

2018-145 - FOI Request - Biomarker testing

1. Do you currently offer a biomarker testing for the following, as of the beginning of 2018?

PD-L1 in NSCLC	
Yes, in house service	
Yes, but send out PD-L1 testing to another laboratory (Please specify which laboratory samples are sent to:	Royal Liverpool & Broadgreen University Hospital Trust.
No, and do not send to another laboratory	
ALK in NSCLC	
Yes, in house service	
Yes, but send out ALK testing to another laboratory (Please specify which laboratory samples are sent to:	Genomics Diagnostic Laboratory, Manchester FT
No, and do not send to another laboratory	
BRAF in Melanoma	
Yes, in house service	
Yes, but send out BRAF testing to another laboratory(Please specify which laboratory samples are sent to:	Genomics Diagnostic Laboratory, Manchester FT
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?

IHC	
Yes, done at same lab or site	√
No, sent to another lab or site Please specify which laboratory samples are sent to:	
FISH /ISH/ NGS / PCR	
Yes, done at same lab or site	
No, sent to another lab or site	√
Please specify which laboratory samples are sent to:	Christie Hospital Manchester

3. Is biomarker testing performed reflexively or upon request for the following biomarkers?

PD-L1 in NSCLC	
Reflexively (i.e. prior to starting 1L treatment)	
Upon request (i.e. case by case after disease progression) -	√
If reflexively - What is the laboratory protocol for PD-L1 testing in lung cancer patients	
Multi-marker panel (i.e. multiple biomarkers, one test)	
Sequential single gene (i.e. one biomarker, one test)	
Other (Please specify)	
ALK for NSCLC	
Reflexively (i.e. prior to starting 1L treatment)	
Upon request (i.e. case by case after disease progression) -	√
If reflexively - What is the laboratory protocol for ALK testing in lung cancer patients	
Multi-marker panel (i.e. multiple biomarkers, one test)	
Sequential single gene (i.e. one biomarker, one test)	
Other (Please specify)	
BRAF in Melanoma	
Reflexively (i.e. prior to starting 1L treatment)	
Upon request (i.e. case by case after disease progression) -	√
If reflexively: What is the laboratory protocol for BRAF testing in melanoma patients	
Multi-marker panel (i.e. multiple biomarkers, one test)	
Sequential single gene (i.e. one biomarker, one test) Other (Please specify)	

4. Which of the following biomarkers are assessed in lung cancer patients in your laboratory? (please select all that apply)

ALK
EGFR
ROS1
DLL3
PDL-1

5. Which of the following testing platforms are used at this laboratory? (Please select all that apply)

FISH	
NGS	
PCR	
IHC	√
Other	

6. What IHC staining platform(s) are used in the laboratory for biomarker testing? (please select all that apply)

Ventana	√
Dako	
Leica	
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?

IVD CDx (commercial)	√
LDT (lab developed)	
None	

What is the main factor in this decision?

Funding constraints	
Control over methodology	√
Other (Please specify)	Quality, standardisation

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?

Yes	?
No	

9. What is the number of samples being tested (or sent-out) are tested for the following biomarkers?

ALK

Please specify number: 0 (per month) Based on March 2018

EGFR

Please specify number: 1 (per month) Based on March 2018

PD-L1

Please specify number: 1 (per month) Based on March 2018

BRAF

Please specify number: 3 (per month) Based on March 2018

10. Where are archived tissues from lung cancer patients stored?

On-site -	✓
Off-site	

11. If on-site; how long are tissues stored on site until transferred to other storage facility?

Never	
<1 yr	
1-2 yrs	
>2 yrs	Permanently stored on site until disposal date.

12. What is the typical turn-around time from tissue/specimen extraction to the report of biomarker testing results in lung cancer patients?

<1 week	
1 - 2 weeks	
>2 weeks	✓

13. How are the following biomarker testing funded at your lab?

Local funding (financed through pathology / lab budget)	Some
Pharma funded initiative, please specify details	
Individual funding through high cost medicines and procedures provision	Possibly some
Unsure	