

TDM	729.89	915.51	185.62	▲25.43%	FLR	660.27	745.28	85.01	▲12.88%
HUM	749.73	924.29	174.56	▲23.28%	UVD	155.59	181.57	25.98	▲16.70%
DMW	833.72	1004.01	170.29	▲20.43%	QUV	440.55	540.21	99.66	▲22.62%
YZJ	903.49	1127.46	223.97	▲24.79%	HZT	285.51	344.98	59.47	▲20.83%
GLY	982.07	1219.39	237.32	▲24.17%	PCW	811.44	1029.66	218.22	▲26.89%
VDA	113.74	143.41	29.67	▲26.09%	AIK	361.77	451.39	89.62	▲24.77%
UVV	468.08	535.41	67.33	▲14.38%	ZJJ	858.36	994.57	136.21	▲15.87%
HJS	545.49	659.05	113.56	▲20.82%	RHJ	894.79	1046.68	151.89	▲16.97%
EBC	566.96	664.89	97.93	▲17.24%	VGV	425.08	509.95	84.87	▲19.97%

NordiQC data Run 72-74:

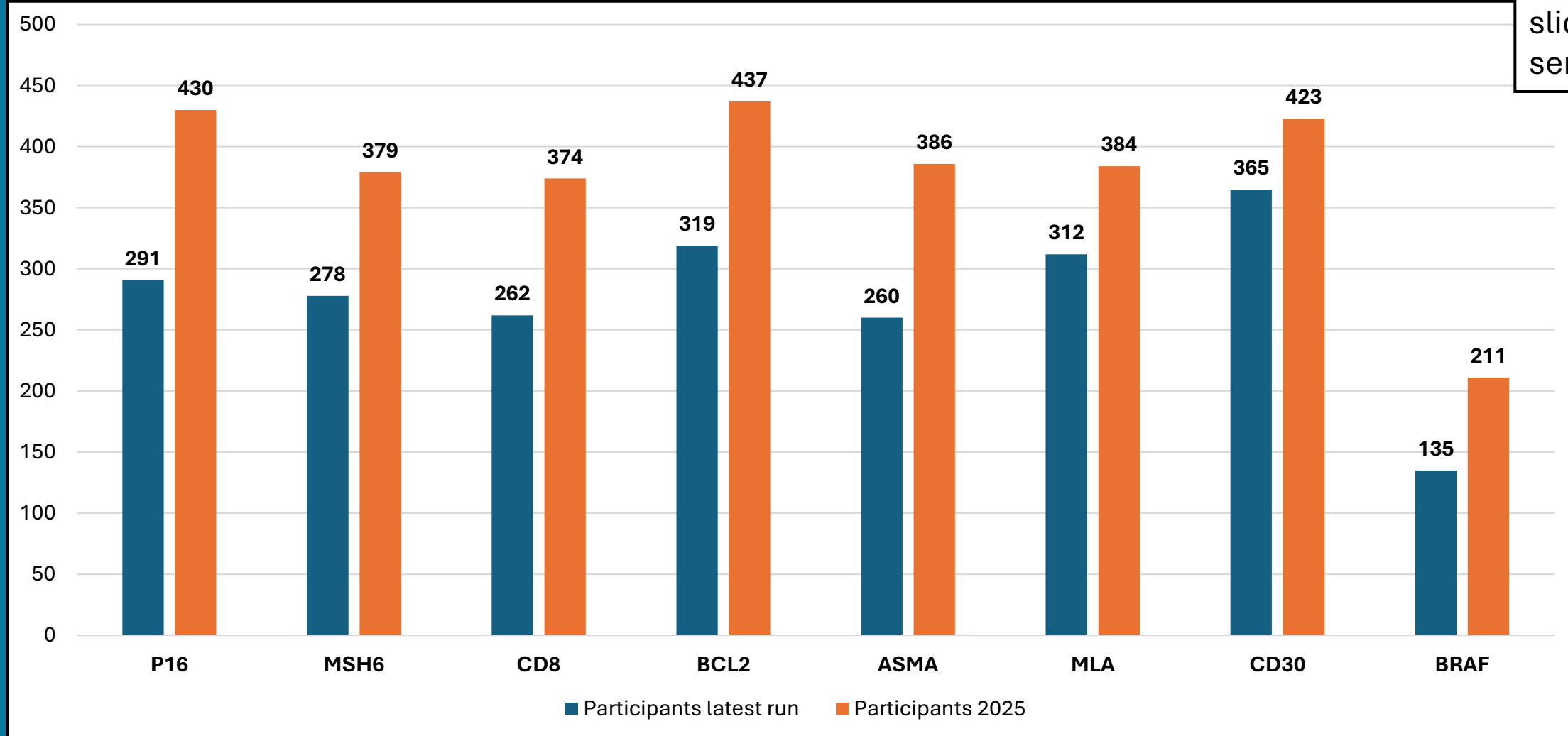
Tips and tricks - protocols and controls

The general module

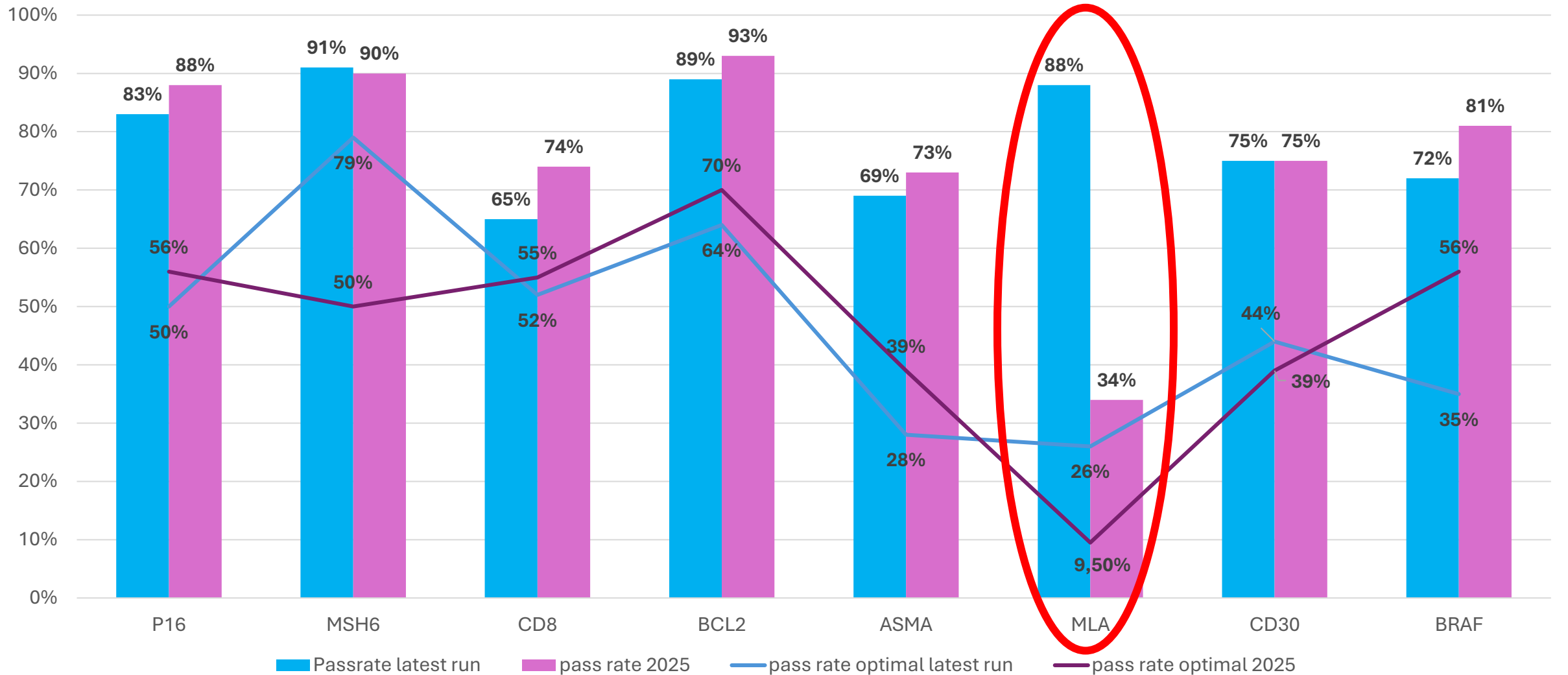
Tanya Julio
Histotechnologist
Pathology department
Aarhus University Hospital, DK

Run 72-74 – number of participants

Run 74 total
slides 5054
sent out



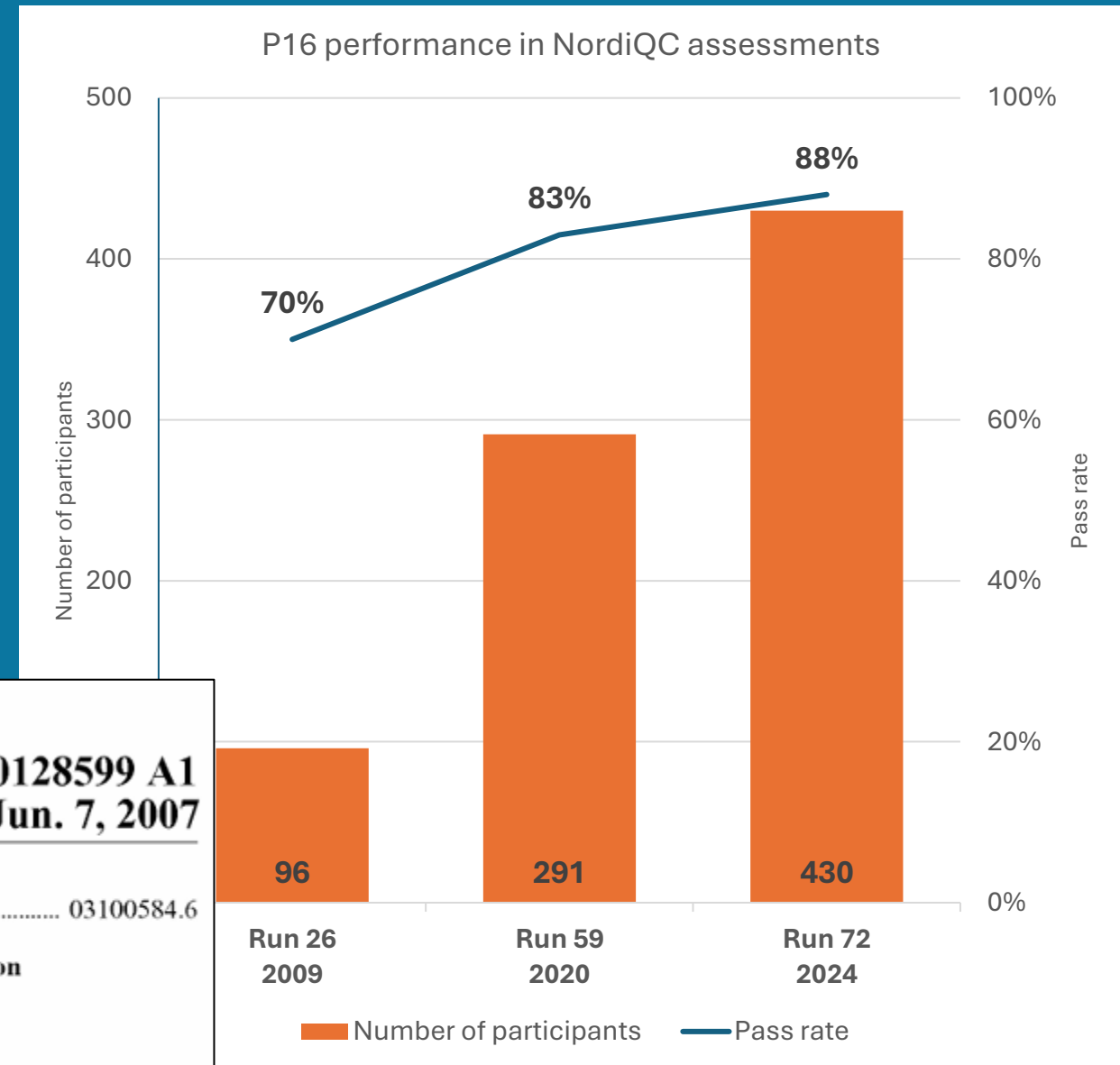
Run 72-74 – Pass-rate



P16

P16 is a tumor suppressor protein

- First run to evaluate performance of P16 on both cervical lesions and HNSCC
- Clone E6H4 was patented – excluding other clones from the market
 - In run 26 9 clones were evaluated
 - In run 59 12 clones were evaluated
 - In run 72 18 clones were evaluated



United States

Patent Application Publication

Ridder et al.

