

Ref: FOI/CAD/ID 3025

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Freedom of Information Act 2000

I am writing in response to your request for information made under the Freedom of Information Act 2000 in relation to molecular pathology BRAF testing.

Since the original response dated 11 November 2015, the Trust now offers clinical testing for BRAF mutation.

Please find below the updated information.

1. Do you currently offer a clinical testing service for BRAF mutation in solid tissue, specifically melanoma? (Yes, No, currently in development)

Yes

2. Which methodology(ies) do you use for BRAF testing in melanoma? e.g. Real time PCR (QPCR), High resolution melting curve analysis (HRMCA), Sanger sequencing, Next Generation Sequencing (NGS), Pyrosequencing, Immunohistochemistry (IHC), Fluorescence In Situ Hybridisation (FISH), Other (please specify). If you use a specific kit I would be grateful if you could provide the name of the kit you use.

Real time PCR (QPCR). Roche Cobas 4800 Assay

3. Which BRAF mutations does your methodology(ies) cover? E.g. V600E, V600K, V600D, V600R etc.

V600E

4. What is your current laboratory turnaround time for BRAF testing in melanoma?

Target of 90% within 7 working days

5. *What is the level of sensitivity of your BRAF methodology(ies)?*

5%

6. *I understand that molecular testing in FFPE tissue can be difficult due to tissue quality and/or quantity. What would you estimate is your current failure rate for BRAF testing for melanoma?*

The numbers are too small at present to provide accurate data

7. *Approximately how many BRAF tests for melanoma would you conduct per month or year (whichever time period is most convenient for you to estimate)?*

12 per month approximately.

8. *Of the BRAF tests performed for melanoma, please estimate how many (or what percentage) are found to be positive for a mutation?*

25% for month 1. (Please note: Numbers too small for accuracy)

9. *Of the positive tests, please estimate how many (or what percentage of the positives) are V600E? How many (or what percentage of the positives) are V600K? How many (or what percentage of the positives) are V600 all other mutations?*

The kit does not detail the specific mutation found