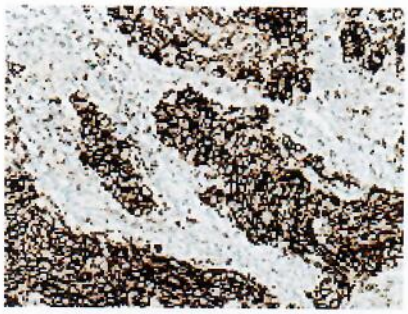
- **ROCHE TISSUE DIAGNOSTICS** | REAGENT CATALOG

VENTANA PD-L1 (SP142) Assay



Catalog Number:	741-4860
Ordering Code:	08008540001
Quantity:	50 tests
Controls:	Tonsil
Isotypes:	IgG
Clone Name:	SP142
Species:	Rabbit
Localization:	Membranous and/or Cytoplasmic Staining
Regulatory Status:	CE-IVD

VENTANA PD-L1 (SP142) Assay is intended for the immunohistochemical assessment of the programmed death-ligand 1 (PD-L1) protein in tumor cells and tumor-infiltrating immune cells in formalin-fixed, paraffin-embedded (FFPE) tissues indicated below stained with OptiView DAB IHC Detection Kit and OptiView Amplification Kit on a BenchMark IHC/ISH instrument.

Determination of PD-L1 status is indication-specific and evaluation is based on either the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity or the percentage of PD-L1 expressing tumor cells (% TC) of any intensity.

VENTANA PD-L1 (SP142) Assay is indicated as an aid for identifying patients for treatment with the therapies listed in Table 1 for the respective indications and cutoffs in accordance with the approved therapeutic product labeling.

VENTANA PD-L1 (SP142) Assay may be associated with enhanced patient benefit with the therapies listed in Table 2 for the corresponding indication and cutoffs in accordance with the approved therapeutic product labeling.

Table 1. VENTANA PD-L1 (SP142) Assay companion diagnostic indications.

Indication for use	Therapy	Cutoff
Urothelial Carcinoma	TECENTRIQ	≥5% IC
Triple-Negative Breast Carcinoma (TNBC)	TECENTRIQ	≥1% IC

Table 2. VENTANA PD-L1 (SP142) Assay complementary diagnostic indication.

Indication for use	Therapy	Cutoff
	TECENTRIQ	≥ 50% TC or ≥ 10% IC

Non-small Cell Lung Cancer (NSCLC)	≥ 1% TC or ≥ 1% IC

Test results of this product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

This product is intended for *in vitro* diagnostic (IVD) use.