(10) Pub. No.: US 2007/0128599 A1

(43) Pub. Date: Jun. 7, 2007

METHOD FOR IMPROVED DIAGNOSIS OF DYSPLASIAS

Inventors: Ruediger Ridder, Schriesheim (DE); Anja Reichert, Nussloch (DE); Marcus Trunk-Gehmacher, Heidelberg (DE); Richard Batrla, Heidelberg (DE)

Mar. 7, 2003 (EP) 03100584.6

Publication Classification

(51) Int. Cl. *C12Q 1/68* (2006.01)
G01N 33/574 (2006.01)

(52) U.S. Cl. 435/6; 435/7.23



P16

Table 1a. Overall results for P16, run 59

	n	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
Concentrated antibodies	50	20	11	17	2	62%	40%
Ready-To-Use antibodies	241	125	85	28	3	87%	85%
Total	291	145	96	45	5		
Proportion		50%	33%	15%	2%	83%	

Table 1a. Overall results for p16, run 72

	n	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
Concentrated antibodies	73	37	20	12	4	78%	51%
Ready-To-Use antibodies	357	204	118	33	2	90%	57%
Total	430	241	138	45	6		
Proportion		56%	32%	11%	1%	88%	

Off- label	Run 59 (n=24)	Run 72 (n=23)
Sufficient	38%	78%
Optimal	13%	48%

Table 1c. Ready-To-Use antibodies and assessment marks for p16, run 72

Ready-To-Use antibodies	n	Vendor	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
mAb clone E6H4, 805/825-4713 (VRPS) ³	94	Ventana/Roche	59	32	3	-	97%	63%
mAb clone E6H4, 805/825-4713 (LMPS) ⁴	123	Ventana/Roche	49	54	20	-	80%	40%
mAb clone E6H4, 9511 (VRPS) ³	3	Ventana/Roche	1	1	1	-	-	-
mAb clone E6H4, 9511 (LMPS) ⁴	54	Ventana/Roche	34	18	2	-	96%	64%
mAb clone JC8, GA783 (VRPS) ³	15	Dako/Agilent	15	-	-	-	100%	100%
mAb clone JC8, GA783 (VRPS) ⁴	12	Dako/Agilent	11	1			100%	92%
mAb clone 6H12, PA0016 (VRPS) ³	22	Leica Biosystems	14	6	2	-	91%	64%
mAb clone 6H12, PA0016 (LMPS) ⁴	5	Leica Biosystems	2	2	-	1	80%	40%
mAb clone BC42, API3231	6	Biocare Medical	5	-	1	-	83%	83%
mAb clone MX007, 8313-C010	3	Sakura Finetek	2	1	-	-	-	-
mAb clone JC2, 416M-10/17/18	3	Cell Marque	2	-	-	1	-	-
mAb clone JC2, MSG123	1	Zytomed systems	-	1	-	-	-	-
mAb clone JC2, Z256/MP	1	Zeta Corporation	-	-	1	-	-	-
mAb clone JC2, PDM575	6	Diagnostic Biosystems	5	-	1	-	83%	83%
mAb clone MX007, MAD-00690QD	3	Master Diagnostica	1	1	1	-	-	-
mAb clone MX007, MAB-0673	1	Fuzhou Maixin	1	-	-	-	-	-
mAb clone IHC116 IHC116-7	1	GenAb	1	-	-	-	-	-
rmAb clone GM501 GT233002	1	Gene Tech	1	-	-	-	-	-
Ab clone 598A6G3	1	Abcarta	-	-	1	-	-	-
Ab clone BPM6147	1	Biolynx Biotechnology	-	1	-	-	-	-
Ab clone BY001	1	BioIn Biotechnology	1	-	-	-	-	-
Total	357		204	118	33	2		
Proportion			57%	33%	9%	1%	90%	

P16 – run 72

Ventana RTU

Ventana Kit –
manuel or AS

Omnis RTU

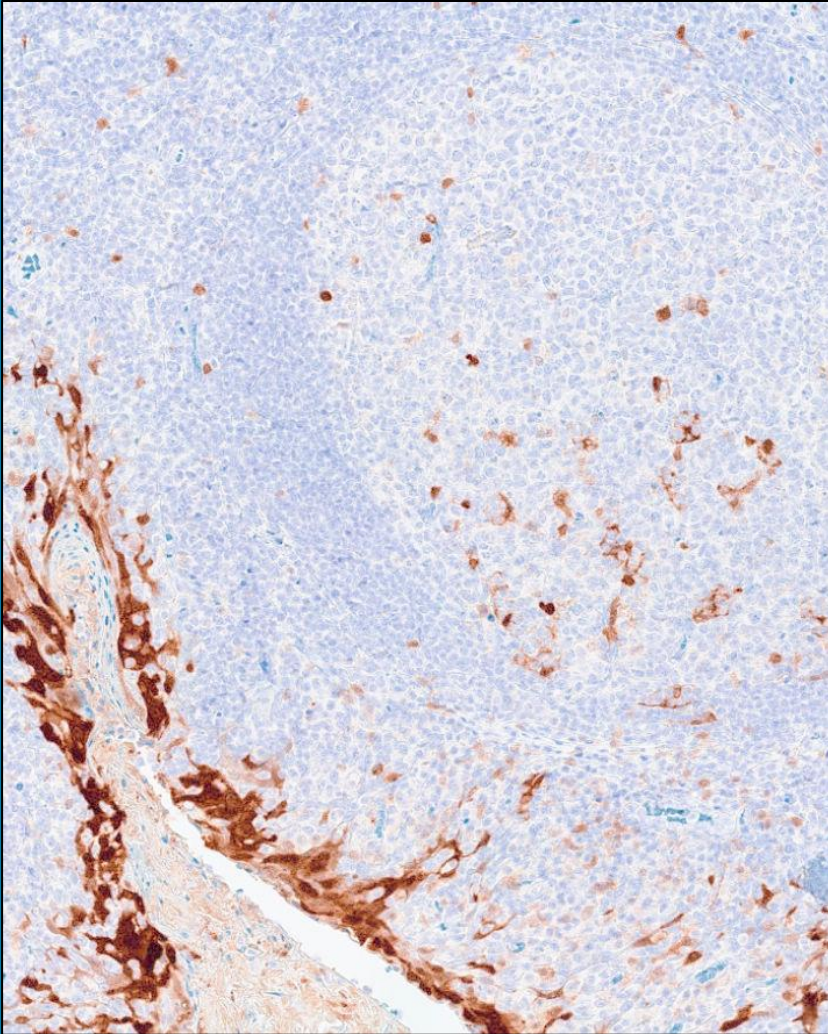
Bond RTU

Table 1c. Ready-To-Use antibodies and assessment marks for p16, run 72

Ready-To-Use antibodies	n	Vendor	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
mAb clone E6H4, 805/825-4713 (VRPS) ³	94	Ventana/Roche	59	32	3	-	97%	63%
mAb clone E6H4, 805/825-4713 (LMPS) ⁴	123	Ventana/Roche	49	54	20	-	80%	40%
mAb clone E6H4, 9511 (VRPS) ³	3	Ventana/Roche	1	1	1	-	-	-
mAb clone E6H4, 9511 (LMPS) ⁴	54	Ventana/Roche	34	18	2	-	96%	64%
mAb clone JC8, GA783 (VRPS) ³	15	Dako/Agilent	15	-	-	-	100%	100%
mAb clone JC8, GA783 (VRPS) ⁴	12	Dako/Agilent	11	1			100%	92%
mAb clone 6H12, PA0016 (VRPS) ³	22	Leica Biosystems	14	6	2	-	91%	64%
mAb clone 6H12, PA0016 (LMPS) ⁴	5	Leica Biosystems	2	2	-	1	80%	40%
mAb clone BC42, API3231	6	Biocare Medical	5	-	1	-	83%	83%
mAb clone MX007, 8313-C010	3	Sakura Finetek	2	1	-	-	-	-
mAb clone JC2, PDM575	6	Diagnostic Biosystems	5	-	1	-	83%	83%
Total	357		204	118	33	2		
Proportion			57%	33%	9%	1%	90%	

Cut-out of table 1c.

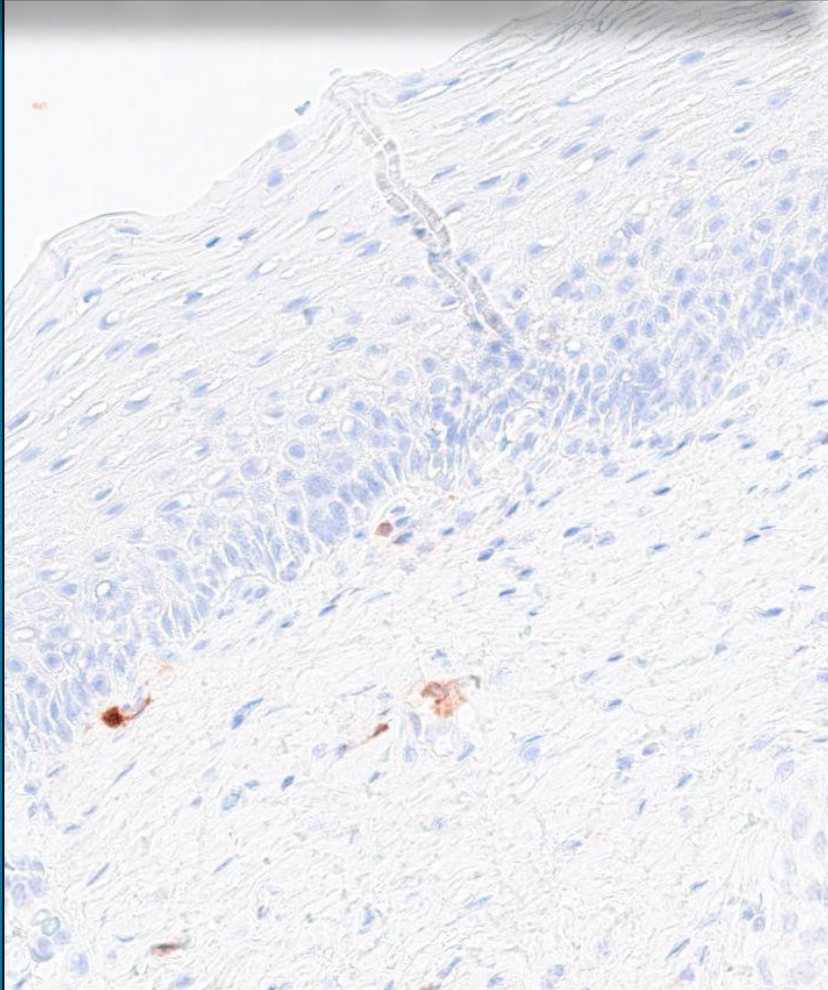
P16 run 72 - ICAPs



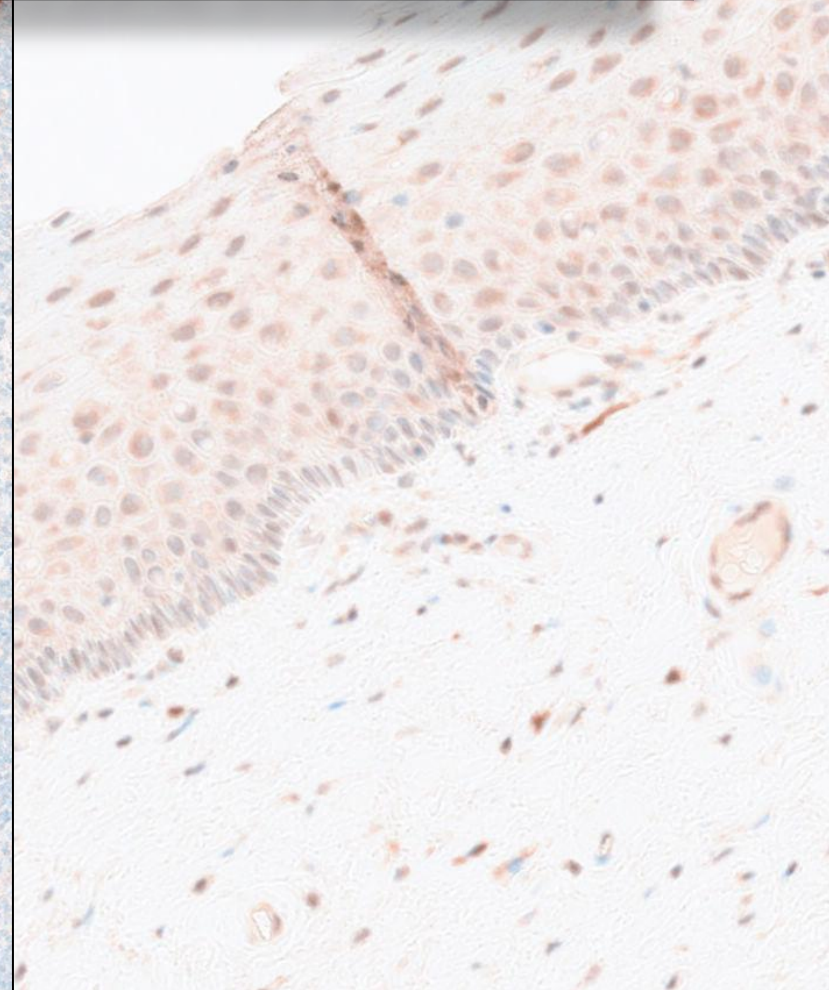
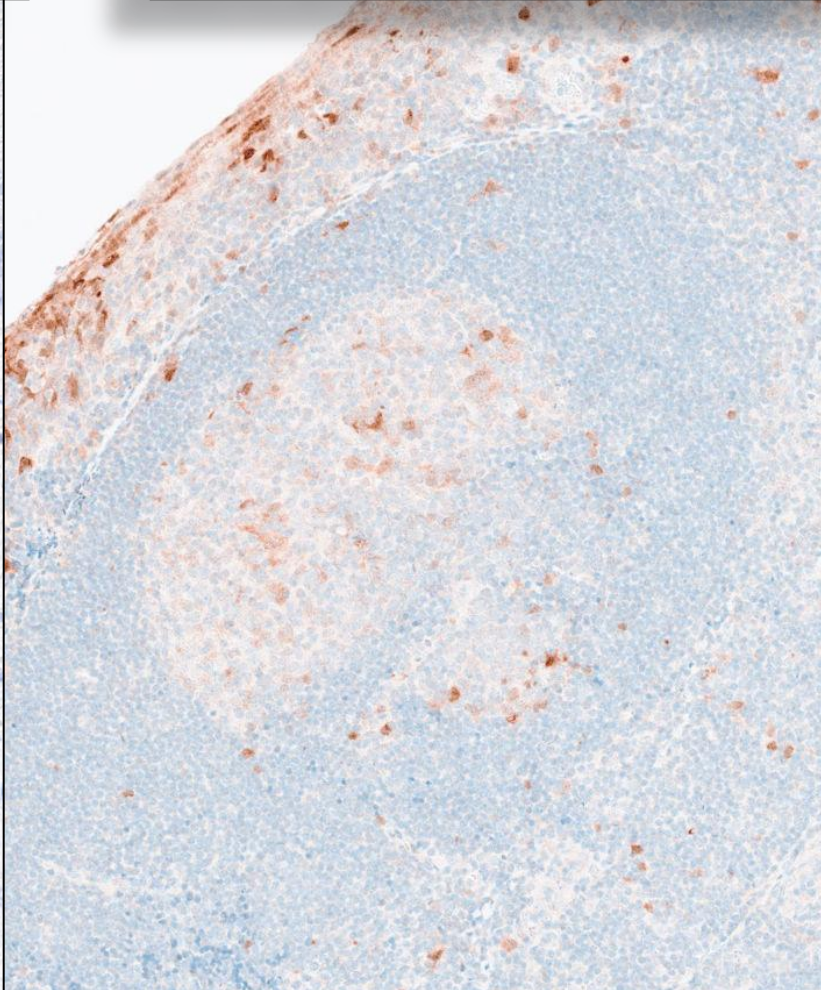
- The germinal centre macrophages/dendritic cells must show an at least weak to moderate but distinct nuclear and cytoplasmic staining reaction.
- Scattered reticulated crypt epithelial cells must show a moderate to strong nuclear and cytoplasmic staining reaction.
- No reaction should be seen in the vast majority of lymphocytes and normal superficial squamous epithelial cells.

