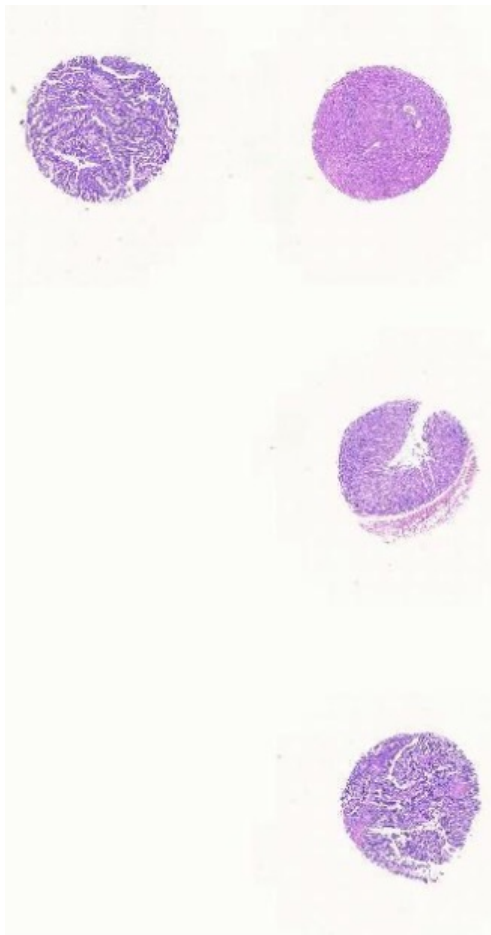
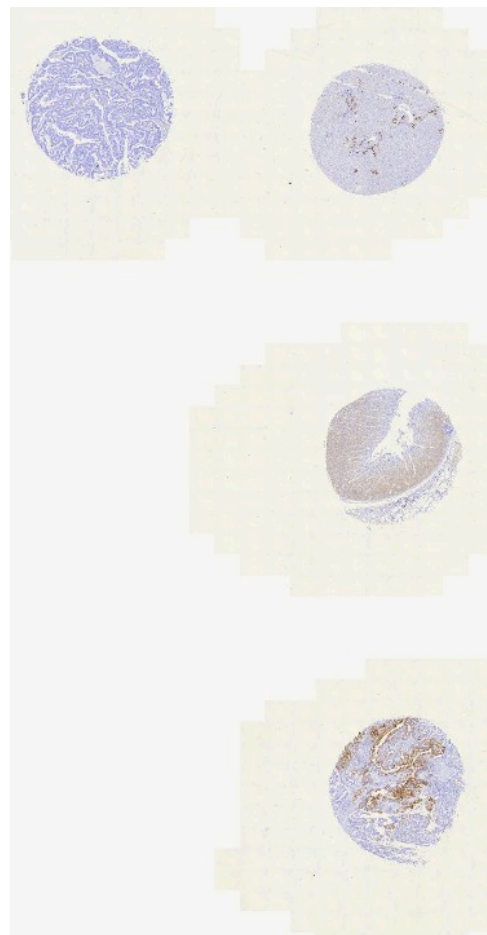


CK7

*HE staining in scanner view.**Immunostaining, scanner view***Provided sections in this run:**

TISSUE	PROPORTION	INTENSITY
Colon Adenocarcinoma	No staining reaction of neoplastic cells in the colon adenocarcinoma.	Negative
Liver	No staining reaction in hepatocytes. The epithelium of the bile duct and few periportal hepatocytes show moderate to intense cytoplasmic staining reaction	Focal intense
Stomach	A weak to moderate, distinct cytoplasmic reaction of the majority of the foveolar epithelial cells of the stomach.	Weak
Pancreatic adenocarcinoma	Pancreatic adenocarcinoma. Nearly 50% of the tumor cells show moderate intensity of cytoplasmic staining reaction	Intense in 50% of the tumour cells



Performance characteristic of the group:

N	35
MEDIAN OVERALL SCORE	50
AVERAGE OVERALL SCORE	41

Criteria for assessment:

	Optimum	Good	Borderline	Poor
Overall score	>49	41-49	37-41	<37

Break up of results

Result	Participants
Optimum	26
Good	6
Borderline	0
Poor	3
Section not submitted	9

Break up of results based on technique

Result Technique	Optimum	Good	Borderline	Poor	Total
Automated	1	0	0	1	2
Automated Ventana Bench Mark XT	4	1	0	1	6
Automated Ventana Benchmark Ultra	0	1	0	0	1
Automated, Ventana Benchmark GX	1	1	0	0	2
Automated, Ventana Medical systems, Inc., Roche Diagnostics	1	1	0	0	2
Manual	17	2	0	1	20
NA	2	0	0	0	2



