

# PD-L1 Project update report

**Jingxin Qiu**

**Professor of Oncology**

**Roswell Park Comprehensive Cancer Center**

### **IQN Path PD-L1 portal of gold standard digital images:**

Portal of gold standard digital images for IQN Path member EQAs to use in PD-L1 interpretation assessment

- Enable international self-assessment by providing a resource of gold standard images delivered within an image management platform for participating IQN Path EQA members to use.
- Expert committee of scoring pathologists (Industry & EQA) evaluate slides & assign consensus scores.
- High resolution images of PD-L1 stained slides of various PD-L1 staining + H&E (No negative controls).

**Acquisition of images:**

- PD-L1 FDA approved biomarkers (PD-L1 IHC 22C3 pharmDx, PD-L1 IHC 28-8 pharmDx, VENTANA PD-L1 (SP263), VENTANA PD-L1 (SP142) Assay) in non-small cell lung cancer (NSCLC).
- Slides &/or digital images provided by Industry partners & pathologists (from routine practice).
- Slides scanned & uploaded to a digital image management portal - Philips (<https://www.pathxl.co.uk/>).

**Consensus scoring & expert pathologist committee:**

- A committee of expert scoring pathologists was established with representation from experts worldwide. Both academic practicing pathologists and also experts and industry scoring pathologists were involved.
- Scoring was organized into buckets according to clinical cut-offs relevant to the FDA-approved IHC assays.

### **Pilot set up:**

- Participants were provided access to 10 cases for each biomarker via the portal - biopsies and some resections
- Images covered a variety of scores & difficulty based on expert pathologist assessment & feedback.
- Wording of survey questions & answers were based on approved guidelines for each FDA-approved assay.
- Pilot participants suggested by local EQA schemes (20-30 at any one time). Participants were asked to score slides following instructions from the FDA-approved IHC assays using clinically-relevant cut-offs.
- Scoring was completed within specified time-frame: 1st pilot: 30th Aug 2018, 2nd pilot: 30th Sep 2018.
- 1st pilot: 23 individual assessments performed by 13 pilot participants worldwide - ESP (Europe) (3); RCPAQAP (Australia) (6); CIQC (Canada) (3); CCPI (China) (1).
- Pilot participants were asked for feedback on general ease of use & any portal technical issues.

**Summary of cases:**







	<b>22C3</b>	<b>28-8</b>	<b>SP263</b>	<b>SP142</b>
Total no. of scanned cases on portal	86	29	23	20
No. of cases assessed by expert pathologists	30	29	23	20
No. of experts assessing each clone (No. of scorers from Industry)	6 (1)	3 (1)	2 (1)	1 (1)
No. of 1 <sup>st</sup> pilot participants assessing each clone	10	3	8	2

- Closed the Pilot 2018
- Feedback technical issues to portal host (e.g. to have PD-L1 & H&E images side-by-side & synchronised)
- Feedback results to-date to expert scorers and pilot participants (requests have been received for this)
- After ascertaining commitment for further development, develop plans for roll-out and associated budgetary requirements for example to extend to other cancer types (GI/GEJ, Cervical, bladder, head and Neck, etc.) and other scoring methods such as combined positive scores (CPS and etc.)

<https://www.ciqcreadout.com/>

The screenshot shows the CIQC Path website. At the top left, the logo for CIQC Path is visible. On the top right, there are navigation links: ABOUT, SIGN UP, LOGIN, and CONTACT US. The main heading is "CAP-ACP / CIQC Proficiency Testing" with the subtitle "Certifying Pathologists' Interpretive Skills". Below this are two buttons: "SIGN UP" (orange) and "LOGIN" (purple). The background of the top section is a dark purple image of a microscope.

## Proficiency Testing

-  BIOMARKER READOUT
-  MALARIA
-  PD-L1  
This exercise will test your readout
-  HER2 Gastric Ca  
This exercise will test your readout
-  HER2 Breast Ca  
This exercise will test your readout
-  ER/PR Breast Ca  
This exercise will test your readout



# PD-L1

**You must be registered and signed-in in order to take the test's for this module and gain Proficiency Testing upon passing.**

