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**Objective:** UK NEQAS operates a scheme for assessing laboratories performing HER2 ISH testing. Since its introduction further improvements have been made to the ISH module including the introduction of a more statistically robust scoring method. The objectives of this study were to assess participant's performance over time and evaluate change in testing methods.
**Method:** Data from NEQAS reports were analysed for performance - (1) across time; (2) in relation to changes in the scheme; and (3) across the assay systems.
**Results:** Over the most recent 2.5 years, an average of 6.7 % of participant results were classified as 'excellent', 60.1 % as 'acceptable', 24.4 % as 'borderline' and 8.7 % as 'unacceptable'. The preceding 2 years where a different scoring system was used demonstrated a higher unacceptable rate of 15.3 %. In the years prior to this where cell lines were used instead of human tissue, the mean unacceptable rate of participants was 15 %. The impact of the assay method used on laboratory performance showed that Fluorescence ISH based methods outperformed colorimetric ISH methods (mean pass rate 81 % vs 61 %).
**Conclusion:** Participation in an EQA scheme is essential for demonstrating competency in HER2 ISH testing. However, the performance of laboratories must be considered in the context of module changes over time.

**PS-01-015**
**FGD5 amplification in breast cancer patients is associated with tumour proliferation and a poorer prognosis**
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**Objective:** By means of a combined genomic approach, FGD5 amplification is identified as a driver of proliferation in Luminal breast cancer. We studied FGD5 copy number change in breast cancer tumours, and assessed a possible association with tumour proliferation and prognosis.
**Method:** We used fluorescence in situ hybridization probes targeting FGD5 and chromosome 3 centromere (CEP3) on formalin-fixed, paraffin-embedded tissue from 430 primary breast cancers and 108 lymph node metastases. All cases were from a cohort of Norwegian breast cancer patients. Using Pearson's Chi-square test, we tested the association between FGD5 copy number status and proliferation (assessed by Ki67 levels and mitotic count). Estimating cumulative risks of death and hazard ratios, we assessed the prognostic impact of FGD5 copy number change.
**Results:** FGD5 amplification (FGD5/CEP3 ratio ≥2 or mean FGD5/tumour cell ≥4) was identified in 9.5 % of tumours. Amplified tumours had higher mitotic counts and Ki67 levels than non-amplified tumours. After 10 years of follow-up, cases with FGD5 amplification had higher cumulative risk of death from breast cancer than non-amplified cases (48.1 % (95 % CI 33.8–64.7) vs. 27.7 % (95 % CI 23.4–32.6)).
**Conclusion:** FGD5 is a new prognostic marker in breast cancer, and amplifications are associated with higher tumour proliferation and poorer long-term prognosis.

**PS-01-016**
**Quality of up to 35 years old archival breast cancer tissue in paraffin-blocks for estrogen receptor evaluation**
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**Objective:** Estrogen receptor (ER) positive breast cancer (BC) can have an insidious course with disease-relapse decades after primary surgery. New analysis performed on archived formalin-fixed paraffin-embedded (FFPE) tissue are important for disease-management in late BC-relapse and an important tool in BC-research. However, although loss of immunoreactivity in tissue slides after sectioning has been shown, little is known of the preservation of biomarker-expression in FFPE tumour-blocks. We aim to investigate the quality of immunohistochemical (IHC) ER-evaluation in FFPE-tissue over time (1978–2000).
**Method:** Tissue-microarrays from a Swedish multicenter cohort of 728 patients with contralateral BC was used for ER IHC-evaluation. BC was studied in three periods (1958–1985, 1986–1993, 1994–2000), and retrospective ER IHC-data was correlated to corresponding prospective ER cytosol-analysis performed on fresh BC-tissue.
**Results:** The concordance between the original ER cytosol-analysis and the new IHC was substantial (1978–1985: 82 %, (117/142), Kappa 0.63. 1986–1993: 91 %, (194/213), Kappa 0.72. 1994–2000: 86 %, (187/218), Kappa 0.61). Discrepancies were mostly found for tumours with ER-values close to cutoff for one or both of the methods.
**Conclusion:** FFPE BC-tissue from the late 70s to millennium shows preserved ER-antigenicity up to 35 years later.

**PS-01-017**
**Bcl-2 and Ki67 as specific prognostic markers in estrogen receptor positive breast cancers**
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**Objective:** Breast cancer is a heterogeneous disease, so many biomarkers can be potential predictors in its outcome. The aim of this study is to test the hypothesis that combinatorial assessment of both Ki-67 proliferation index and B-cell Lymphoma 2 (Bcl-2) protein, would provide prognostic information on occurrence of relapses in breast cancer patients.
**Method:** Immunohistochemical expression of Ki67 and Bcl-2, represented as Ki67/Bcl-2 index, were evaluated in 183 Estrogen Receptor positive breast cancer patients from 2007 to 2012, compared with other clinical-pathologic findings. During the follow up period (45–114 months) recurrences were observed in 36 patients (19.7 %).
**Results:** A significant correlations were notified between Ki67/Bcl-2 index with age, tumour size, nuclear grade, histologic grade, lymphovascular invasion, progesterone receptor status and expression of p53 protein product ($p < 0,05$). The occurrence of relapses in the group of low Ki67/high Bcl-2 index was lower, compared with the group of high Ki67/low Bcl-2 index breast cancer patients ($p < 0.01$).
**Conclusion:** The combination of Ki67 and Bcl-2 biomarkers is useful tool in prediction of relapses in Estrogen positive breast cancer patients.

**PS-01-018**
**The scale of androgen expression in triple negative breast cancer**
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**Objective:** The predictive and prognostic role of androgen receptors (AR) expression in patients with breast cancer still remains controversial. Moreover immunohistochemical scale for AR evaluation, as that for ER and PR expression, has not been developed yet. The aim of this study was to determine the intensity of AR expression in the group of triple negative breast cancer, as well as to create AR evaluation scale, similarly to the existing Allred system.
**Method:** We determined the intensity of expression of AR of 71 FFPE tumour tissue in triple negative breast cancer cases by immunohistochemical method (clone AR441, DAKO).
**Results:** AR were expressed in 47 cases (66 %). In these cases the staining intensity was homogenous and ranged from weak to strong. In 17