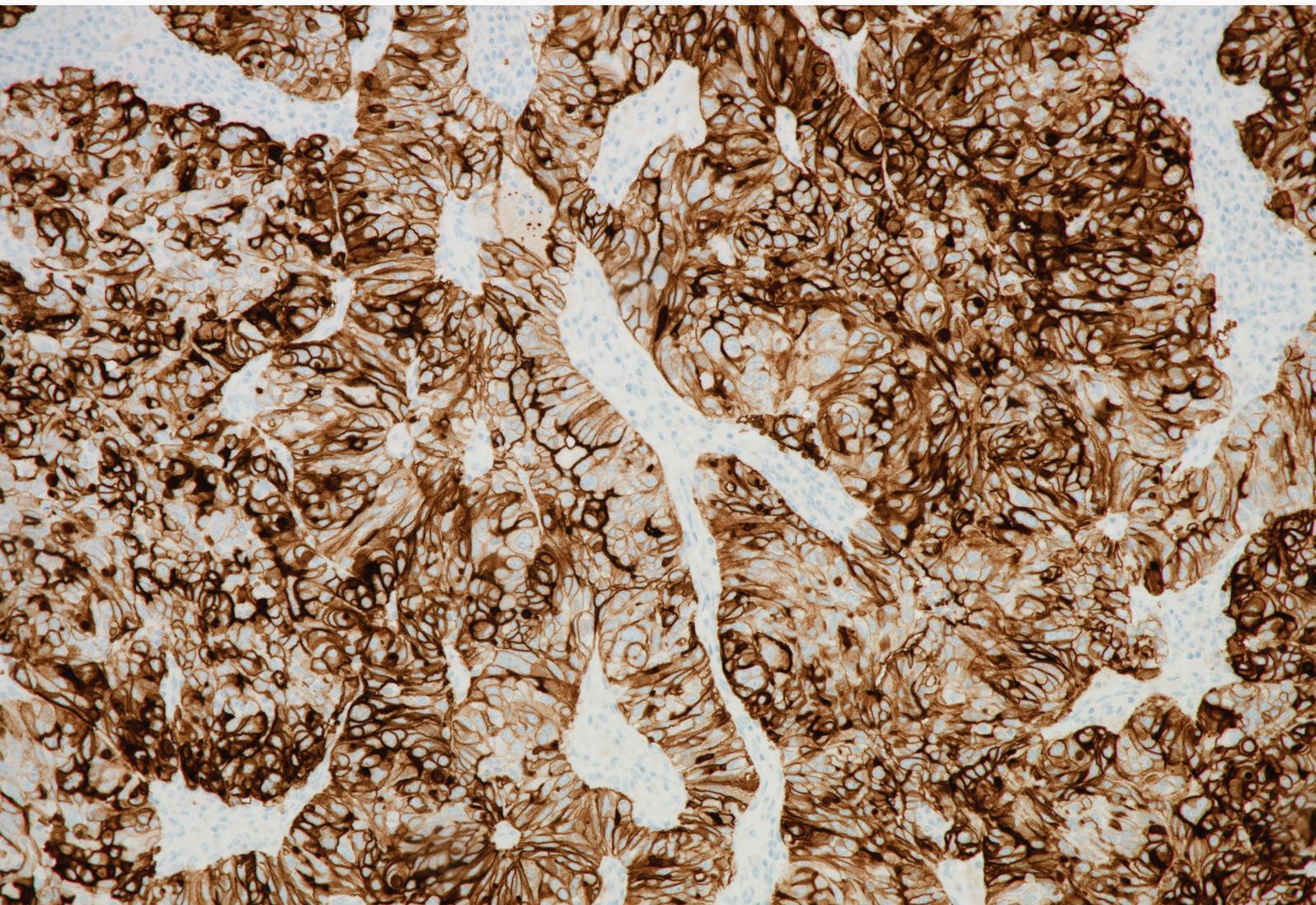
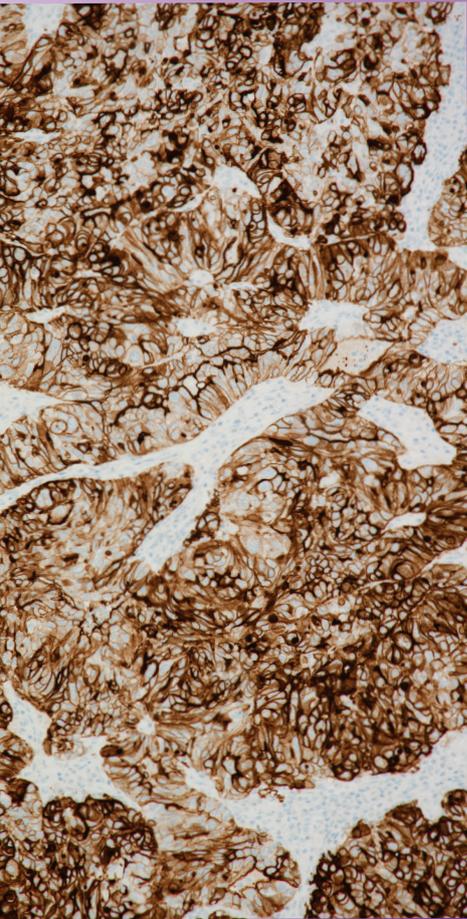