**Please select an ASSAY to continue..**

VENTANA PD-L1 (SP142) Assay, NSCLC, atezolizumab  
VENTANA PD-L1 (SP142) Assay, Urothelial carcinoma (UC), atezolizumab  
VENTANA PD-L1 (SP263) Assay, NSCLC, nivolumab  
VENTANA PD-L1 (SP263) Assay, Urothelial carcinoma (UC), durvalumab  
PD-L1 IHC 28-8 pharmDx, Non-Squamous NSCLC (nsNSCLC), nivolumab  
PD-L1 IHC 28-8 pharmDx, Squamous cell carcinoma of the head and neck (SCCHN), nivolumab  
PD-L1 IHC 28-8 pharmDx, Urothelial carcinoma (UC), nivolumab  
PD-L1 IHC 28-8 pharmDx, Melanoma, nivolumab & ipilimumab  
PD-L1 IHC 22C3 pharmDx, NSCLC, pembrolizumab  
PD-L1 IHC 22C3 pharmDx, Gastric and GEJ Ca, pembrolizumab  
PD-L1 IHC 22C3 pharmDx, Cervical Ca, pembrolizumab  
PD-L1 IHC 22C3 pharmDx, Urothelial carcinoma (UC), pembrolizumab

Please select an ASSAY to continue..

PD-L1 IHC 22C3 pharmDx, NSCLC, pembrolizumab



## Definition of Tumor Proportion Score (TPS)

This scoring is relevant to pembrolizumab, pharmDx 22C3 for NSCLC and nivolumab, pharmDx 28-8 for nsNSCLC, SCCHN, UC, and nivolumab/ipilimumab for melanoma.

The Tumor Proportion Score is the percentage of viable tumor cells showing partial or complete membrane staining (? 1+) relative to all viable tumor cells present in the sample (positive and negative). **Guidelines and Methods to Determine Tumor Proportion Score** At low magnification, examine all well-preserved tumor areas. Evaluate overall areas of positive and negative tumor cells, keeping in mind that partial membrane staining or 1+ membrane staining may be difficult to see at low magnification. Ensure there are at least 100 viable tumor cells in the sample At higher magnifications, including 10x, 20x, and 40x, observe all tumor areas with and without cell membrane staining At this stage of working with multiple magnifications, primary analysis involves: ◆ Distinguishing tumor cells from tumor-associated immune cells ◆ Determining positive tumor areas and negative tumor areas ◆ Determining partial and complete membrane staining ? 1+ Calculate the Tumor Proportion Score by evaluating the percentage of PD-L1 positive tumor cells relative to all viable tumor cells present in the specimen. **Note:** Carefully consider the overall tumor area without any perceptible and convincing cell membrane staining **Make sure to exclude immune cells and necrotic tissue from scoring** The following considerations can help distinguish tumor cells from immune cells: Immune cells may have smaller nuclei than tumor cells Macrophages may contain pigmented particles in their cytoplasm Macrophages may have a scattered distribution. Pulmonary macrophages are present in the alveolar space.

Please select an ASSAY to continue..

PD-L1 IHC 22C3 pharmDx, NSCLC, pembrolizumab

  
 TEST DETAILS

  
**READOUT CRITERIA**

  
 START TEST

## Resources

Please review the following resources before starting the test.

File	Download Link	Resource id	Resource Name	Resource URI
1	<a href="#">22C3 pharmDx for nsclc for pembrolizumab.pdf</a>	9	1	http://testotherur
2	<a href="#">Z_multiple_22C3 PD-L1 IHC pharmDx for NSCLC- GEJ- Cervical Ca- UC.pdf</a>	19	2	http://testotherur

Please select an ASSAY to continue..

PD-L1 IHC 22C3 pharmDx, NSCLC, pembrolizumab



TEST DETAILS



READOUT CRITERIA



START TEST

## Cases and Slide Viewer

Each questions slide will appear just below the question number. The slide will open in a new "Tab" within your browser.

We strongly recommend clicking on the "full screen" button (the left most button) after the slide has appeared.

The "Home" button within the slide viewer will reset the ZOOM.

Click the "full screen" button again to exit out of full screen. Close the "Tab" for the slide when you are no longer needing to view it.

You need to be registered and signed in to take this test

PLEASE ENTER YOUR INFORMATION BELOW

**PLEASE NOTE:** If the correct membership options are not selected and applied, the tests will not be free.

First name*		Last name*	
<hr/>		<hr/>	
Degree*	Other Degrees	Profession*	
MD	<hr/>	Pathologist	
Password* (8 Characters minimum)			
<hr/>			
Confirm Password*			
<hr/>			
E-mail*			
<hr/>			
Country*		Province*	
Australia		Sask	

Your email address used during the sign-p process must be the same as the email address used for your CAP-ACP membership. Valid membership will be verified by CAP-ACP

CAP-ACP Member

IQN Path members must use the supplied IQNPATH affiliation code. Valid membership will be verified by an IQN PATH affiliation code.

IQN Path Member

Affiliation Code

---

SUBMIT

# Live Demo