P16 run 72

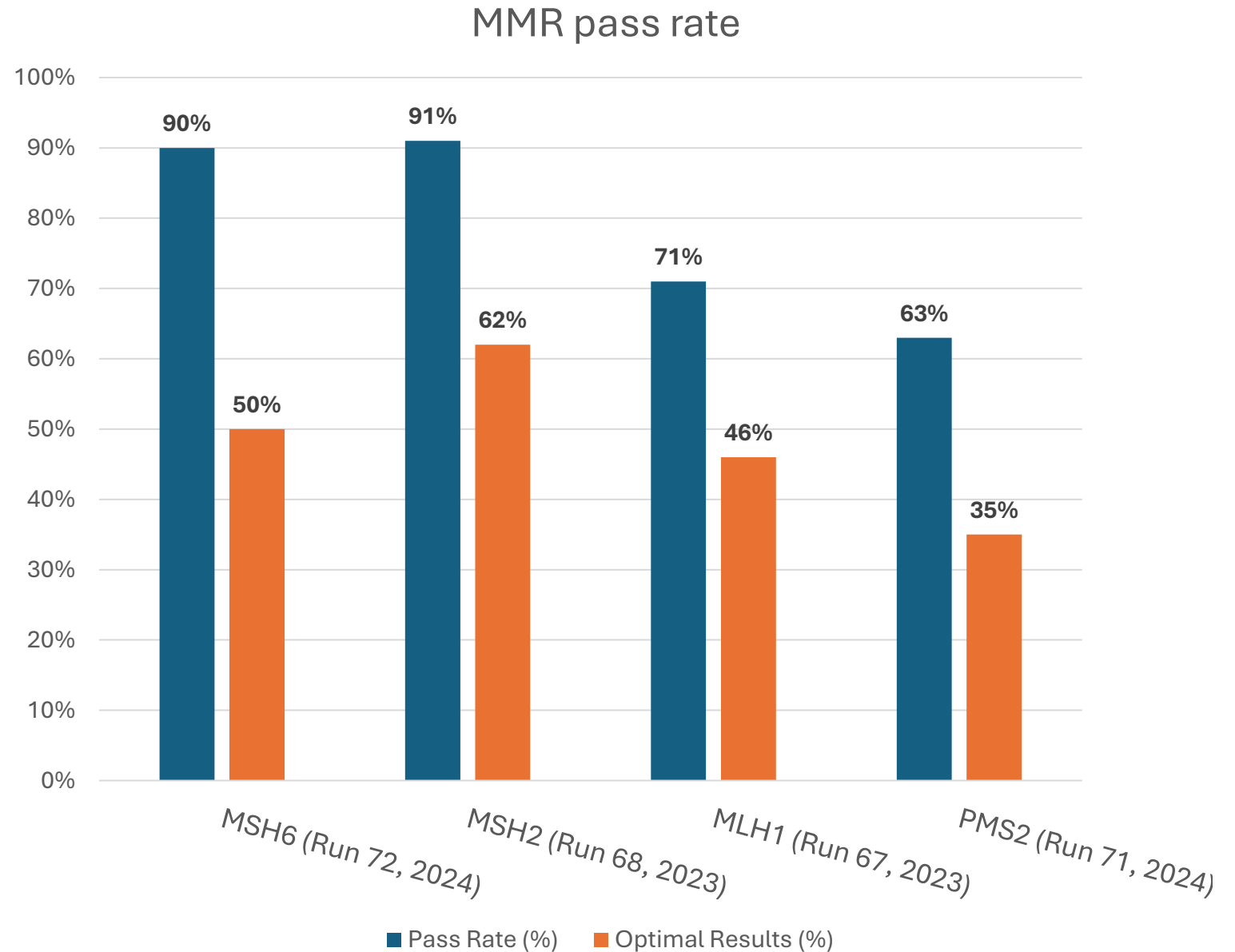
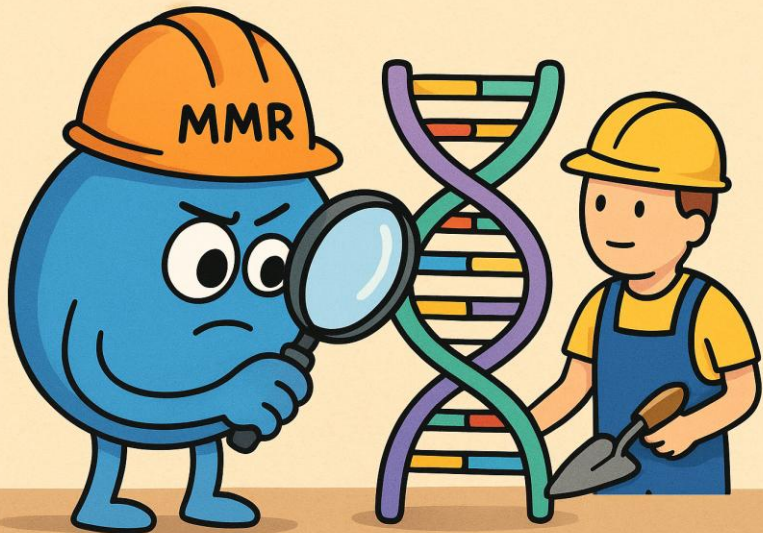
Optimal – GA783 (J8) - VRPS



Insufficient – Ventana RTU 805-4713 (E6H4)– LMPs: AB > 28 min



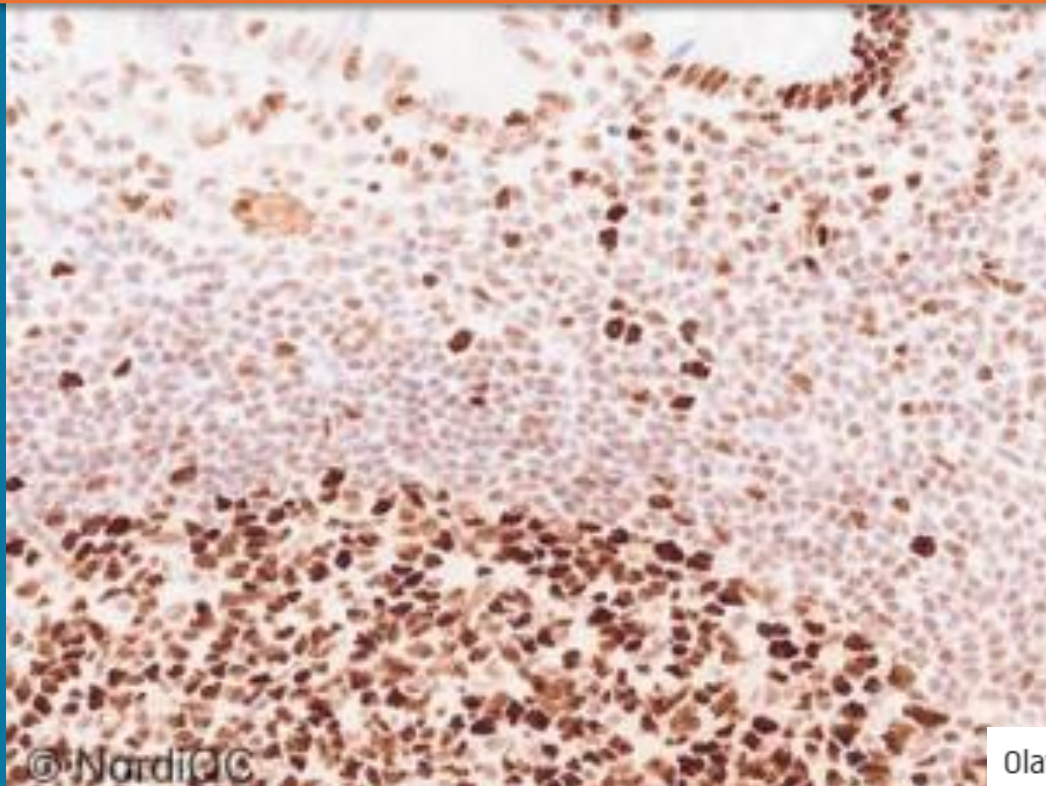
MSH6 – the mismatch panel



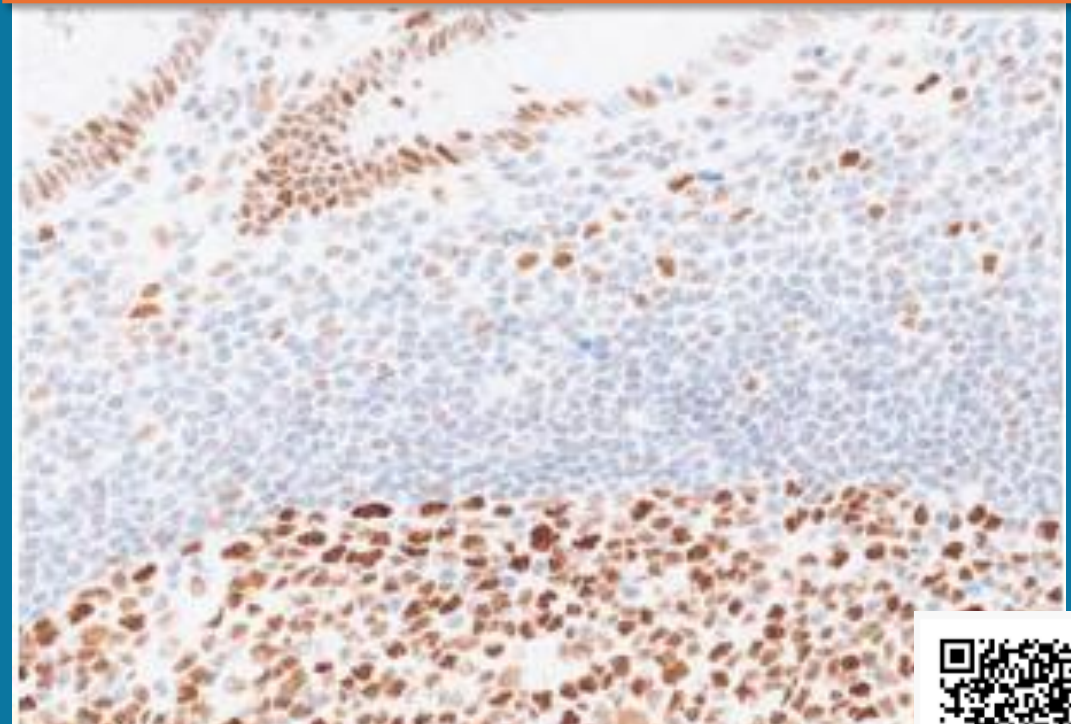
MSH6 run 72

68% of insufficient results experienced too weak or false negative staining

Dako RTU GA086 VRPS, Envision Flex++ - tonsil



Dako RTU GA086, Envision Flex - tonsil



© NordiIQC

Olave, Maria C., and Rondell P. Graham. "Mismatch Repair Deficiency: The What, How and Why It Is Important." *Genes Chromosomes & Cancer*, vol. 61, no. 6, 2022, pp. 314–21, <https://doi.org/10.1002/gcc.23015>.



