

Request title: Molecular Pathology BRAF Testing

Date of Response: 19th November 2015

Further to your Freedom of Information request, the Trust has answered your questions in the order they appear in your request.

Request and reply

I would like to access information with regard to the molecular pathology BRAF testing that you offer in your institution. I have the following questions, the answers to which I believe should be easily accessible by the laboratory and therefore shouldn't take up too much staff time or resources.

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.
Primary testing by Sanger Sequencing. Reflex testing by Taqman.
3. Which BRAF mutations does your methodology(ies) cover? E.g. V600E, V600K, V600D, V600R etc.
Sanger Sequencing covers *BRAF* exon 15 (including all codon 600 mutations). Taqman assay is designed to detect V600E but has also detected V600K.
4. What is your current laboratory turnaround time for BRAF testing in melanoma?
Mean turnaround time: 5.8 working days; Median 5 working days.
5. What is the level of sensitivity of your BRAF methodology(ies)?
The Trust quotes a 10% sensitivity although it is able to detect below that level.
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?
Failure rate (requires new FFPE sections) for solid tumour testing is approximately 2%.
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)?
Approximately 100 *BRAF* tests per year for melanoma.
8. Of the BRAF tests performed for melanoma, please estimate how many (or what percentage) are found to be positive for a mutation?
Approximately 35% are positive for a mutation.
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?
Approximately 90% are *BRAF* V600E, 5-10% V600K and Other V600 mutations likely to make up 2-3%.