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Our ref: 4636

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Freedom of information request

I am writing in response to your request for information which has been handled under the Freedom of Information Act 2000 (FOIA).

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: [Queen Elizabeth Hospital, Birmingham](#))

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: [Source BioScience](#))

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: [Royal Surrey County Hospital](#))

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: [As above](#))

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: _____)

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) [upon request at Multi-Disciplinary Meeting](#)

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) [upon request at Multi-Disciplinary Meeting](#)

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) [upon request at Multi-Disciplinary Meeting](#)

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 – [sent away](#)

EGFR – [sent away](#)

ROS1 - No

DLL3 - No

PDL-1 – [sent away](#)

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

- FISH
- NGS
- PCR
- IHC
- Other

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

- 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? N/A

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

What is the main factor in this decision?

- Funding constraints
- Control over methodology
- 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?

- Yes
- No

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

ALK
Please specify number: ___8___ (per month)

EGFR
Please specify number: ___8___ (per month)

PD-L1
Please specify number: ___9___ (per month)

BRAF
Please specify number: ___5___ (per month)

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

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)
Pharma funded initiative, please specify details
Individual funding through high cost medicines and procedures provision
Unsure