MSH6

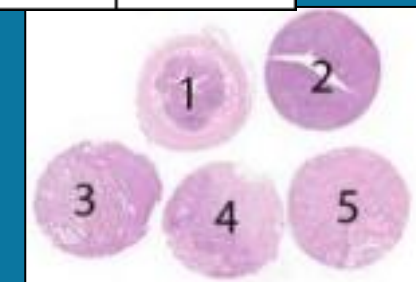
RTU-systems used

Table 2. Proportion of optimal results for MSH6 for the most commonly used antibody concentrate on the 4 main IHC systems*

Concentrated antibodies	Dako/Agilent Autostainer ¹		Dako/Agilent Omnis		Ventana/Roche BenchMark ²		Leica Biosystems Bond ³	
	TRS pH 9.0	TRS pH 6.1	TRS pH 9.0	TRS pH 6.1	CC1 pH 8.5	CC2 pH 6.0	BERS2 pH 9.0	BERS1 pH 6.0
rmAb clone EP49	2/2	-	3/5 (60%)	-	10/14 (71%)	-	10/12 (83%)	0/1
rmAb clone EPR3945	-	-	1/1	-	2/3	-	1/1	-

Table 1c. Ready-To-Use antibodies and assessment marks for MSH6, run 72

Ready-To-Use antibodies	n	Vendor	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
rmAb clone SP93 760-5092³	78	Ventana/Roche	20	57	1	-	99%	26%
rmAb clone SP93 760-5092⁴	82	Ventana/Roche	13	57	12	-	85%	16%
rmAb clone EP49 GA086³	41	Dako/Agilent	38	3	-	-	100%	93%
rmAb clone EP49 GA086⁴	32	Dako/Agilent	24	4	4	-	88%	75%
rmAb clone EP49 IR086³	12	Dako/Agilent	11	1	-	-	100%	92%
rmAb clone EP49 IR086⁴	33	Dako/Agilent	28	3	2	-	94%	85%
rmAb clone EP49 PA0990³	15	Leica Biosystems	8	5	2	-	87%	53%
rmAb clone EP49 PA0990⁴	14	Leica Biosystems	7	7	-	-	100%	50%
rmAb clone EP49 8326-C010	3	Sakura Finetek	2	1	-	-	-	-

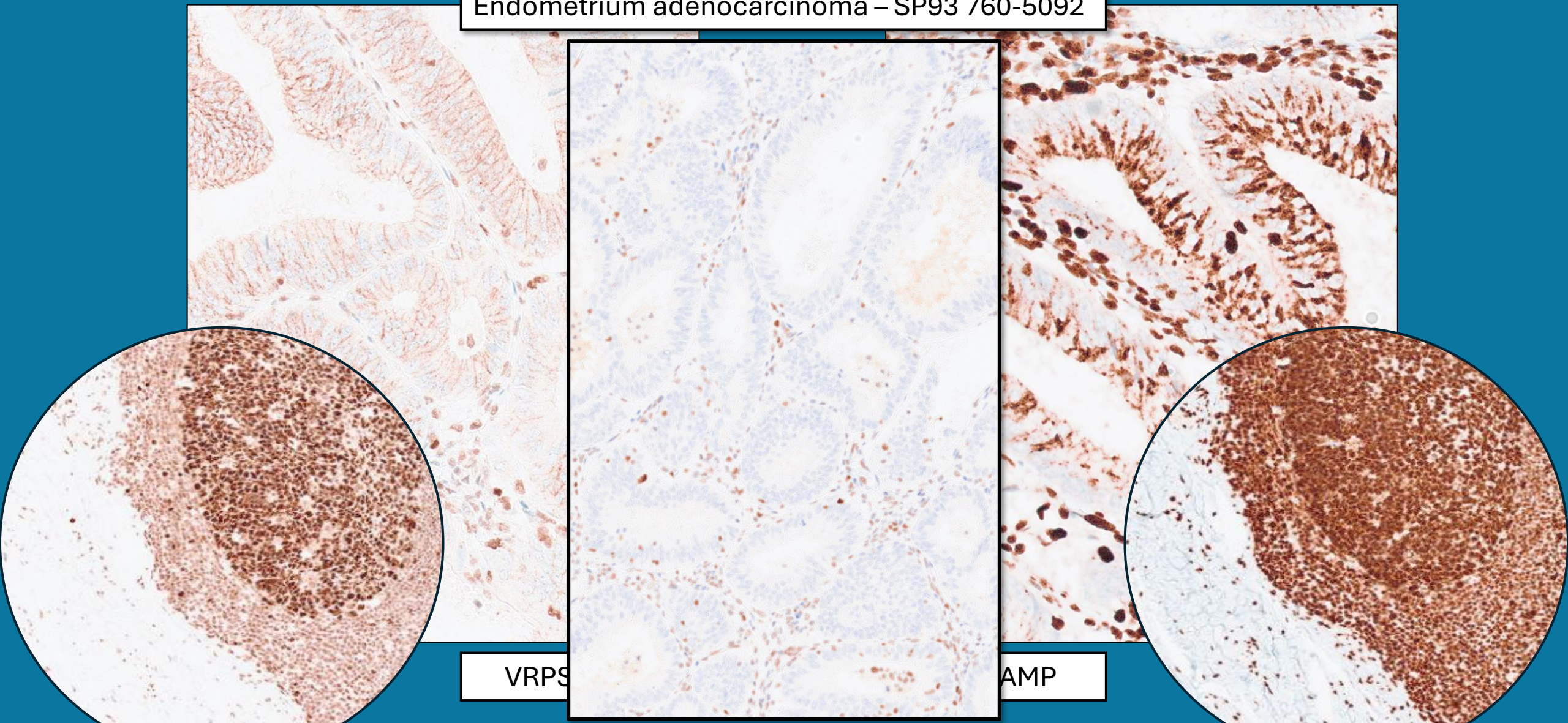


1. Appendix
2. Tonsil
3. Endo adeno with loss
4. Colon adeno with loss
5. Colon adeno normal

Cut-out of table 1c.

MSH6 run 72

Endometrium adenocarcinoma – SP93 760-5092



VRPS

AMP

MMR – is there a perfect system?

	MLH1 suff.	MLH1 opti.	MSH2 suff.	MSH2 opti.	MSH6 suff.	MSH6 opti.	PMS2 suff.	PMS2 opti.
Ventana	63%	20%	100%	79%	99%	26%	32%	4%
Agilent autostainer	67%	67%	94%	69%	100%	92%	66%*	66%*
Agilent Omnis	83%	66%	100%	46%	100%	93%	98%	71%
Leica	50%*	25%*	100%	92%	87%	53%	100%	33%

