA detection kits. Technicians were trained and standard operating procedures prepared under guidance of experts. Key steps included proper tissue preparation and hybridization with dual colour DNA probes (HER2 and CEP17). Strategies for optimization included hybridization at 37°C for 14-20 hours duration, precise saline sodium citrate (SSC) and detergent concentrations for washing stringency and maintaining deionized water conductivity at 0 -5uS/cm. Strict quality control measures, including positive and negative controls, were implemented at each step to ensure reproducibility. Validation covered preanalytical, analytical, and clinical stages.

Results and Discussion: Twenty-five breast cancer tissue samples (resection and core biopsy) were tested using the HER2/DISH protocol, with results compared to IHC and FISH. The HER2/DISH test showed a 96% agreement with IHC and FISH, with high precision and no significant issues during validation. Since commencement, 43 tests have been performed, with nine showing amplification.

Conclusion: The successful implementation of the HER2 DISH method enhances the accuracy of HER2 status determination in breast cancer patients. Key technical optimizations and rigorous quality control measures are essential for reliable results. The HER2 DISH method offers a valuable addition to the diagnostic toolkit, aiding in personalized treatment planning.

Keywords: HER 2 DISH, breast cancer

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