Abstract

Objectives: To determine the status of the HER2 amplification in Breast cancer performed in peripheral laboratories in Colombia by immunohistochemistry and its comparison with central laboratories and the FISH status. Methods: Four thousand one hundred and five cases referred for the determination of the HER2 status by FISH and/or IHQ to the Department of Pathology of the Fundacion Santa Fe were studied. The analysis included correlation between the IHQ HER2 score submitted by the peripheral laboratory (PL), the HER2 score emitted in the LC and the FISH studies performed in the central laboratory (CL). Results: two thousand five hundred and eight HER2 IHQ studies were performed in the (CL), using the Dako Herceptest. With the following results: 68.2 % negative (0-1+); 16.4% indeterminate (2+); 15.3% 3+ and 2.3 % not adequate. 1360/ 1719 cases studied by FISH came from the (PL), and 329 (19.1%) from the (Lc). Comparing the IHQ score emitted by the PL and the positive FISH status showed: 6/28 0+ were positive (21. 4%); 7/31 1+ (22, 5%); 397/1,240 2+ (32. 8%) and 74/91 3+ (81. 3%). In the CL the results were 1/9 0+ (11.1%); 3/18 1+ (16.7%); 154/292 2+ (53%); and 9/9 3+ (100%). Only 1/4 negative cases (0/1+) was in house. Conclusion: The false negative rate (22%), and false positive results (18.7%), of the HER2 status performed by IHQ in peripheral laboratories in Colombia is unacceptable high as well as the inadequacy of tissue indicating that pre-analytical factors have to be improved in Colombia in order to get optimal results.

Keywords
FISH, HER2, Immunohistochemistry, breast cancer.