VENTANA® FOLR1 (FOLR1-2.1) RxDx Assay

Driving diagnostic certainty for life-changing
decisions in ovarian cancer





VENTANA® FOLR1 (FOLR1-2.1) RxDx Assay is the first⁴ IHC companion diagnostic for determining folate receptor alpha protein expression in epithelial ovarian cancer patients who may benefit from ELAHERE® (mirvetuximab soravtansine)

VENTANA® FOLR1 (FOLR1-2.1) RxDx Assay is a qualitative immunohistochemical assay using mouse monoclonal anti-FOLR1 clone FOLR1-2.1 intended for use in the assessment of folate receptor alpha (FR α) in formalin-fixed, paraffin-embedded epithelial ovarian, fallopian tube, or primary peritoneal cancer tissue specimens by light microscopy. This assay is for use with OptiView DAB IHC Detection Kit for staining on a BenchMark ULTRA instrument.

VENTANA FOLR1 (FOLR1-2.1) RxDx Assay is indicated as an aid in identifying patients with epithelial ovarian cancer (EOC) who may be eligible for treatment with ELAHERE.¹

Assay interpretation

VENTANA FOLR1 (FOLR1-2.1) RxDx Assay staining in EOC tissue follows a cytoplasmic and membranous pattern; only membranous staining is evaluated for the determination of FOLR1 status. The signal is classified as strong (3+), moderate (2+), weak (1+), and negative (0) based on membrane localisation only. EOC tissue must be evaluated according to the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay scoring algorithm, provided in Table 1. Please refer to the Interpretation Guide for the complete scoring algorithm.¹

Table 1. VENTANA FOLR1 (FOLR1-2.1) RxDx Assay scoring algorithm for EOC

IHC interpretation	Staining description
Positive for FOLR1	≥ 75% of viable tumour cells with moderate (2+) and/or strong (3+) membrane staining
Negative for FOLR1	< 75% of viable tumour cells with moderate (2+) and/or strong (3+) membrane staining

Clinical diagnosis positive

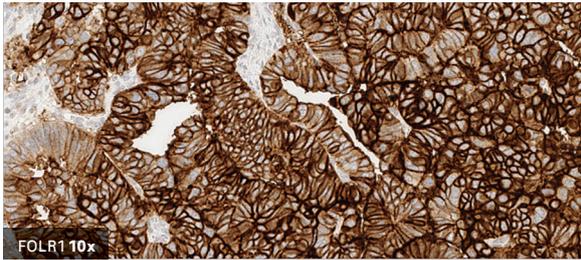


Figure 1: Positive case by VENTANA FOLR1 (FOLR1-2.1) RxDx Assay with 98% moderate and strong membrane staining

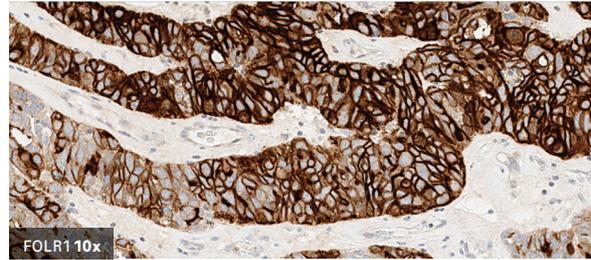


Figure 2: Positive case by VENTANA FOLR1 (FOLR1-2.1) RxDx Assay with 95% moderate and strong membrane staining