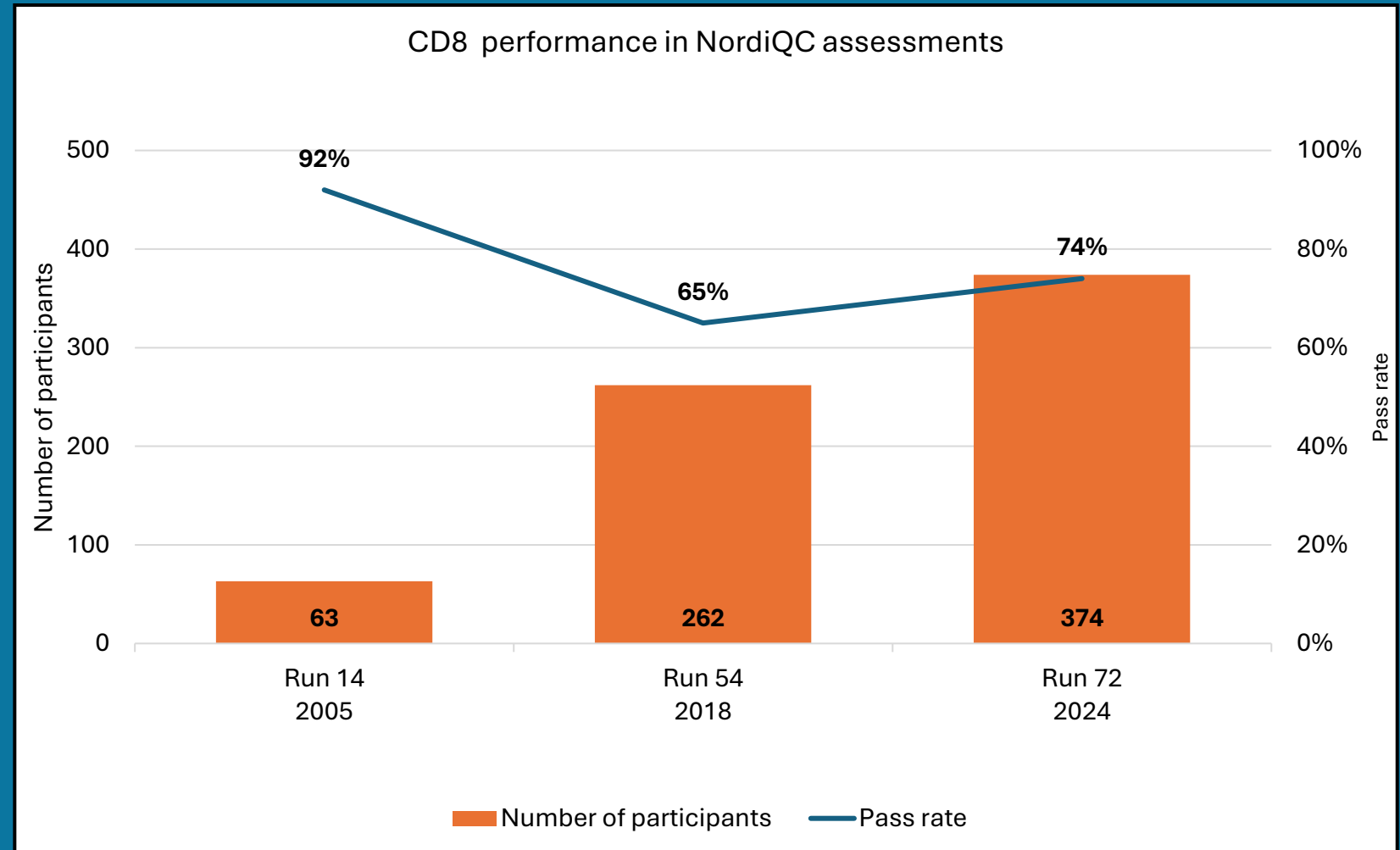
* Low number for statistic



CD8 run 72



1. Appendix
2. Spleen
3. B-Chronic Lymphatic Leukemia (B-CLL)
4. Tonsil
5. T-Cell Lymphoma (TCL)
6. Breast carcinoma



CD8

Appendix

GA623 – clone C8/144B

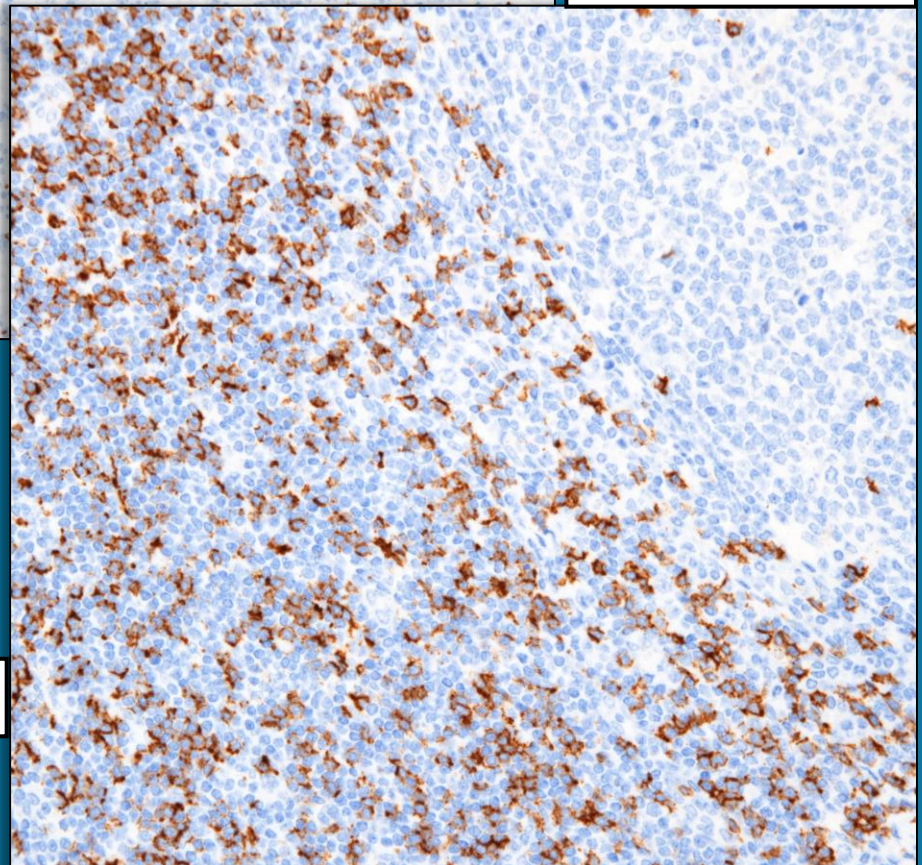
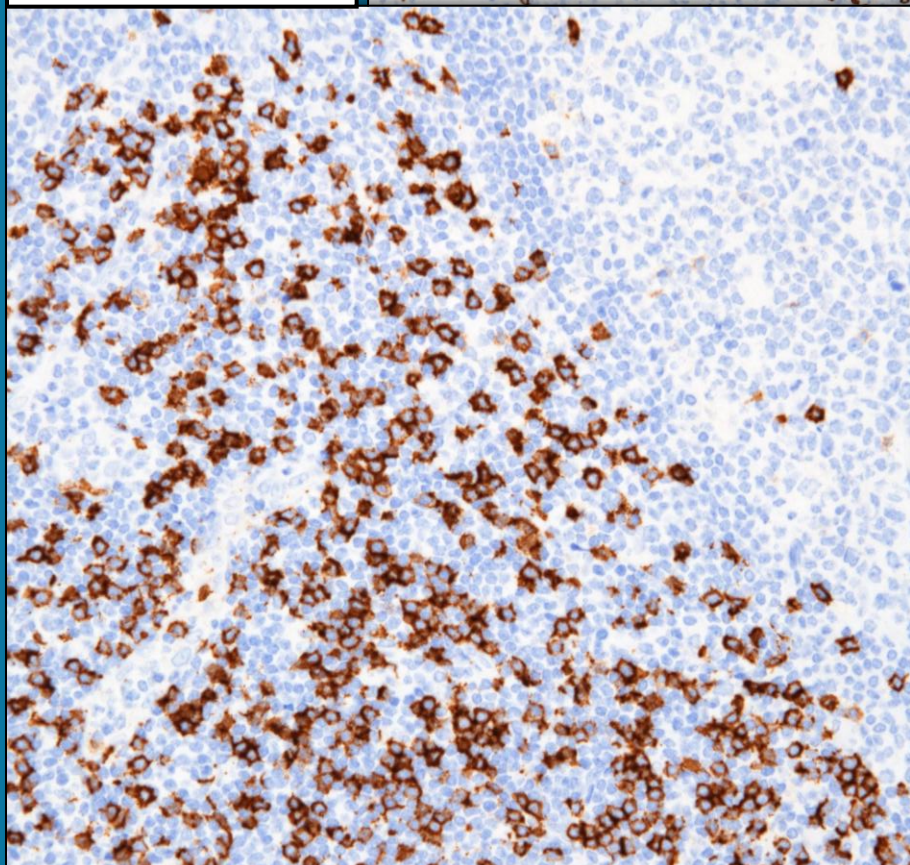
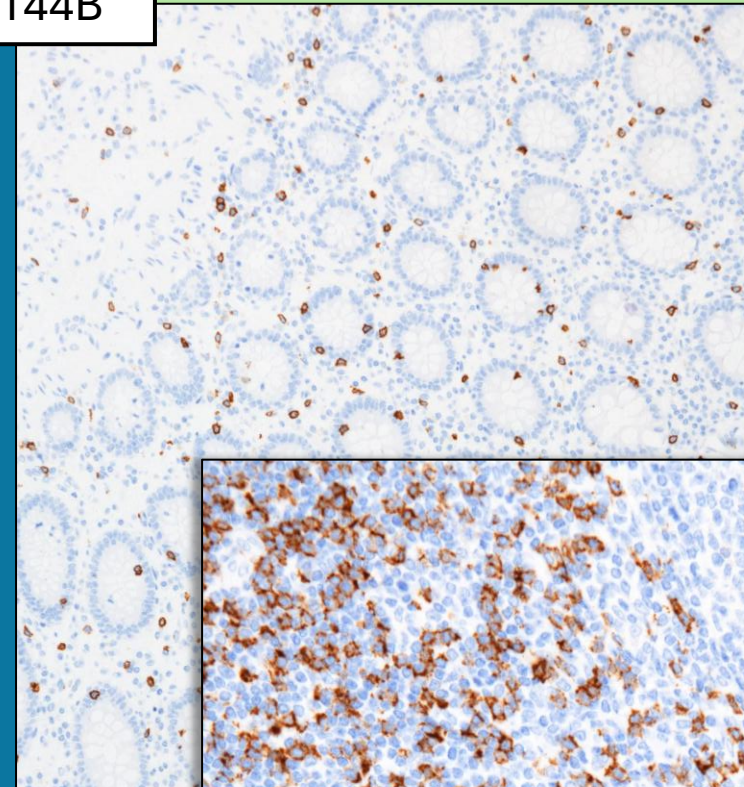
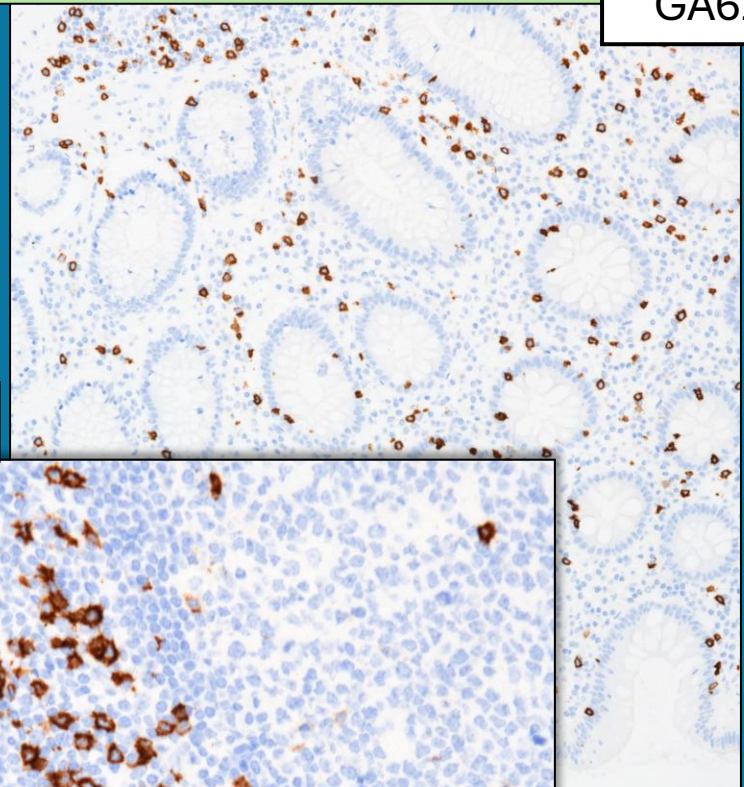
Appendix

Tonsil

Tonsil

Flex+

Flex

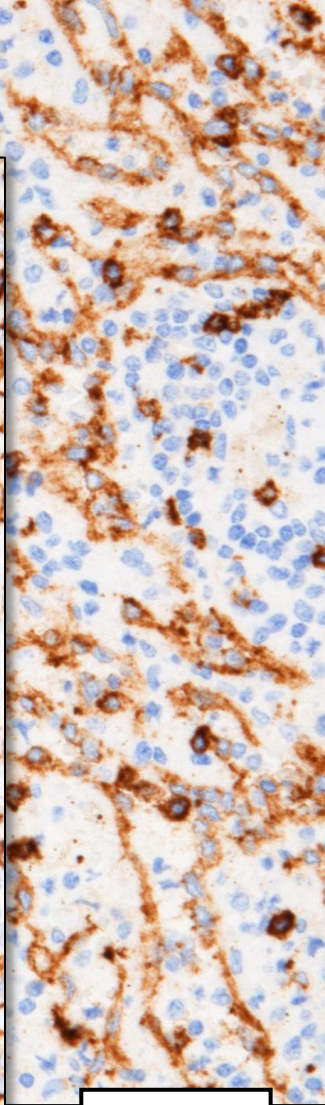
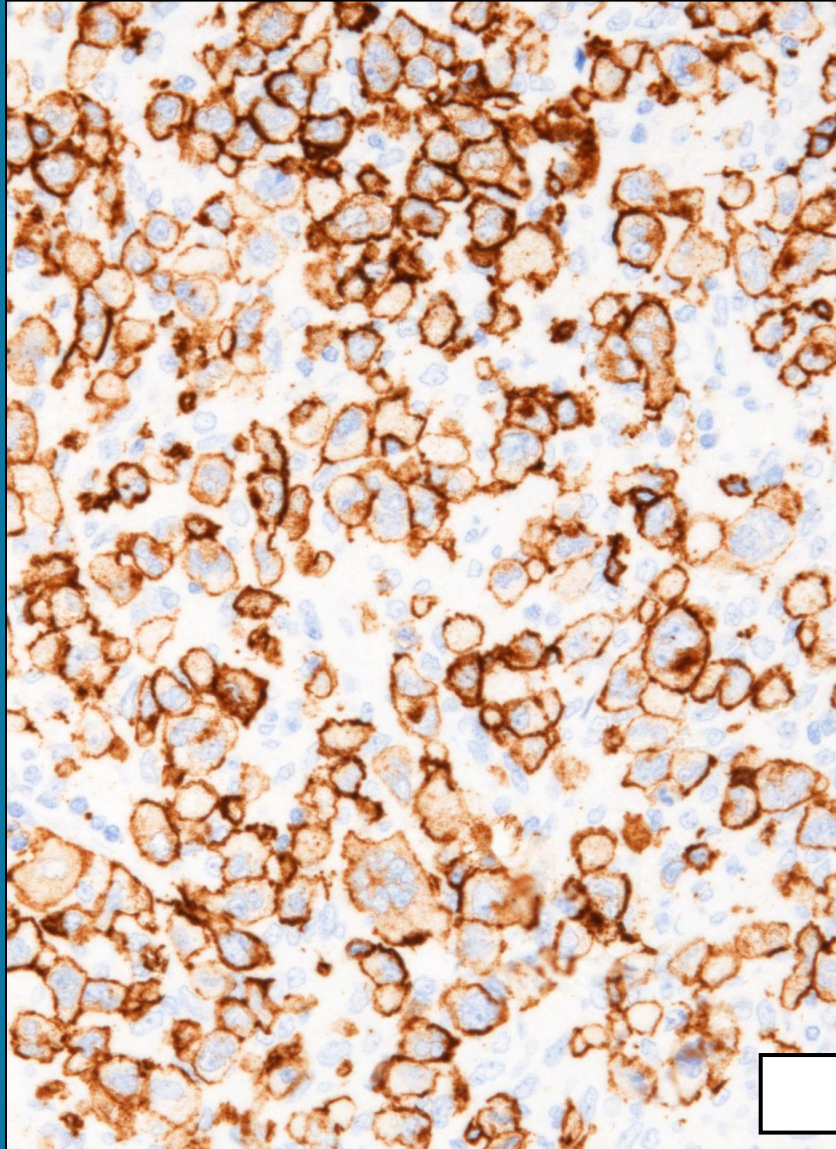


