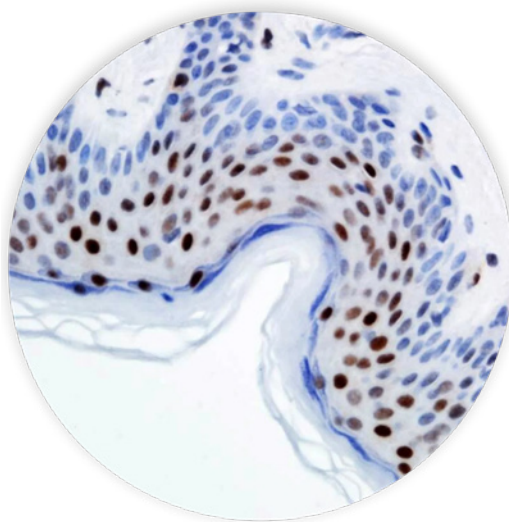# DISCOVERY

L I F E   S C I E N C E S™

Science at your Service™

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™

to propel your clinical trial or companion diagnostic projects with superior IHC assays and validation services

—

info@dls.com | (866) 838-2798 | +359 2 870-2117 | www.dls.com

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.

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:
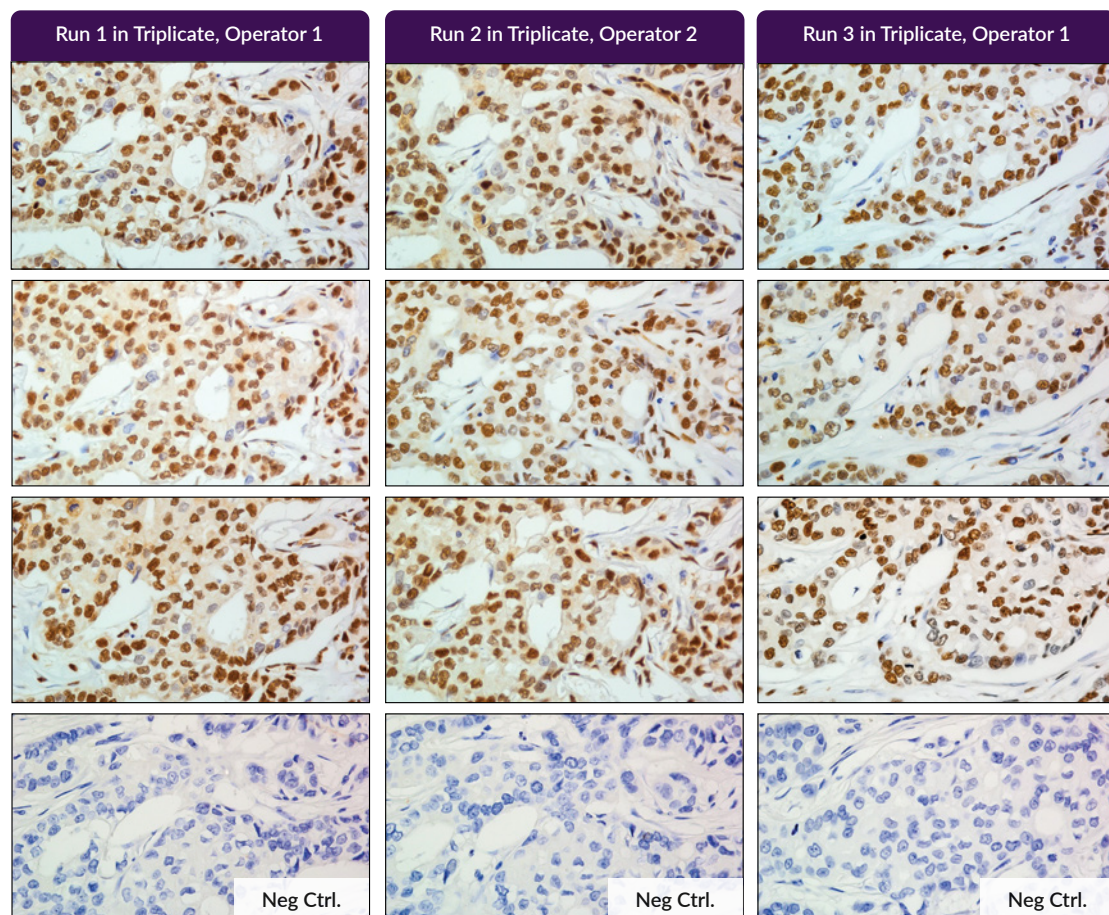
- Conduct large scale sensitivity screening of cancer patient populations to understand expression patterns within and among tumor indications

- 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

- CLIA-certified, CAP-accredited, and GCLP compliant laboratories in Europe and the US.

