**Introduction**

Accurate determination of HER2 positivity is a prerequisite for treatment with Herceptin® (anti-HER2 antibody therapy; trastuzumab). Fluorescence in situ hybridisation (FISH) and immunohistochemistry (IHC) are the most commonly used methods to determine HER2 status in breast cancer; both tests are highly reliable and reproducible. Chromogenic in situ hybridisation (CISH) has been developed as an alternative technique for detection of HER2 gene amplification. This assay is highly specific and sensitive, and comparable to FISH and IHC with the established HER2 testing methods, FISH and IHC. Samples of tumour tissue for both FISH and CISH were retrospectively tested by CISH to assess the utility of this technique for HER2 status assessment. Concordant CISH and FISH results were compared with previous FISH and IHC results for the same tumours.

**Methods**

Tumour samples from a phase II study of Herceptin® monotherapy were retrospectively reassessed by CISH using the PathVysion™ (Vysis) 2-colour assay. The PathVysion™ (Vysis) 2-colour assay was used for FISH. For example, 54% of the 86 samples included in this analysis, 19 responded to monotherapy treatment with Herceptin®. Sensitivity of these 19 patients was determined by IHC. Concordance between FISH and CISH was seen in 17 of 19 cases (90% sensitivity), compared to 16 of 19 cases (84% sensitivity) for IHC. Concordance between FISH and CISH was assessed in a retrospective analysis of a large international study (96% sensitivity). Concordance between IHC, FISH and CISH was assessed in a large prospective study (90% sensitivity).

**Results**

Concordance between FISH and CISH was assessed in a large prospective study (90% sensitivity). Concordance between IHC, FISH and CISH was assessed in a large prospective study (90% sensitivity). Concordance between IHC, FISH and CISH was assessed in a large prospective study (90% sensitivity). Concordance between IHC, FISH and CISH was assessed in a large prospective study (90% sensitivity).

**Conclusions**

HER2 status assessment by chromogenic in-situ hybridisation (CISH) demonstrates high sensitivity for predicting response to Herceptin®.