

Ref: 01918\_03955\_2018-03-28\_01  
Date: 28 March 2018

Standing Way  
Eaglestone  
Milton Keynes  
MK6 5LD  
Tel: 01908 660033  
[www.mkhospital.nhs.uk](http://www.mkhospital.nhs.uk)  
For people who have hearing loss  
Minicom 01908 243924

**Request under Freedom of Information Act 2000**

Thank you for your request for information which we received on 09 March 2018.

I am pleased to confirm the following:

**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: **Source BioScience** \_\_\_\_\_)

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: **John Radcliffe 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: **Source BioScience** \_\_\_\_\_)

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: **Source BioScience** \_\_\_\_\_)

**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).....both**

*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 **Unknown** \_\_\_\_\_)

ALK for NSCLC

**Reflexively (i.e. prior to starting 1L treatment)**

**Upon request (i.e. case by case after disease progression).....both**

*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)....both**

Other (Please specify \_\_\_\_\_)

BRAF in Melanoma

**Reflexively (i.e. prior to starting 1L treatment)**

**Upon request (i.e. case by case after disease progression)....both**

*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 **unknown** \_\_\_\_\_)

**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:   6   (per month)

EGFR

Please specify number:   6   (per month)

PD-L1

Please specify number:   9   (per month)

BRAF

Please specify number:   2   (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

**1-2 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 – 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

The lab is in the process of moving the PD-L1 and EGFR/ALK testing to the Royal Brompton and The Marsden Hospital respectively due to recent poor turnaround times received from Source BioScience.

You are advised that this information is provided in accordance with the Freedom of Information Act 2000 and is for your personal use. Any re-use of this information will be subject to copyright and the Re-Use of Public Sector Information Regulations (1st July 05) and authorisation from Milton Keynes Hospital NHS Foundation Trust will be required. In the event of any re-use, the information must be reproduced accurately and not used in a misleading manner.

If you are unhappy with the information received in response to this request, please address your complaint to the Patient Affairs Office at Milton Keynes Hospital NHS Foundation Trust, Standing Way, Eaglestone, Milton Keynes MK6 5LD. If, after exhausting our internal process, you are still unhappy with the information received, you may write to the Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

If you need any further assistance, please do not hesitate to contact us at the address above.

Yours sincerely,

Freedom Of Information Co-ordinator  
For and on behalf of Milton Keynes Hospital NHS Foundation Trust

<p>Any re-use of this information will be subject to the 'Re-use of Public Sector Information Regulations' and best practice.</p>
---------------------------------------------------------------------------------------------------------------------------------------