

Ref: FOI/CAD/ID 3383

Please reply to:
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29 June 2016

Freedom of Information Act 2000

I am writing in response to your request for information made under the Freedom of Information Act 2000 in relation to PD-L1 testing.

I would like to access information with regard to PD-L1 testing offered by your institution as detailed in the document attached; this testing will likely be performed in pathology/histopathology laboratories. If your institution does not currently offer PD-L1 testing in-house then I would please ask that the request is still sent to the relevant laboratory as there are questions included regarding whether they send samples for this testing to be conducted in other laboratories and also whether they have any plans to introduce this testing in-house in the future. If your institution does not in fact have any testing laboratories then do please let me know.

Please see the completed attached form:

PD-L1 Freedom of Information request

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

In each case please all that apply

1. Do you currently offer an in-house clinical testing service for PD-L1?
 - Yes
 - No
 - Evaluating
 - Validating

Send-out PD-L1 testing to another laboratory

If you have selected Evaluating or Validating above, when do you predict that your PD-L1 test will be available for clinical use?

If you have selected send-out testing above, to which laboratory do you send

To the laboratory directed to us according to EAMS scheme in operation

samples for PD-L1 testing?

2. If you are offering, or sending out, for PD-L1, when is this testing typically being conducted? For example, is it being tested for in parallel with ALK/EGFR in lung cancer or after these

On request from Oncologist following eligibility review according to EAMS scheme

tests? Is it tested at diagnosis or on request following an MDT meeting?

If you offer, or send-out for, PD-L1 testing, please also provide as much of the following information as you are able:

3. What is the number of samples being tested (or sent-out) for PD-L1 (per month or per year, whichever is easier to determine, delete below as appropriate)? Please break this down by

Of which:	Total number:	7-10 per month
	Lung:	7-10 per month/
	Melanoma:	per month/year (delete as appropriate)
	Other (please specify):	per month/year (delete as appropriate)

tissue type if possible.

4. How many methods do you (or the lab to which you send-out your samples) have available to test for PD-L1?

- One as far as we know
 Two
 Three
 >3

5. For the number of PD-L1 methodologies available as stated in question 4 above, please state how many are being performed using a kit and how many using a laboratory developed test?

Number of kit methods offered = all as far as we know

Number of LDT methods offered = unknown

6. If a kit(s) is used, which kit(s)? (Tick all that apply)

- Dako PD-L1 IHC 22C3 pharmDx
 Dako PD-L1 IHC 28-8 pharmDx
 Other(s) (please specify):

7. If an LDT is used, which Antibody(ies) is being used?

- 22C3
- 28-8
- E1L3N
- SP142
- SP263
- Other(s) (please specify):

8. If multiple methods are offered, what testing algorithm is used to determine which method(s) will be used?

9. What platform(s)/Autostainers are used in the laboratory that performs the PD-L1 testing e.g. Ventana, Dako etc?

- Ventana (please specify):
- Dako (please specify): unknown
- Leica (please specify):
- Other (please specify):

10. What clinical cutoff(s) of positive cells in a biopsy are used for the PD-L1 method(s) used?

Depends on EAMS scheme. Their criteria are followed

11. What percentage of samples that you test (or send out) for PD-L1 testing) are found to be

Unknown at this time

positive?

12. What is the average turnaround time from sample receipt to report being issued?

13. What are the current bottlenecks that prevent this turnaround time from being quicker?

none

< 7days

14. For what specific cancer(s) is PD-L1 testing being offered/requested?

According to open EAMS schemes

15. Is the cost of the test an issue when choosing to order PD-L1 testing?

- Yes

No

16. Is your PD-L1 testing funded locally or by a pharma-funded initiative?

Local funding

Pharma-funded initiative. Please specify the pharma initiative:
Pembrolizumab scheme currently open but have had other schemes.