- Health Institution status of Discovery's laboratory in Germany confirmed by German Regional Council
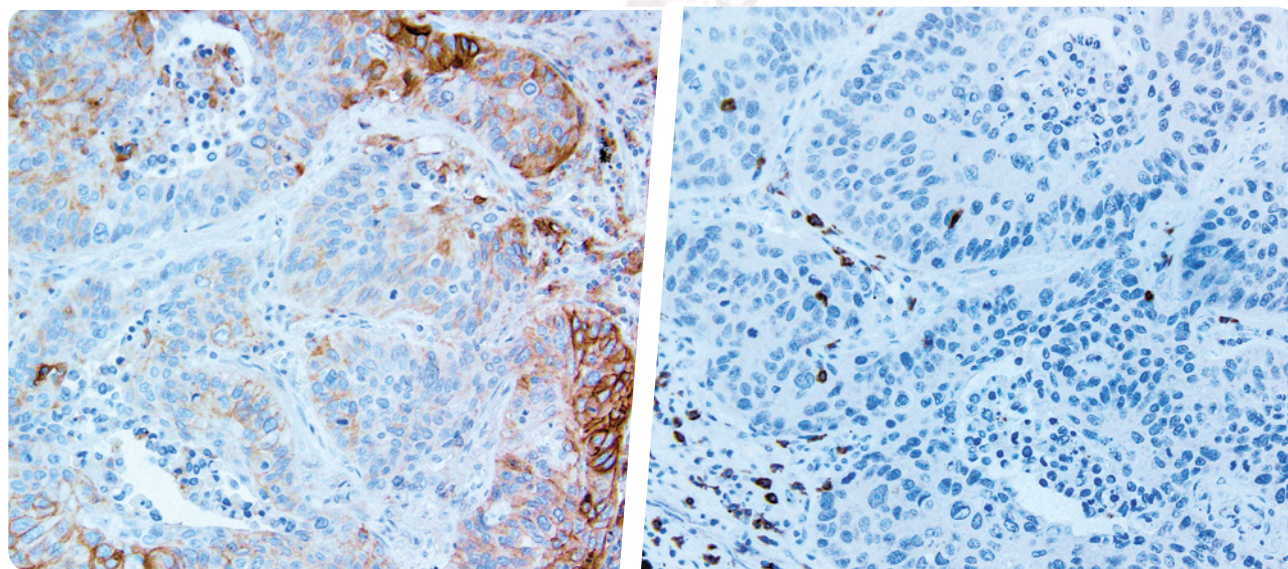
Figure 1: Our validated PD-L1 (left) and PD-1 (right) assays showing positive expression in tumor and infiltrate, respectively, in serial sections of non-small cell lung cancer.

Precision and Reproducibility Testing: High Expression Level Example

| Run 1 in Triplicate, Operator 1 | Run 2 in Triplicate, Operator 2 | Run 3 in Triplicate, Operator 1 |

Figure 2: 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 a Large Menu of Validated Assays to Support Clinical Trial and Diagnostic projects.

IVD/CE Menu

- ALK
- CD3
- CD8
- ER
- HER2
- MLH1
- MSH2
- MSH6
- PD-L1 (28-8)
- PD-L1 (22C3)
- PD-L1 (22C3)
- PR
- C-MET
- HER2
- BRAF
- EGFR
- HPV
- KRAS

LDT Menu

- CD10/MUM1
- AKT
- ATM
- AXL
- B7-H4
- BCL6
- CASPASE-3
- CD20
- CD25
- CD31
- CD58
- CD68
- CDH17
- CEA
- CEACAM5
- CLDN18
- C-MET
- ERK
- GCET1

- GPC-3
- GR
- HER2
- HRAS
- LAIR-1
- mATRC101 N297A
- MSH2
- MSH6
- Ny-Eso-1
- P53
- PD-L1
- PMS2
- PR
- PTEN
- RCC
- RCC
- ROR1
- ROR2
- Stn

- Survivin
- TIGIT
- C-MET
- FGFR
- HER2
- KRAS
- AXL
- EBV
- FGFR1
- FGFR1/FGFR2 /FGFR3
- FGFR2
- FGFR3
- FGFR4
- HPV
- LGR-5
- SLFN12/PDE3A
- FGFR
- PIK3CA

VD/CE and LDT tests are validated for specific indication(s). Consult with our experts for more detail.

If You Don't See Your Biomarker of
Interest, Contact Us for a Custom
Validation Project.

DISCOVERY
L I F E   S C I E N C E S™

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