

**Freedom of Information Act 2000 - Request Reference FoI/20/370**  
**Breast Core Biopsies**

**Request details**

**1. What method or test is used to determine the amplification status of equivocal HER2 “2+” breast core biopsies? (e.g. Fluorescence In Situ Hybridisation)**

FISH

**2. Is this test performed in-house or externally? (If externally, please state where the test is performed.)**

Externally as part of the All Wales Genomics Centre.

**3. What is the individual cost to perform one of these tests?**

After considering your request, Cardiff and Vale University Health Board (the UHB) considers this information to be exempt from disclosure under the Freedom of Information Act 2000 (Section 43) Commercial Interests. This section of the Act sets out an exemption from the right to know if:

- the information requested is a trade secret, or
- release of the information is likely to prejudice the commercial interests of any person. (A person may be an individual, a company, the public authority itself or any other legal entity).

This exemption was considered by the UHB when deciding whether to disclose information because it considered that in doing so there could be a significant risk in prejudicing the commercial interests of the company in question. As this is a qualified exemption, the UHB is required to complete a public interest test in deciding whether it is in the public’s interest to withhold or disclose the information.

**In favour of disclosure:** There is a public interest in transparency and in the accountability of spending of public funds. Furthermore, it is in the public’s interest that public funds be used effectively and that public sector bodies obtain the best value for money when contracting for the provision of services.

**Against disclosure:** There is a risk of disclosure prejudicing the commercial interests of the UHB by affecting its bargaining position with agencies. This in turn could lead to less effective use of public funds in future. It has been established above that releasing the information under the Freedom of Information Act, to which the UHB is subject, will give an unfair advantage to the supplier’s competitors. The UHB believes that there is wider established public interest in companies not being prejudiced merely because they have contracted with a public sector body (as upheld in ICO decision notice FS50473543 ICO v Royal Marsden Hospital Trust).

**Decision:** The UHB considers that the public interest in withholding the information is greater than the interests in disclosing it and thereby giving unfair commercial advantage to competitors of the supplier to which this information concerns. The UHB believes that disclosure of information in a manner which fails to protect the interests and relationships arising in a commercial context could have the effect of discouraging companies from dealing with the Health Board because of fears that the disclosure of information could damage them commercially. In turn this could then jeopardise the Health Board's ability to compete fairly and pursue its function to bring forward development in the area and obtain value for money. It was therefore decided that it was not in the public's interest to disclose this information.

**4. What is the average waiting time (in days) for an exact HER2 score (HER2:CEP17 ratio) to be received by a consultant for a breast core biopsy once it has been proven to be equivocal "2+"? (If an exact time is not available, please could you provide an approximation?)**

The lab follows the reporting times as recommended by the Association for Clinical Genomics Science (ACGS) <https://www.acgs.uk.com/quality/best-practice-guidelines/>. Day 0 is the day the sample is received into the laboratory with all appropriate information and all other required samples are received, and KPI reflects day at which report is authorised and issued .

**5. What is the range in waiting times (in days) for an exact HER2 score (HER2:CEP17 ratio) to be received by a consultant for a breast core biopsy once it has been proven to be equivocal "2+"? (If an exact time is not available, please could you provide an approximation?)**

In Genomics, we aim to turnaround our HER2 samples in 7 calendar days. Day 0 is the day we receive the sample and the last day is the day the result is authorised and issued. We then report our results to Cellular Pathology for a combined report.

Here is our HER2 data for the last 6 months (this includes breast and gastric biopsies):

200 samples received during April 2020 to September 2020, with an average turnaround of 7CD and 80% of these samples went out in the 7CD period.

**6. How many breast core biopsies were tested for their HER2 amplification status in 2019? Of these, how many were equivocal "2+" cases that needed an additional test to calculate the exact score (HER2:CEP17 ratio)?**

In 2019 the HER2 service (breast and gastric biopsies) reported 478 samples. This is assuming that all the referrals are equivocal IHC 2+ results.