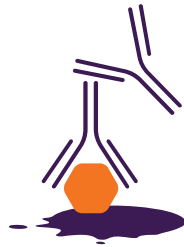




# DISCOVERY

L I F E S C I E N C E S <sup>TM</sup>

Science at your Service <sup>TM</sup>



## VALIDATED IHC BIOMARKERS

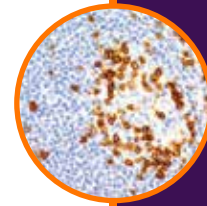
Discovery's validated assays are developed, optimized, and rigorously tested for sensitivity, specificity, expression rate, precision and reproducibility to ensure dynamic and robust performance for your clinical trial or companion diagnostic programs.

## Use the Power of Discovery <sup>TM</sup>

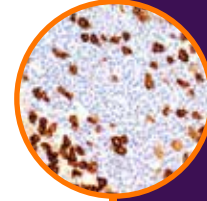
to propel your clinical trial or companion diagnostic projects with superior IHC assay validation services.

Contact us today to get your assay validation project started or ask us about our comprehensive IHC assay testing menu.

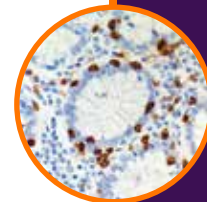
[info@dls.com](mailto:info@dls.com) | (866) 838-2798 | [www.dls.com](http://www.dls.com)



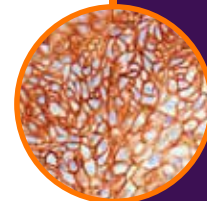
CD3



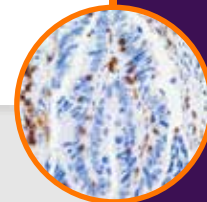
PD1



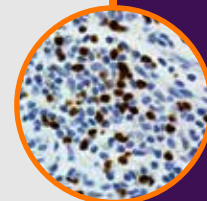
CD8



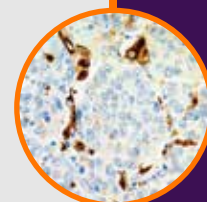
PDL1



CD4



FoxP3



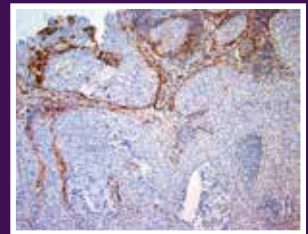
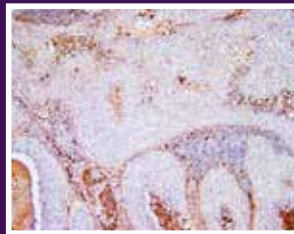
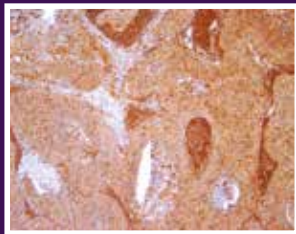
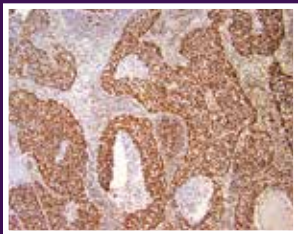
CD68

## What sets us apart?

Not all assays and antibodies are created equal... Everything starts and ends with a high quality assay that you can use to generate reliable data to make important strategic decisions. When you review a vendor's *Validated IHC Biomarkers* their definition of *validated* is critical. Our IHC assays are rigorously vetted to ensure the most accurate and optimal conditions are used and tested in the most relevant tissue types for your study.

## Assay Development Difficulties...

**... that our team has the experience to recognize and overcome**



Antibody comparison: 4 different antibodies produce 4 different answers?