Clinical diagnosis negative

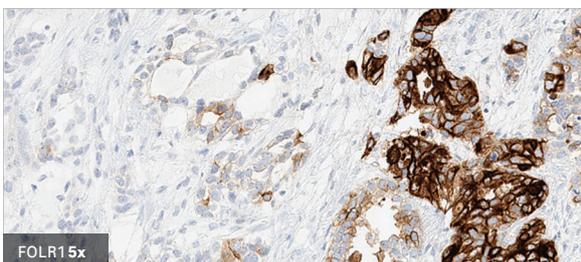


Figure 3: Negative case by VENTANA FOLR1 (FOLR1-2.1) RxDx Assay staining with 20% moderate and strong membrane staining

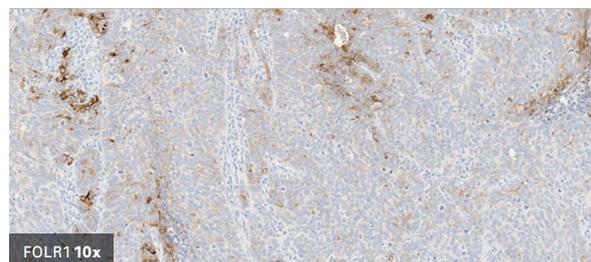


Figure 4: Negative case by VENTANA FOLR1 (FOLR1-2.1) RxDx Assay staining with 7% moderate and strong membrane staining

Partial circumferential membrane staining patterns are acceptable for FOLR1 positivity. FOLR1 positivity does not require complete circumferential membrane staining.

Clinical performance

Efficacy results from SORAYA study²

The efficacy of ELAHERE (mirvetuximab soravtansine) was investigated in a single-arm SORAYA study of patients with FR α (FOLR1) positive, platinum-resistant EOC (n=106). Patients received one to three prior lines of therapy, including at least one line of therapy containing bevacizumab. All patients received ELAHERE (mirvetuximab soravtansine) 6 mg/kg AIBW as an IV infusion until disease progression or unacceptable toxicity. Positive FR α expression of the tumour was defined by the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay.

Endpoint	ELAHERE (mirvetuximab soravtansine)
Confirmed ORR (95% CI)	32.4% (23.6, 42.2)
Complete response rate	4.8%
Partial response rate	27.6%
Duration of response	
Number of responders	34
Median duration of response, months (95% CI)	6.9 (5.6, 9.7)

Abbreviations: ORR = Objective Response Rate; DOR = Duration of Response; CI = confidence interval; + = censored.

Note: DOR is defined as the time from the date of first response (CR or PR) to the date of progressive disease or death from any cause, whichever occurred first.

Efficacy results from MIRASOL study³

The results from the SORAYA study were confirmed in the Phase III, double-arm MIRASOL study. Patients received ELAHERE (6 mg/kg AIBW as an IV infusion until disease progression or unacceptable toxicity) or chemotherapy (paclitaxel, pegylated liposomal doxorubicin, or topotecan). Positive FRα expression (n = 453) of the tumour was defined by the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay.

Patients who received mirvetuximab soravtansine experienced a

33% reduction in death³

Endpoint	ELAHERE	Chemotherapy
Median progression-free survival (PFS)	5.62 months	3.98 months
Overall Survival (OS)	16.46 months	12.75 months
Overall Response Rate (ORR)	42.3%	15.9%

Ordering information

Product name	Catalog number	Ordering code	Quantity
VENTANA FOLR1 (FOLR1-2.1) RxDx Assay	740-5065	07727917001	50 tests
OptiView DAB IHC Detection Kit	760-700	06396500001	250 tests

For more information, refer to the method sheet and Interpretation Guide.

References

¹ Roche. VENTANA FOLR1 (FOLR1-2.1) RxDx Assay Package Insert (23385EN Rev 1), 2025.

² Matulonis UA, et al. Efficacy and Safety of Mirvetuximab Soravtansine in Patients With Platinum-Resistant Ovarian Cancer With High Folate Receptor Alpha Expression: Results From the SORAYA Study. *J Clin Oncol*, JCO2201900, doi:10.1200/JCO.22.01900 (2023).

³ Moore K, et al. Phase III MIRASOL (GOG 3045/ENGOT-ov55) study: Initial report of mirvetuximab soravtansine vs. investigator's choice of chemotherapy in platinum-resistant, advanced high-grade epithelial ovarian, primary peritoneal, or fallopian tube cancers with high folate receptor-alpha expression. *J Clin Oncol*, 41:17_suppl, LBA5507-LBA5507 (2023).

⁴ First IHC companion diagnostic for determining folate receptor alpha (FOLR1) protein expression in EOC patients who may benefit from ELAHERE™ (mirvetuximab soravtansine) <https://diagnostics.roche.com/global/en/products/lab/ventana-folr1-folr1-2-1-assay-pid00000474.html>

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