

Freedom of Information request 121-18

Request

1. Do you currently offer a biomarker testing for the following, as of the beginning of 2018?
 - a. PD-L1 in NSCLC
 - i. Yes, in house service
 - ii. Yes, but send out PD-L1 testing to another laboratory
 - iii. (Please specify which laboratory samples are sent to: _____)
 - iv. No, and do not send to another laboratory
 - b. ALK in NSCLC
 - i. Yes, in house service
 - ii. Yes, but send out ALK testing to another laboratory
 - iii. (Please specify which laboratory samples are sent to: _____)
 - iv. No, and do not send to another laboratory
 - c. BRAF in Melanoma
 - i. Yes, in house service
 - ii. Yes, but send out BRAF testing to another laboratory
 - iii. (Please specify which laboratory samples are sent to: _____)
 - iv. No, and do not send to another laboratory
2. Is predictive biomarker testing conducted at the same lab (or similar location such as in same building) as the initial cytological and histological (H&E stain) assessment, or is this done at a different site?
 - a. IHC
 - i. Yes, done at same lab or site
 - ii. No, sent to another lab or site
 - iii. (Please specify which laboratory samples are sent to: _____)
 - b. FISH /ISH/ NGS / PCR
 - i. Yes, done at same lab or site
 - ii. No, sent to another lab or site
 - iii. (Please specify which laboratory samples are sent to: _____)
3. Is biomarker testing performed reflexively or upon request for the following biomarkers?
 - a. PD-L1 in NSCLC
 - i. Reflexively (i.e. prior to starting 1L treatment)
 - ii. Upon request (i.e. case by case after disease progression)
 - iii. *If reflexively* – What is the laboratory protocol for PD-L1 testing in lung cancer patients
 - iv. Multi-marker panel (i.e. multiple biomarkers, one test)
 - v. Sequential single gene (i.e. one biomarker, one test)
 - vi. Other (Please specify _____)
 - b. ALK for NSCLC
 - i. Reflexively (i.e. prior to starting 1L treatment)
 - ii. Upon request (i.e. case by case after disease progression)
 - iii. *If reflexively* – What is the laboratory protocol for ALK testing in lung cancer patients
 - iv. Multi-marker panel (i.e. multiple biomarkers, one test)
 - v. Sequential single gene (i.e. one biomarker, one test)
 - vi. Other (Please specify _____)
 - c. BRAF in Melanoma

- i. Reflexively (i.e. prior to starting 1L treatment)
 - ii. Upon request (i.e. case by case after disease progression)
 - iii. *If reflexively* – What is the laboratory protocol for BRAF testing in melanoma patients
 - iv. Multi-marker panel (i.e. multiple biomarkers, one test)
 - v. Sequential single gene (i.e. one biomarker, one test)
 - vi. Other (Please specify_____)
4. Which of the following biomarkers are assessed in lung cancer patients in your laboratory? (please select all that apply)
- i. ALK
 - ii. EGFR
 - iii. ROS1
 - iv. DLL3
 - v. PDL-1
5. Which of the following testing platforms are used at this this laboratory? (please select all that apply)
- i. FISH
 - ii. NGS
 - iii. PCR
 - iv. IHC
 - v. Other
6. What IHC staining platform(s) are used in the laboratory for biomarker testing? (please select all that apply)
- i. Ventana
 - ii. Dako
 - iii. Leica
 - iv. Other (If possible, please supply the model of the platform_____)
7. What type of test does the institution prefer to use for biomarker-predictive IHCs?
- i. IVD CDx (commercial)
 - ii. LDT (lab developed)
 - iii. None
- b. What is the main factor in this decision?
- i. Funding constraints
 - ii. Control over methodology
 - iii. Other (Please specify_____)
8. Does your lab / trust seek separate reimbursement from NHS under the “high-cost medicines and tests” provision for biomarker tests that have been excluded from tariff?
- i. Yes
 - ii. No
9. What is the number of samples being tested (or sent-out) are tested for the following biomarkers?
- a. ALK
Please specify number: _____ (per month)
 - b. EGFR
Please specify number:_____ (per month)
 - c. PD-L1
Please specify number:_____ (per month)
 - d. BRAF
Please specify number:_____ (per month)
10. Where are archived tissues from lung cancer patients stored?
- i. On-site
 - ii. Off-site

11. If on-site; how long are tissues stored on site until transferred to other storage facility?
 - i. Never
 - ii. <1 yr
 - iii. 1-2 yrs
 - iv. >2 yrs

12. What is the typical turn-around time from tissue/specimen extraction to the report of biomarker testing results in lung cancer patients?
 - i. <1 week
 - ii. 1 – 2 weeks
 - iii. >2 weeks

13. How are the following biomarker testing funded at your lab?
 - i. Local funding (financed through pathology / lab budget)
 - ii. Pharma funded initiative, please specify details
 - iii. Individual funding through high cost medicines and procedures provision
 - iv. Unsure

Response

NHS Borders do not provide any of the above services. These services are delivered in full by NHS Lothian for Borders patients. Therefore under Section 17 of the FOI(S)A 2002 this data is not held.

If you are not satisfied with the way your request has been handled or the decision given, you may ask NHS Borders to review its actions and the decision. If you would like to request a review please apply in writing to, Freedom of Information Review, NHS Borders, Room 2EC3, Education Centre, Borders General Hospital, Melrose, TD6 9BS or foi.enquiries@borders.scot.nhs.uk.

The request for a review should include your name and address for correspondence, the request for information to which the request relates and the issue which you wish to be reviewed. Please state the reference number **121-18** on this request. Your request should be made within 40 working days from receipt of this letter.

If following this review, you remain dissatisfied with the outcome, you may appeal to the Scottish Information Commissioner and request an investigation of your complaint. Your request to the Scottish Information Commissioner should be in writing (or other permanent form), stating your name and an address for correspondence. You should provide the details of the request and your reasons for dissatisfaction with both the original response by NHS Borders and your reasons for dissatisfaction with the outcome of the internal review. Your application for an investigation by the Scottish Information Commissioner must be made within six months of your receipt of the response with which you are dissatisfied. The address for the Office of the Scottish Information Commissioner is, Office of the Scottish Information Commissioner, Kinburn Castle, Doubledykes Road, St Andrews, Fife.