## Superior Assay Validation - Beyond Optimization

Our experts have designed an industry-leading assay validation approach that starts with careful assay development and optimization, but doesn't stop there. We do more than simply demonstrate that an assay can detect a target in various conditions, we:

- ✓ Conduct large scale sensitivity screening of cancer patient populations to understand expression patterns within and among tumor indications
- ✓ Demonstrate precision and reproducibility using serial sections from samples with various levels of known target expression (from sensitivity screen)
- ✓ Analyze specificity in cell lines, xenografts, and normal human tissues
- ✓ Develop a robust scoring scheme to properly and consistently capture level of target expression
- ✓ Analyze expression rate for cut-off determination in various disease indications

## Precision and Reproducibility Testing: High Expression Level Example

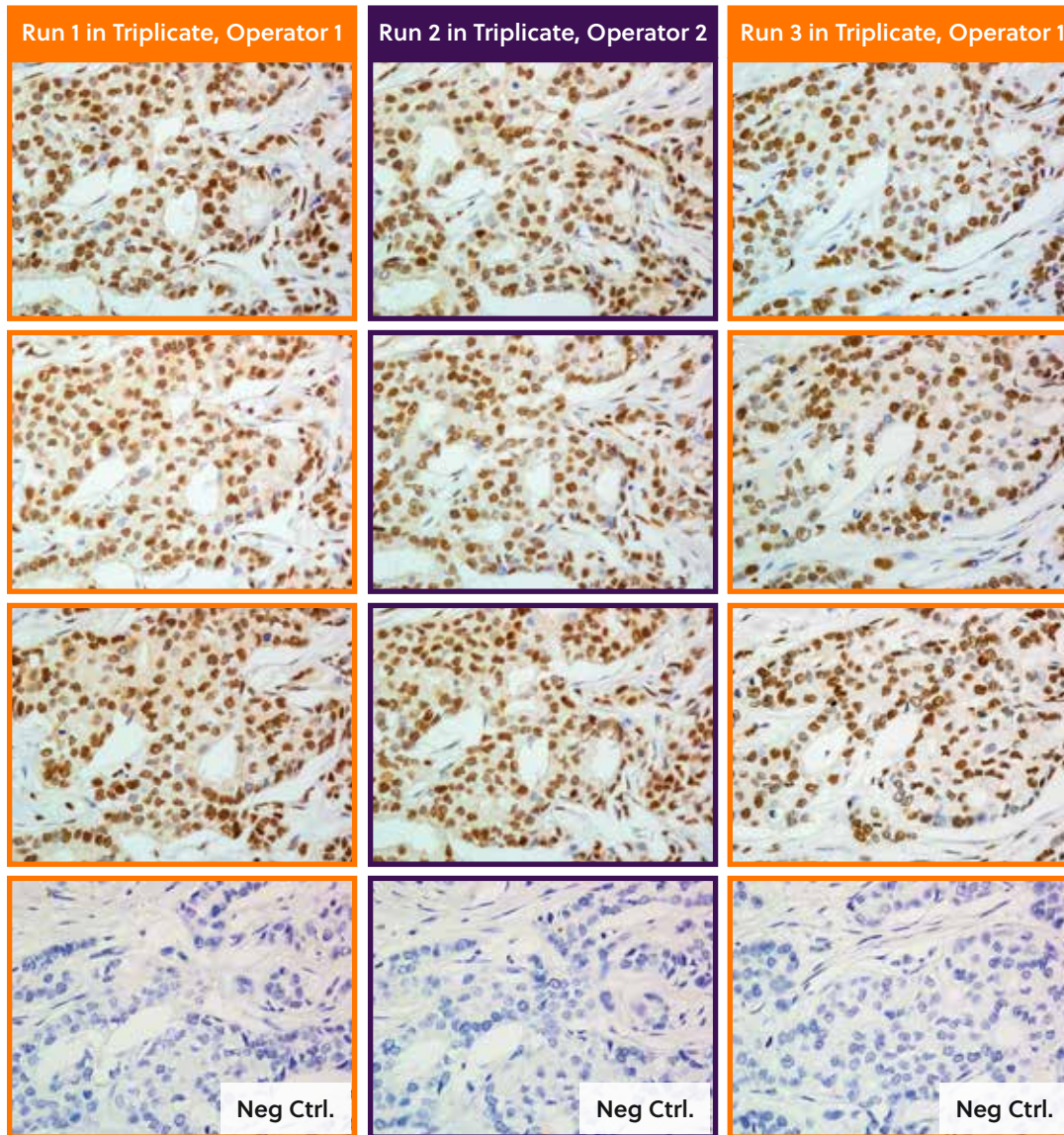


Figure 1:

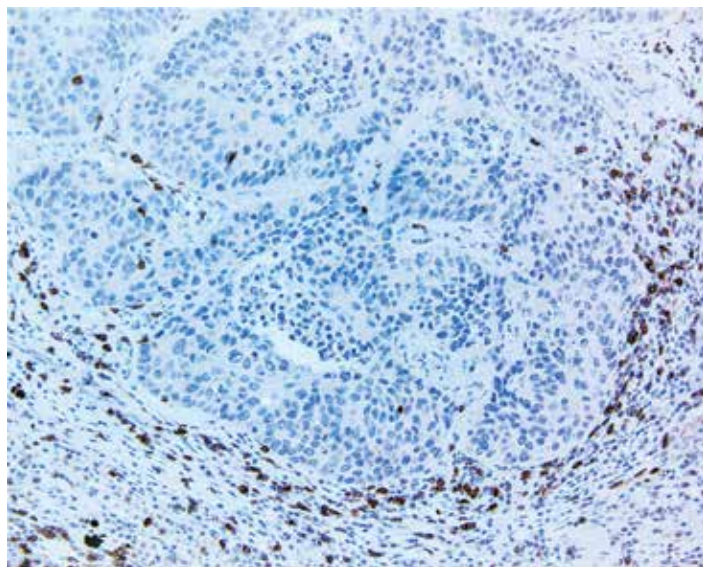
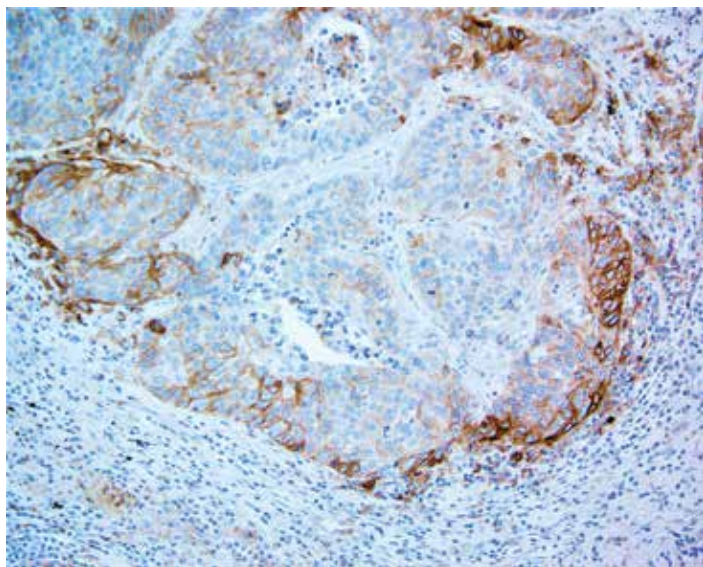
Precision and reproducibility testing is formatted such that samples from each expression level (high, moderate, low and negative) are tested in 3 different runs (only high shown here), by at least 2 different operators, in triplicate. In each run, an isotype control (e.g. Rb IgG, Ms IgG1, Ms IgG2a depending on primary antibody) is also tested as the negative control (bottom row).

## Discovery has validated a broad menu of assays for human and mouse immuno-oncology (I/O) markers.

Here are examples of human specific validated I/O assays in our service menu:

- CD3 (Total T-cells)
- CD4 (T-Helper cells)
- FOXP3 (T-Regs)
- CD8 (Cytotoxic T-Cells)
- CD20 (B-cells)
- CD68 (macrophages)
- Ki67 (proliferating cells)
- PD-1 (immune checkpoint receptor)
- PD-L1 (PD-1 ligand)





**Figure 2:**

Our validated PD-L1 (left) and PD-1 (right) assays showing positive expression in tumor and infiltrate, respectively, in serial sections of non-small cell lung cancer.

Discovery has fully validated scores of IHC assays for specific sponsor studies.

We have developed hundreds of assays, meaning we have tested multiple antibodies to a target across various pretreatment conditions, but have not performed our complete P&R validation process.

**Contact us to request our full IHC biomarker menu.**



**DISCOVERY**

L I F E S C I E N C E S

Science at your Service™

The global leader in:

**BIOSPECIMENS**

**GENOMICS**

**IHC**

**FLOW CYTOMETRY**

**Use the Power of Discovery™**

to propel your clinical trial or companion diagnostic projects with superior IHC assay validation services.

**Contact us today to get your assay validation project started or ask us about our comprehensive IHC assay testing menu.**

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