

Information Governance

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Ref: FOI2018/4527

Date Received: 9th March 2018
Response Due: 10th April 2018

29th March 2018

Dear

INFORMATION REQUEST UNDER THE FREEDOM OF INFORMATION ACT 2000

We are now pleased to respond to your request for information under the FOI Act.

You asked

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:_____)

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:_____)

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:_____)

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:_____)

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 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_____)

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: _____ (per month)
EGFR
Please specify number:_____ (per month)
PD-L1
Please specify number:_____ (per month)
BRAF
Please specify number:_____ (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?

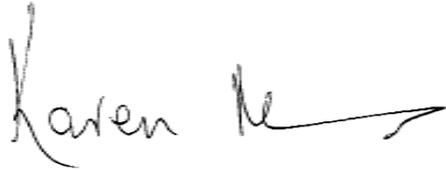
Local funding (financed through pathology / lab budget)
Pharma funded initiative, please specify details
Individual funding through high cost medicines and procedures provision
Unsure

Salford Royal NHS Foundation Trust and Wrightington, Wigan and Leigh NHS Foundation Trust have joined forces to create a joint pathology service called Pathology at Wigan and Salford.

This information should be held by Salford Royal NHS FT. Please submit a request to them by emailing FOIrequest@srft.nhs.uk or informationsecurity&dataprotection@srft.nhs.uk,

I trust that this information is helpful to you, however if you are not entirely satisfied with this response please do not hesitate to contact the Information Governance Department on 01257 488271. If we do not hear from you within 28 days we will assume that we have been able to accommodate your request under the Freedom of Information Act 2000.

Yours sincerely,

A handwritten signature in black ink that reads "Karen Morris". The signature is written in a cursive style with a long horizontal stroke at the end.

Karen Morris
Information Governance Officer

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If you are unhappy with the service you have received in relation to your request and wish to make a complaint or request a review of our decision, you should write to: Information Governance Department, Wrightington, Wigan and Leigh NHS Foundation Trust, Wrightington Hospital, Hall Lane, Appley Bridge, Wigan, WN6 9EP

If you are not content with the outcome of your complaint, you may apply directly to the Information Commissioner for a decision. Generally the ICO cannot make a decision unless you have exhausted the complaints procedure at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF