The Dudley Group
NHS Foundation Trust

Freedom of Information request 013992

3 April 2018

For convenience, most questions are multiple choice, with space for extra details where relevant.
In each case please mark all that apply

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:__**UHB**___
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:_**UHB**__
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:_ **UHB_**
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:__**UHB**__

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:_**UHB**_

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) After MDT discussion
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) After MDT discussion
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: ___**10**___ (per month)

EGFR
Please specify number:___**10**___ (per month)

PD-L1
Please specify number**:____10__** (per month)

BRAF
Please specify number:__**14_** (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

Thank you very much for taking the time to complete this FOI questionnaire as fully as you are able.