

Freedom of Information Request: Our Reference CTHB_103_18

You asked:

For convenience, most questions are multiple choice, with space for extra details where relevant.

In each case please mark all that apply

Please see our responses highlighted in yellow below:

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: All Wales molecular genetics laboratory (AWMGL) UHW)
- 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:All Wales molecular genetics laboratory UHW)
- 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:UCLAD or AWMGL UHW)

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) but with reflex section preparation for all ICC cases to avoid delay following MDT decision

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) but with reflex section preparation for all ICC cases to avoid delay following MDT decision

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: IVD kit that is ready to use and requires no adjustment from lab)

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 the PDL1 testing has been funded through the NICE budget
- No

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

ALK

Please specify number: ____1____ (per month)

EGFR

Please specify number: ____4____ (per month)

PD-L1

Please specify number:____12_ (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 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 – PDL1
- 1 – 2 weeks – EGFR,Alk
- >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 PDL1
- Central All Wales funding for EGFR/Alk