

## **Quality Standards for GMPN commissioned laboratories providing Her2 Testing.**

**Technical Standards** – broadly based on the recommendations for Her2 testing in the UK including the April 08 update to the original guidelines. IHC testing will be performed as the preliminary screening with subsequent FISH/CISH evaluation on appropriate cases.

- Laboratories performing Her2 IHC must report at least 250 cases per annum
- Laboratories performing Her2 FISH/CISH must report at least 100 cases per annum.
- Laboratories must have carried out validation studies on the Her2 IHC method in use.
- In house controls must be used in every staining run and these should include negative, 1+, 2+, 3+ tissues.
- Evaluation of results may be undertaken by BMS/Clinical Scientists who have had appropriate training and experience in the interpretation of histological features of breast tissue. The Her2 status should only be reported on the invasive portion of a tumour. Support from a Consultant Histopathologist with specialist breast pathology experience for the interpretation of complex histology must be available in the reporting laboratory.
- Participating laboratories will share information on changes in methodology within the GMPN forum.

**Quality Assurance** – Laboratories must participate in the appropriate external quality assurance schemes for IHC/FISH/CISH.

- Participating laboratories should hold CPA or equivalent accreditation.
- Written annual confirmation of acceptable performance in each scheme to be sent to the GMPN
- In confidence, notification to the Network Director of any performance warnings issued by the EQA schemes.
- Participating laboratories will share information on methodology in use and any changes in methodology

### **GMPN general standards for participating laboratories**

- Target turnaround times for IHC and FISH will be agreed after considering potential earlier treatment with Herceptin and the inclusion of some patients into clinical trials. These will be discussed further and agreed at the PAG meeting. (suggest results should be available for the 2<sup>nd</sup> MDT following surgery date as a maximum)
- All laboratories should have a contingency or back up plan for provision of a timely service and all participating Greater Manchester laboratories should provide cross cover for each other when needed.
- Any difficulties in Her2 service provision should explicitly be reported to the GMPN in a timely manner.

- There is a mandatory requirement to provide and submit data to the UK database scheme as required.
- Invoices for work done should be submitted on a quarterly basis with a breakdown of how many tests are being claimed for each hospital.
- Laboratories/GMPN will undertake annual user surveys or similar of both referring pathologists and oncologists with the results being conveyed back to the PAG/NAG on an annual basis.

### **Audit**

The percentage of tests that were reported within the target turnaround time for each laboratory should be supplied to the PAG on a quarterly basis.

- TAT will be audited and reported to the GMPN

AY/CJS/June 2009