CD8

GA623 – clone C8/144B

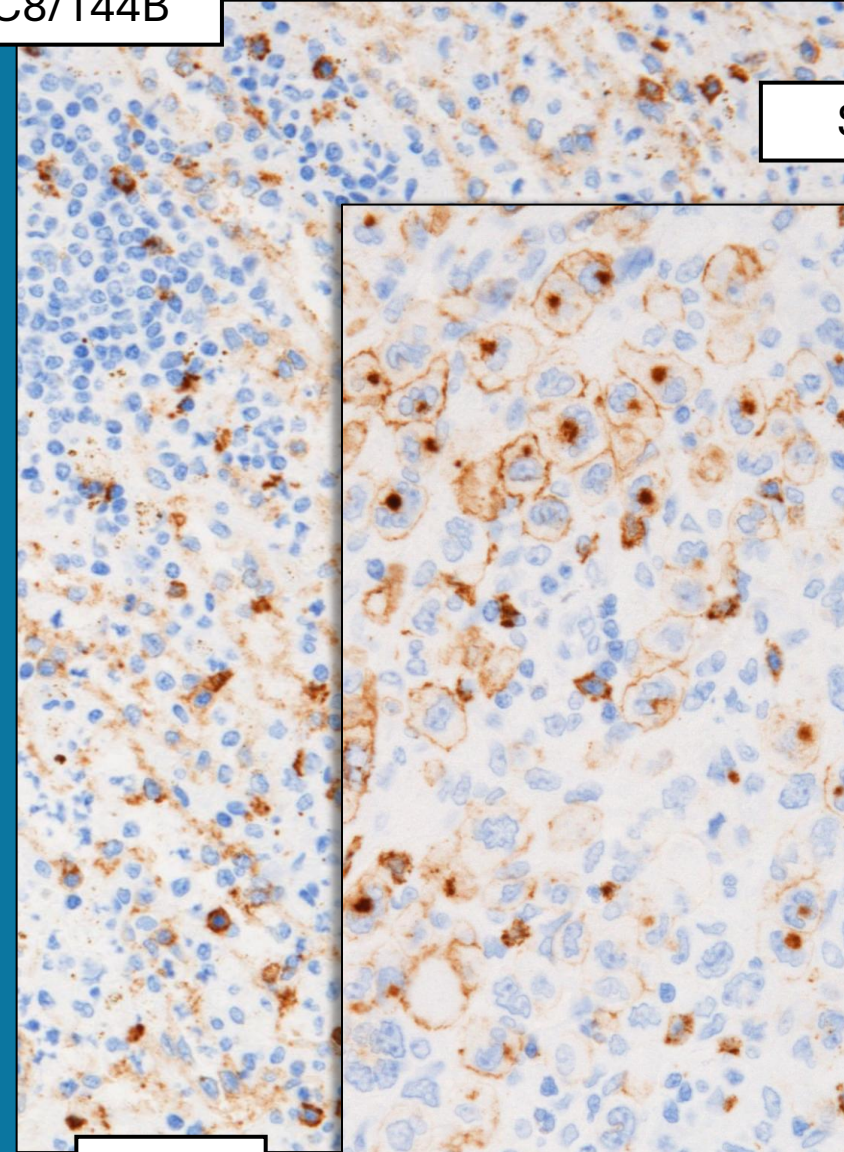
Spleen

Spleen



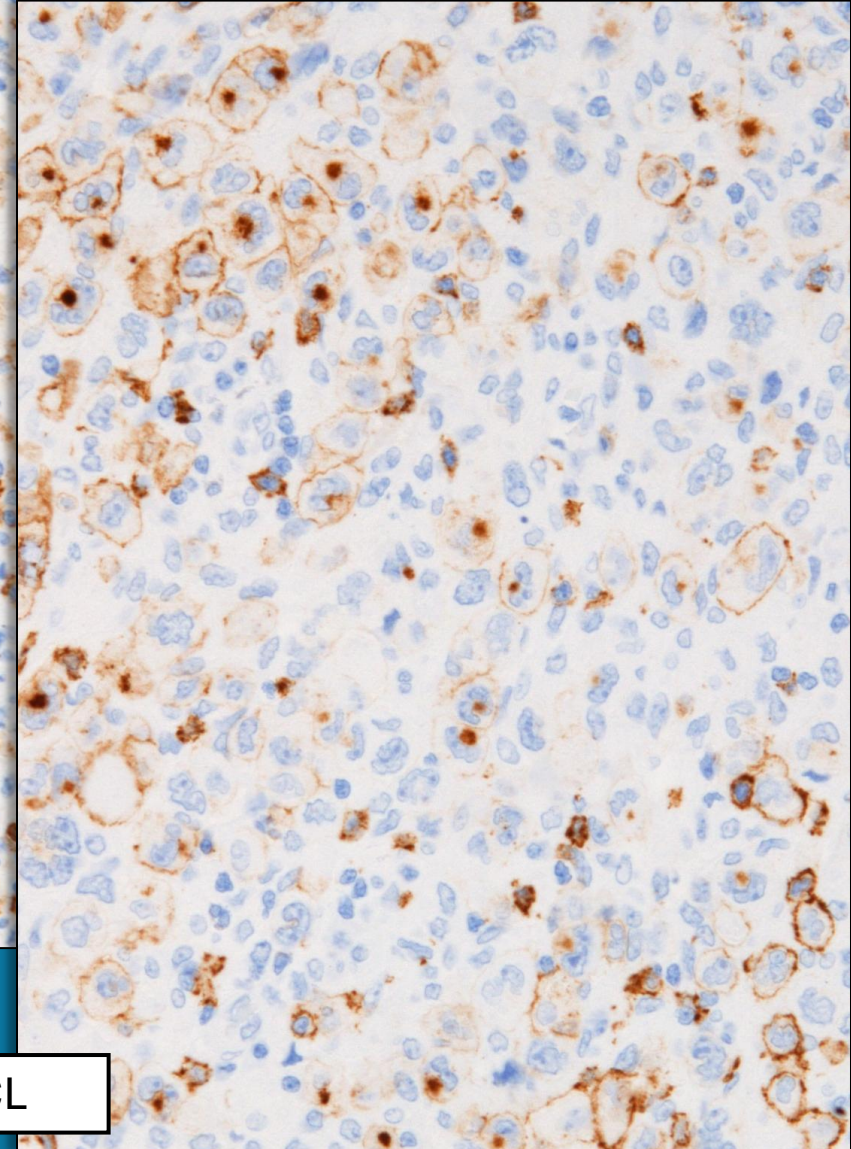
Flex+

TCL



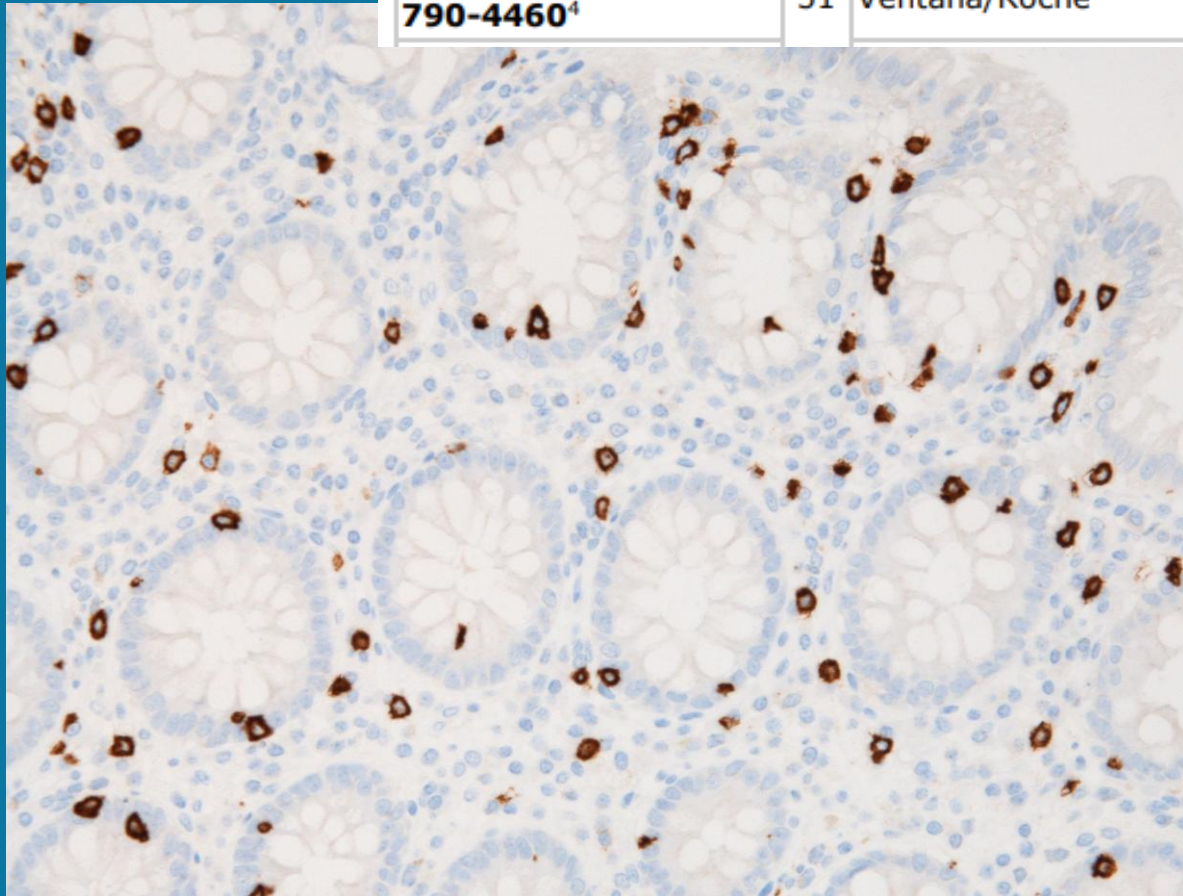
Flex

TCL

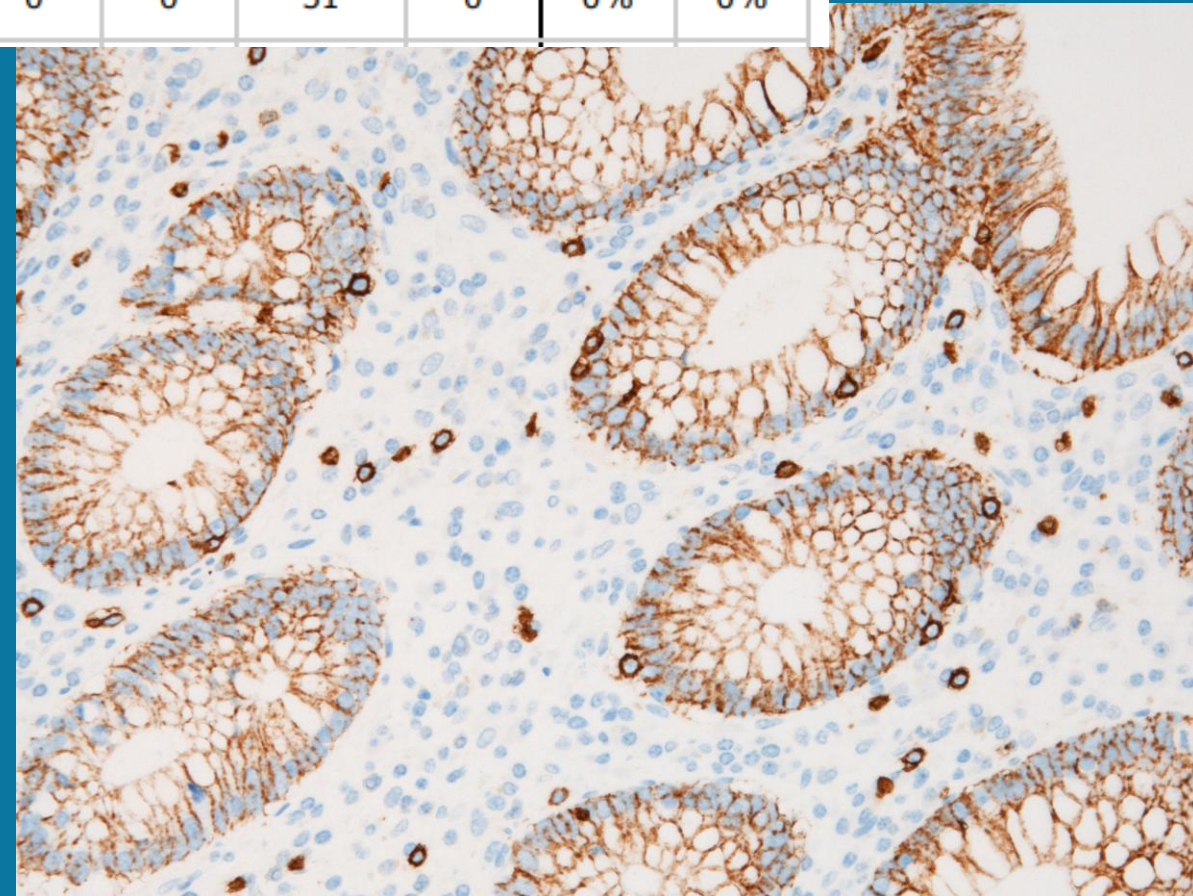


CD8

rmAb clone SP239 790-7176 ³	19	Ventana/Roche	18	0	1	0	95%	95%
rmAb clone SP239 790-7176 ⁴	19	Ventana/Roche	14	5	0	0	100%	74%
rmAb clone SP57 790-4460 ³	17	Ventana/Roche	0	0	17	0	0%	0%
rmAb clone SP57 790-4460 ⁴	51	Ventana/Roche	0	0	51	0	0%	0%



