The Dudley Group
NHS Foundation Trust

Date: 07/04/2017

FREEDOM OF INFORMATION REQUEST 013367 – PD-L1 testing

The requested information will be held within your pathology/histopathology laboratories and is in relation to PD-L1 testing offered. Attached to this email is a questionnaire, in a multiple-choice tick box format. The nature of the information requested and the format of the questionnaire should mean that this will not be time consuming for the laboratories to complete. Even if PD-L1 testing is not performed in-house by your own laboratories, please still forward the questionnaire to the relevant department, as the laboratory may send-out their PD-L1 testing to an external institution and information regarding the institution to which they send their samples is also relevant to this request.

In each case please ☑ all that apply

1. Do you currently offer a clinical testing service for PD-L1 in non-small cell lung carcinoma (NSCLC) as off the beginning of 2017?
   - ☐ No
   - ☐ Validating
     - Please specify when you predict this service with be available for clinical use:
   - ☐ Yes, in-house clinical service
   - ☑ Yes, but send-out to an external laboratory
     - Please specify which external laboratory samples are sent to: **University Hospital Birmingham**

2. How is PD-L1 testing in NSCLC normally requested by the clinician? (please select all that apply)
   - ☑ As a retrospective test on archived NSCLC samples that have already had EGFR and ALK testing
   - ☑ As a standalone test for newly diagnosed NSCLC samples
   - ☑ As part of a NSCLC panel of tests (PD-L1, EGFR, ALK) for new diagnosed NSCLC samples
   - ☐ Other, please specify:

3. If requested as part of a NSCLC panel of tests, how is PD-L1 testing performed in the lab
   - ☐ Prior to EGFR and ALK
   - ☑ Sequentially after EGFR and ALK
   - ☐ In parallel with EGFR and ALK
   - ☐ Other, please specify:

4. What sample types are processed by the lab for NSCLC testing (EGFR/ALK/PD-L1)? (please select all that apply)
   - ☑ Resection
   - ☑ Needle Core Biopsy
   - ☑ EBUS cytology
   - ☑ EBUS cytological cell block
   - ☐ Other, please specify:

5. What is the number of NSCLC samples being tested (or sent-out) are tested for:?
   - ☐ ALK *Please specify number:* 10-15 (per month)
   - ☐ EGFR *Please specify number:* 10-15 (per month)
   - ☐ PD-L1 *Please specify number:* 10-15 (per month)

6. What proportion of PD-L1 NSCLC samples tested are cytology/ cytological cell block samples? (per month or per year or as a percentage of PD-L1 samples tested, whichever is easier to determine)
   10% (data from Jan/Feb 2017)

7. What proportion of PD-L1 NSCLC samples are NOT tested because the samples are EBUS/cytology samples? (per month or per year or as a percentage of PD-L1 samples tested, whichever is easier to determine)
   0% (data from Jan/Feb 2017)

8. What methods are used for PD-L1 testing in NSCLC and their associated clinical cut-off? (please select all that apply)

   ☑ Dako PD-L1 IHC 22C3 pharmDx

   - ☐ Dako PD-L1 IHC 28-8 pharmDx
   - ☐ Ventana PD-L1 (SP263) Assay
   - ☐ Ventana PD-L1 (SP142) Assay
   - ☐ 22C3 Standalone antibody
   - ☐ 28-8 Standalone antibody
   - ☐ E1L3N Standalone antibody
   - ☐ SP142 Standalone antibody
   - ☐ SP263 Standalone antibody
   - ☐ Other(s) (please specify):

9. What is the clinical cut offs are used in relation to the antibodies selected above?

1/ Second line treatment with Pembrolizumab Adult patients who have received at least one prior chemotherapy regime and have a PD-L1 expression TPS of >1% are eligible for treatment with Pembrolizumab for locally advanced or metastatic non-small cell lung carcinoma (NSCLC). Patients with EGFR or ALK positive tumour mutations should also have received therapy for these mutations prior to receiving Pembrolizumab. 2/ First line treatment with Pembrolizumab Treatment naive patients with a PD-L1 expression TPS of >50% are eligible for treatment with Pembrolizumab for metastatic non-small cell lung carcinoma (NSCLC) through the Pembrolizumab EAMS.

e.g. Dako 22C3 pharmDx ≥ 1% = positive or ≥ 50% = positive)
(e.g. Dako 22C3 pharmDx ≥ 1% = positive or ≥ 50% = positive)

10. What IHC staining platform(s) are used in the laboratory that performs the PD-L1 testing e.g. Ventana,

Ventana

Dako, Leica, Menarini, Shandon, Labvision, etc? (If possible, please supply the model of the platform)

11. What percentage of samples tested have ≥1% PD-L1 expression?
12. What percentage of samples tested have ≥50% PD-L1 expression

Questions 11 & 12 - Manual search through reports required to provide this data

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

Unable to complete this as not clear what turnaround is being requested – time from initial specimen receipt to PDL1 report being issued or from when sample sent for PDL1 testing to external laboratory.

14. Are there bottlenecks that prevent this turnaround time from being quicker?

Only bottleneck is the reliance on off site testing as transport of specimen to another laboratory adds in an inherent delay.

12. Who pays for DLBCL testing?

- ☐ Heamatologists
- ☑ Laboratory
- ☐ Commissioners
- ☐ National Services Division
- ☐ Other, please specify details
- ☐ Pharma initiative, please specify details