Clones used in the run by participants

Clone	Participants
EP16	11
GM003	1
IHC 007	1
NA	11
OVTL 12/30	14
SP52	6

Break up of results based on the clones used

Clone	Result	Optimum	Good	Borderline	Poor	Section not submitted	Total
EP16		9	1	0	1	0	11
GM003		1	0	0	0	0	1
IHC 007		1	0	0	0	0	1
NA		2	1	0	0	8	11
OVTL 12/30		9	3	0	1	1	14
SP52		4	1	0	1	0	6



Break up of results based on the vendors

Vendor	Result	Optimum	Good	Borderline	Poor	Total
Biocare		2	0	0	0	2
BiogeneX AM255-5M		1	1	0	0	2
BioSB		0	0	0	0	0
Cell Marque		1	0	0	0	1
Dako		2	0	0	1	3
DAKO, M7018		1	0	0	0	1
Gene Ab		1	0	0	0	1
Master Diagnostica		0	1	0	0	1
NA		2	0	0	0	2
Pathnsitu		2	1	0	0	3
PathnSitu MM1154		1	0	0	0	1
PathnSitu PR0037		8	0	0	1	9
Quartette		1	1	0	0	2
Roche		1	0	0	0	1
Ventana		1	1	0	0	2
Ventana, 790-4462		2	1	0	1	4



Break up of results based on format

Result Format	Optimum	Good	Borderline	Poor	Section not submitted	Total
Concentrated	4	0	0	0	0	4
NA	2	0	0	0	8	10
RTU	20	6	0	3	1	30

Break up of results based on temperature of dewaxing

Result Dewax Minutes	Optimum	Good	Borderline	Poor	Section not submitted	Total
37	1	0	0	0	0	1
>75	0	0	0	0	0	0
55-60	8	1	0	0	0	9
61-65	7	1	0	1	0	9
66-70	1	1	0	0	1	3
71-75	5	2	0	1	0	8
NA	3	0	0	0	8	11
RT	0	1	0	0	0	1



Break up of results based on pH of retrieval buffer

Result pH	Optimum	Good	Borderline	Poor	Section not submitted	Total
6.0-6.9	4	0	0	0	0	4
7.0-8.0	2	1	0	1	0	4
8.1-9.0	15	5	0	2	1	22
>9.0	0	0	0	0	0	0
NA	3	0	0	0	8	3

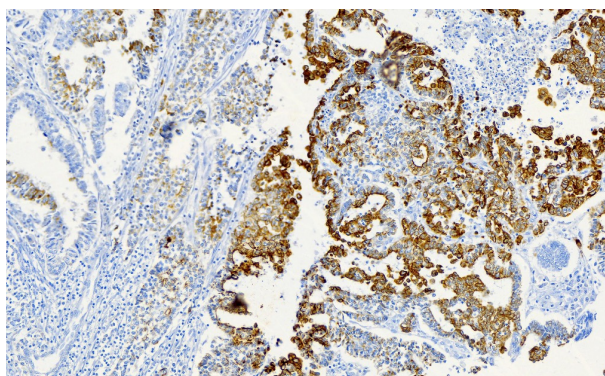
Break up of results based on incubation time of primary antibody

Result Time in minutes	Optimum	Good	Borderline	Poor	Section not submitted	Total
<15	0	0	0	0	0	0
15-30	7	0	0	2	0	9
31-45	7	2	0	0	0	9
46-60	10	4	0	1	1	16
NA	3	0	0	0	8	11