SP239 Ventana RTU

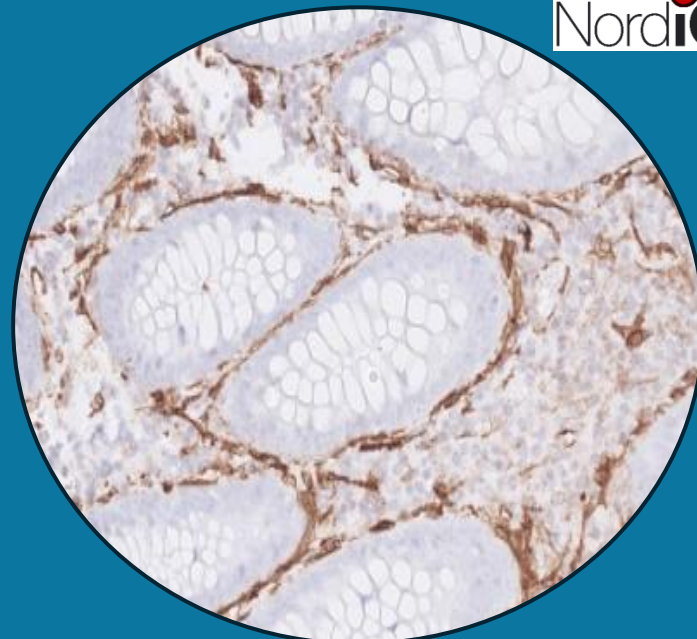


SP57 Ventana RTU

ASMA run 73

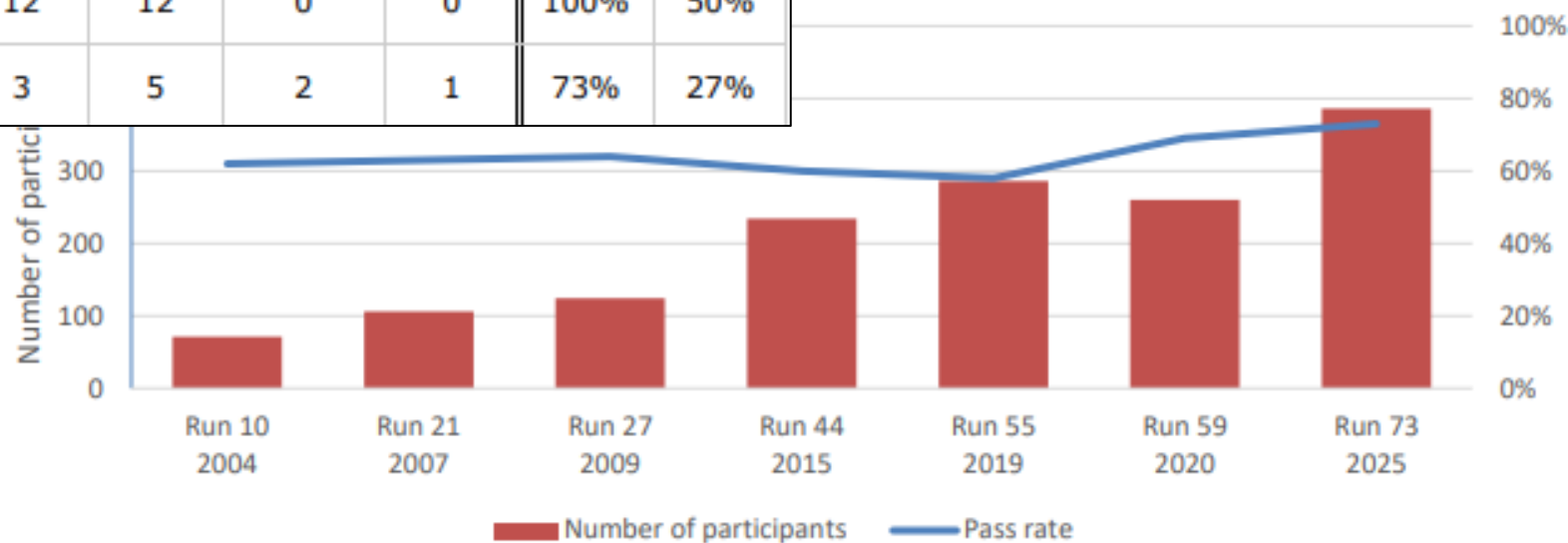
Table 1c. Ready-To-Use antibodies and assessment marks for ASMA, run 73

Ready-To-Use antibodies	n	Vendor	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
mAb clone 1A4 IR/IS611 (VRPS) ³	12	Agilent/Dako	7	5	0	0	100%	58%
mAb clone 1A4 IR/IS611 (LMPS) ⁴	16	Agilent/Dako	7	5	4	0	75%	44%
mAb clone 1A4 GA611 (VRPS) ³	54	Agilent/Dako	48	4	2	0	96%	89%
mAb clone 1A4 GA611 (LMPS) ⁴	32	Agilent/Dako	18	13	1	0	97%	56%
mAb clone 1A4 760-2833 (VRPS) ³	13	Ventana/Roche	0	8	5	0	62%	0%
mAb clone 1A4 760-2833 (LMPS) ⁴	76	Ventana/Roche	3	29	43	1	42%	4%
mAb clone asm-1 PA0943 (VRPS) ³	24	Leica Biosystems	12	12	0	0	100%	50%
mAb clone asm-1 PA0943 (LMPS) ⁴	11	Leica Biosystems	3	5	2	1	73%	27%



seven NordiQC runs performed

NordiQC assessments



1A4 used by 81% participants

ASMA run 73

Table 3. Proportion of optimal results for ASMA for the most commonly used antibody as concentrate on the four main IHC systems*

Concentrated antibodies	Dako/Agilent Autostainer ¹		Dako/Agilent Omnis		Ventana/Roche BenchMark ²			Leica Biosystems Bond ³	
	TRS pH 9.0	TRS pH 6.1	TRS pH 9.0	TRS pH 6.1	CC1 pH 8.5	CC1 pH 8.5 + Protease	CC2 pH 6.0	BERS2 pH 9.0	BERS1 pH 6.0
mAb clone 1A4	3/8 (38%)	-	12/14 (86%)	-	0/18 (0%)	0/1	-	8/15 (53%)	1/4
mAb clone BS66	-	-	-	-	2/3	1/2	-	-	-
rmAb clone EP188	-	-	-	-	0/3	6/12 (50%)	-	-	-
rmAb clone QR110	-	-	-	-	3/4	-	-	0/1	-

Recommended staining protocol with *ultraView*

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	No antigen retrieval
Enzyme (Protease)	Not required
Antibody (Primary)	BenchMark ULTRA or ULTRA PLUS instrument: 32 minutes at room temperature. BenchMark XT instrument: 32 minutes at room temperature.
Amplification	Selected
Counterstain	Hematoxylin II, 4 minutes
Post Counterstain	Bluing, 4 minutes

ASMA run 73

Immunostainer

Type: Ventana Benchmark Ultra

Primary antibody

Clone: QR110
Producer: Quartett
Product no. / lot no.: C-S010-05 / 443604T0730
Diluent: REAL Antibody Diluent
Diluent producer / no.: Dako / S2022
Dilution factor: 1:150
Incubation time / temperature: 32 min. / 37°C

Epitope retrieval, HIER

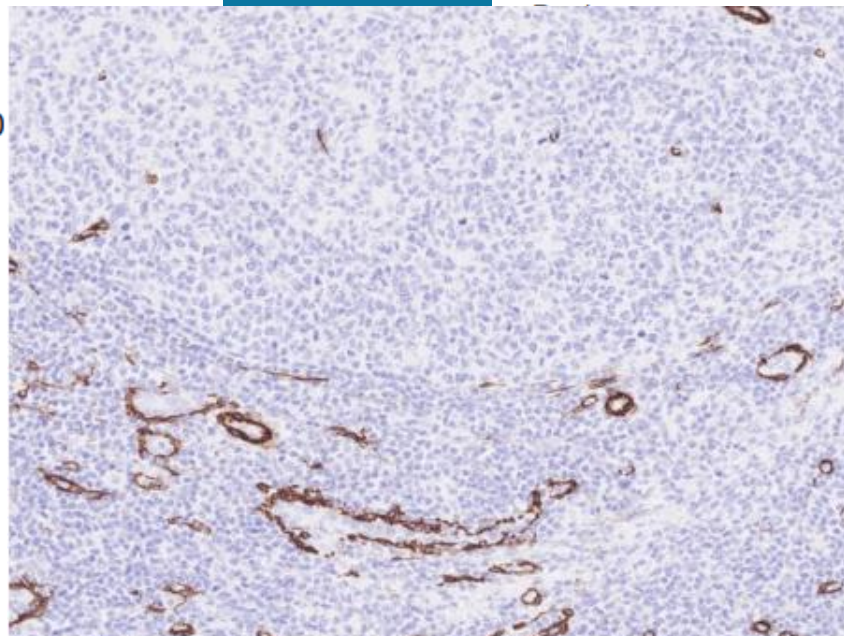
Device: On Board / On Machine
Buffer: Ventana Ultra CC1
Heating time at max. temp.: 48 min.
Maximum heating temp.: 100°C

Visualization system

Producer: Ventana
Product / no: OptiView DAB IHC Detection Kit / 760-700
Incubation time linker: 12 min.
Incubation time polymer: 12 min.
Incubation temperature: 37°C

Chromogen

Producer: Ventana
Product / no: OptiView DAB IHC Detection Kit / 760-700
Incubation time / temperature: 8 min. / 37°C
Enhancement: CuSO4



Immunostainer

Type: Ventana Benchmark Ultra

Primary antibody

Clone: EP188
Cell Marque
AC-0167 / 230104709
Antibody Diluent
Ventana / 251-018
1:100
32 min. / 36°C

On Board / On Machine
Ventana Ultra CC1
32 min.
100°C

Protease 2
Ventana / 760-2019
4 min. / 36°C

Visualization system

Producer: Ventana
Product / no: OptiView DAB IHC Detection Kit / 760-700
Incubation time linker: 8 min.
Incubation time polymer: 8 min.
Incubation temperature: 36°C

Chromogen

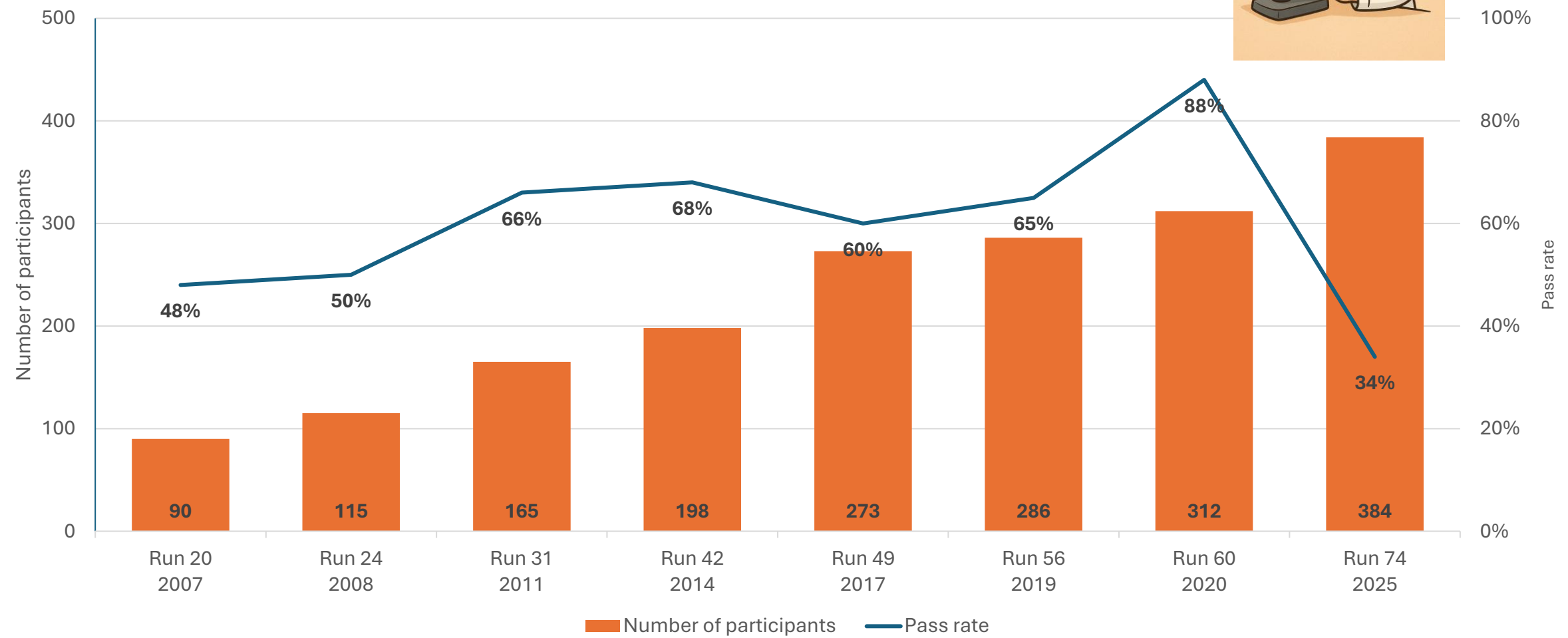
Producer: Ventana
Product / no: OptiView DAB IHC Detection Kit / 760-700
Incubation time / temperature: 8 min. / 36°C
Enhancement: CuSO4