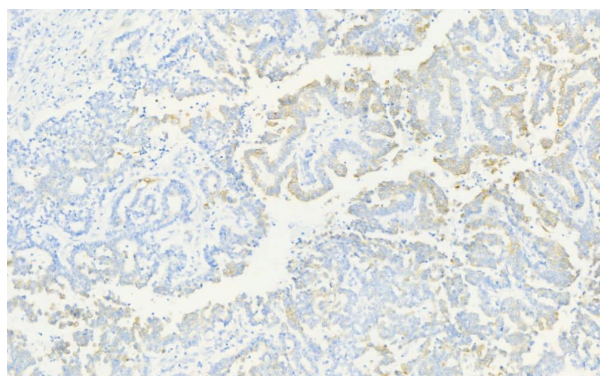
General observations in Run 17



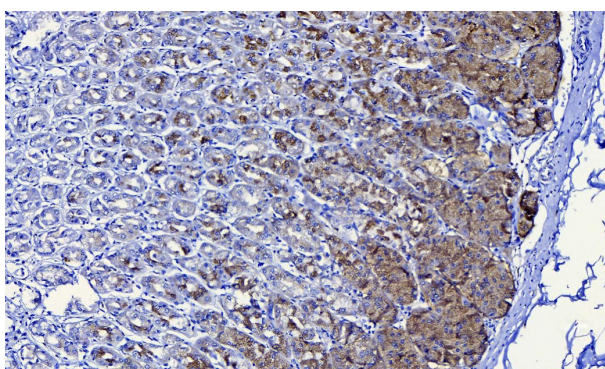
VARIABLE	1	2	3
Technique	Use manual technique	Automated Ventana Bench Mark XT	Automated, Ventana XT-Benchmark Fully automated
Clone	EP16	EP16	OV-TL-12/13
Vendor	Pathn situ and PR037	PATH N SITU , CAT# HAR037	DAKO and 20079523
Format	RTU	RTU	Concentrated
Batch/Year	RO9037NA	LOT# H08037MA, 12/2021	M7018
Expiry	12/2023	Jun-23	26/03/2023
Dewaxing temperature	60. C	75 DEGREE	74°C in company system
Retrieval	HIER	HIER	HIER
Enzyme	-	0	Not Applicable
HIER	Pressure cooker	COMPANY SYSTEM/VENTANA MACHINE	Company system- Ventana XT
Peak T and Time	100.C & 10 min	95 DEGREE ONE HOUR	Temperature: 94°C AND Time: 60 minutes
Peak Pressure and Time	5 min	NO PRESSURE NA	Not Applicable
Retrieval Buffer	Retrieval buffer-inhouse	CC1 , ROCHE VENTANA	Company provided, Cell conditioning (CC1) Ventana
pH	9.0 PH	PH 8.5	pH 8.4
Blocking	-	UV DAB INHIBITOR -4 MINUTES 37 DEGREE	Ultra view Universal DAB inhibitor Time: 4 Minutes
Wash sol	Tris buffer with twin 20	REACTION BUFFER TRIS BUFFER	Reaction buffer
Dilution of RTU	-	NO	No
Dilution of conc	-	NO	1:150
Diluent	-	-	Ventana Antibody Dilution Buffer ADB250
Inc time of Primary	1 hour	28 MINUTES	40 minutes
Detection	Polymer base system	MULTIMER BASE TECHNOLOGY (UV DAB KIT)	Polymer based system
Cat No	Polymer- Masterdiagnosis- 040322- 1/2024	ULTRA VIEW UNIVERSAL DAB DETECTION KIT	Ultra view universal DAB detection system Ventana
Inc time of Sec	30 min.	8 MINUTES	8 Minutes
Chro-substrate	5 min.	8 MINUTES	8 Minutes
Post-treatment	N.A	UV DAB COPPER 4 MINUTES	Yes, Ultra view Universal DAB copper- enhancer-8 minutes
Counterstain	4 dips	0	Hematoxylin



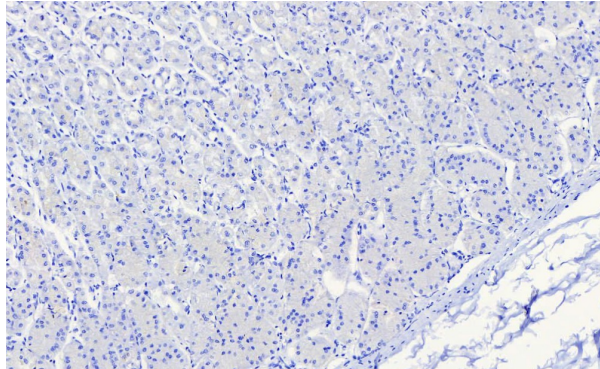
Optimum staining of tumor cells in pancreatic adenocarcinoma.



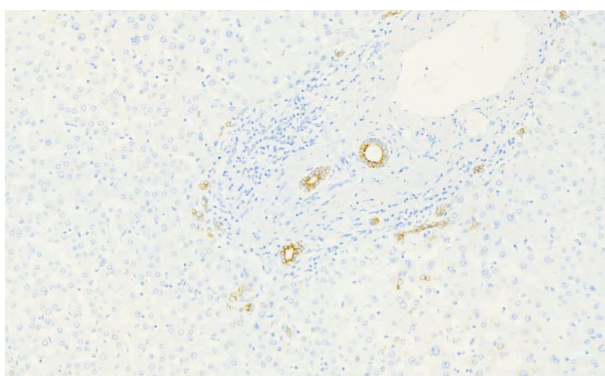
Suboptimal staining of pancreatic adenocarcinoma. This is the same case that failed to stain bile duct epithelium also.



Optimum staining of the foveolar epithelial cells in stomach by participant using optimal staining protocol



Non staining of foveolar epithelial cells was the major reason of suboptimal performance. A sensitive protocol would stain these cells. We recommend putting stomach as control.



Weak intensity staining of bile duct, and less in proportion too due to inadequate epitope retrieval.