MLA run 74 – also on podcast

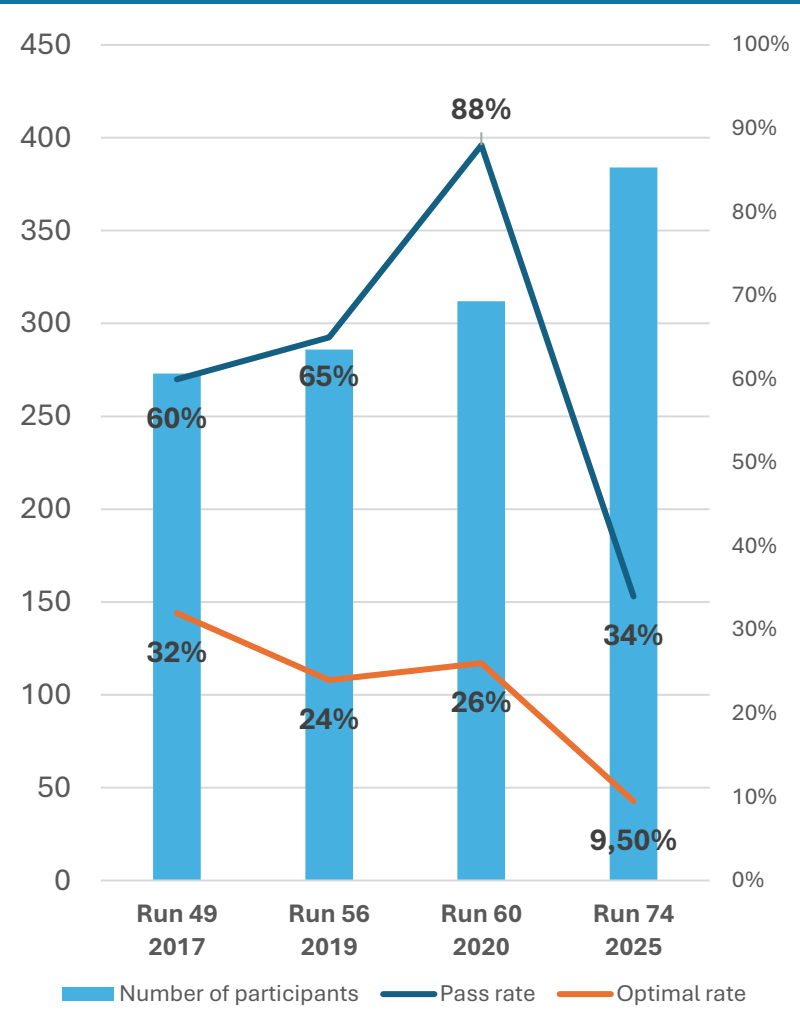
<https://nordiqc.org/downloads/documents/232.mp3>

MLA performance in NordiQC assessments



MLA run 60

First assessment of Melan A where steroid hormone procing cells and corresponding tumours were excluded



Ready-To-Use antibodies								
mAb clone A103 790-2990³	3	Ventana/Roche	0	0	3	0	-	-
mAb clone A103 790-2990⁴	94	Ventana/Roche	6	74	11	3	85%	6%
mAb clone A103, IR633/IS633³	14	Dako/Agilent	1	13	0	0	100%	7%
mAb clone A103, IR633/IS633⁴	56	Dako/Agilent	12	36	7	1	85%	21%
mAb clone A103, PA0233/PA0044³	7	Leica Biosystems	2	5	0	0	100%	29%
mAb clone A103, PA0233/PA0044⁴	10	Leica Biosystems	6	4	0	0	100%	60%

Table 3. Proportion of optimal results for MLA for the most commonly used antibody as concentrate on the four main IHC systems*

Concentrated antibodies	Dako Autostainer		Dako Omnis		Ventana BenchMark GX / XT / Ultra			Leica Bond III / Max	
	TRS pH 9.0	TRS pH 6.1	TRS pH 9.0	TRS pH 6.1	CC1 pH 8.5	CC1 pH 8.5 + Protease 3	CC2 pH 6.0	ER2 pH 9.0	ER1 pH 6.0
mAb clone A103	0/5** (0%)	0/1	6/9 (66%)	-	5/34 (15%)	-	-	7/17 (41%)	0/1
rmAb clone EP43	-	-	5/5 (100%)	-	5/6 (83%)	6/6 (100%)	-	1/1	-

MLA run 74



1. Skin
2. Kidney
3. Colon adenocarcinoma
- 4-5. Malignant melanoma

78% of insufficient results were too weak or false negative

A103 was used by 90%

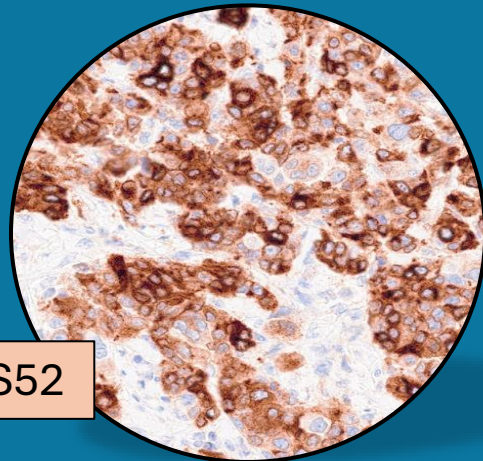
Table 1a. Overall results for MLA, run 74

	n	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
Concentrated antibodies	93	28	25	40	-	57%	30%
Ready-To-Use antibodies	291	10	67	212	2	27%	4%
Total	384	38	92	252	2		
Proportion		9.5%	24%	66%	0.5%	34%	

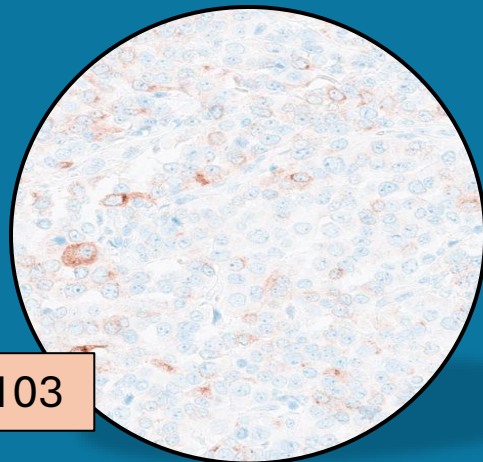
Table 1c. Ready-To-Use antibodies and assessment marks for MLA, run 74

Ready-To-Use antibodies	n	Vendor	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
mAb clone A103 790-2990 (VRPS) ³	13	Ventana/Roche OptiView	-	3	10	-	23%	0%
mAb clone A103 790-2990 (VRPS) ³	15	Ventana/Roche UltraView Red	-	5	10	-	33%	0%
mAb clone A103 790-2990 (LMPS) ⁴	110	Ventana/Roche	1	8	100	1	8%	1%
mAb clone HMB45+A103+T311 790-4677	2	Ventana/Roche	-	2	-	-	-	-
mAb clone A103 IR/IS633 (VRPS) ³	15	Dako/Agilent	-	5	10	-	33%	0%
mAb clone A103 IR/IS633 (LMPS) ⁴	80	Dako/Agilent	1	40	39	-	51%	1%
mAb clone A103 PA0233/PA0044 (VRPS) ³	26	Leica Biosystems	-	1	25	-	4%	0%
mAb clone A103 PA0233/PA0044 (LMPS) ⁴	13	Leica Biosystems	-	1	12	-	8%	0%

MLA run 74



BS52



A103

Table 1b. Concentrated antibodies and assessment marks for MLA, run 74

Concentrated antibodies	n	Vendor	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
mAb clone A103	41	Dako/Agilent	3	20	38	-	38%	5%
	11	Leica Biosystems						
	5	Cell Marque						
	2	Bio SB						
	1	Quartett						
	1	Zeta Corporation						
mAb clone BS52	5	Nordic Biosite	5	-	-	-	100%	100%
rmAb clone EP43	11	Nordic Biosite	17	3	-	-	100%	85%
	8	Epitomics						
	1	Cell Marque						
rmAb clone EP1422Y	1	Abcam	1	-	-	-	-	-
rmAb clone QR138	1	Quartett	1	-	-	-	-	-

Table 2. Proportion of optimal results for MLA for the most commonly used antibody as concentrate on the four main IHC systems*

Concentrated antibody	Dako/Agilent Autostainer ¹		Dako/Agilent Omnis		Ventana/Roche BenchMark ²			Leica Biosystems Bond ³	
	TRS pH 9.0	TRS pH 6.1	TRS pH 9.0	TRS pH 6.1	CC1 pH 8.5	CC1 pH 8.5 + P3	CC2 pH 6.0	BERS2 pH 9.0	BERS1 pH 6.0
mAb clone A103	2/5** (40%)	-	0/11	-	1/27 (4%)	-	-	0/15	0/1
mAb clone BS52	-	-	1/1	-	3/3	-	-	1/1	-
rmAb clone EP43	-	-	5/5 (100%)	-	5/7 (71%)	6/6 (100%)	-	1/2	-

DAB Detection

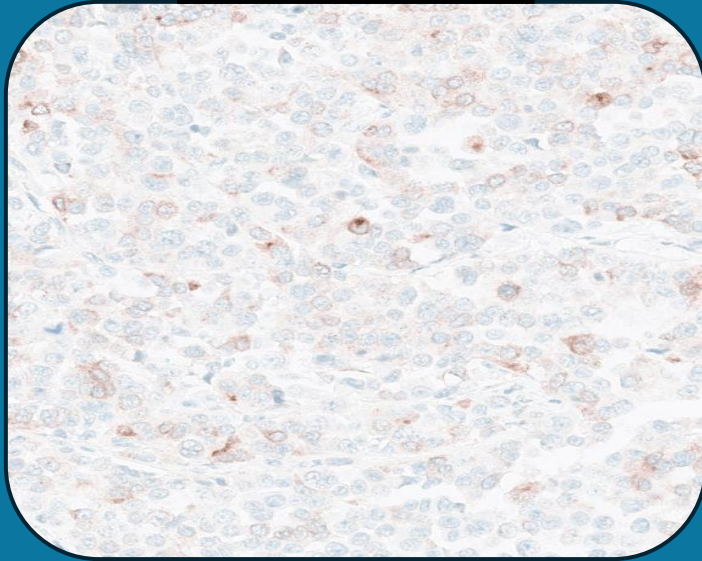
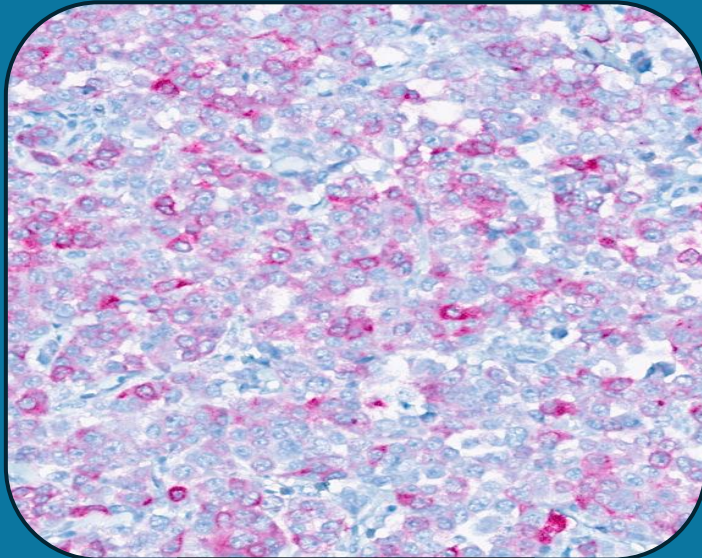


Table 4. Assessment marks for mAb clone A103 used as a concentrate on the four main IHC systems and their detection systems.

Staining platforms	n	Detection systems	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
Dako/Agilent Autostainer³	1	FLEX HRP magenta	-	-	1	-	-	-
	4	FLEX+ DAB	2	2	-	-	-	-
Dako/Agilent Omnis	1	FLEX+ HRP magenta	-	1	-	-	-	-
	10	FLEX+ DAB	-	7	3	-	70%	-
Leica Biosystems Bond⁴	6	Bond Refine Red	-	1	5	-	17%	-
	10	Bond Refine DAB	-	1	9	-	10%	-
Ventana/Roche BenchMark⁵	15	OptiView DAB	1	4	10	-	33%	7%
	5	UltraView AP	-	4	1	-	80%	-
	7	UltraView DAB	-	-	7	-	-	-
Total	59		3	20	36	-		

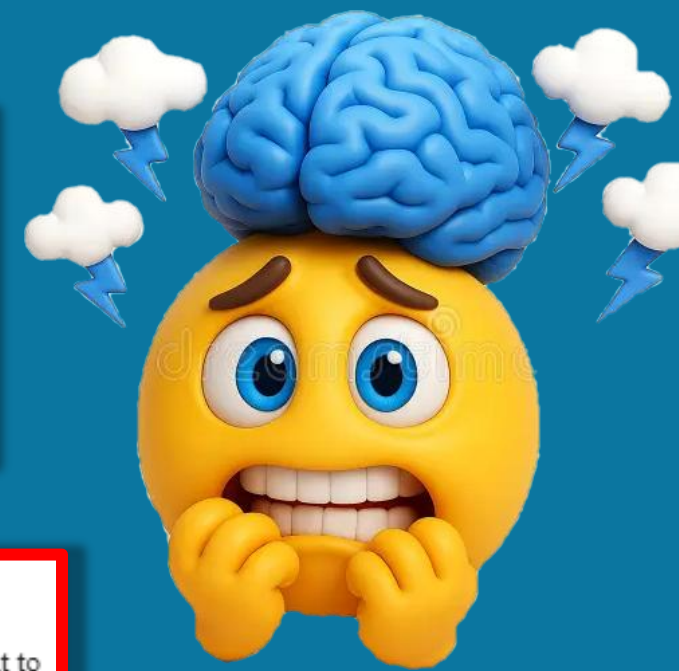


Red Detection

Assessment marks for mAb clone A103 used as a RTU on the four main IHC systems and their detection systems.

Staining platforms	n	Detection systems	Optimal	Good	Borderline	Poor	Suff. ¹	OR ²
Dako/Agilent Autostainer³	2	FLEX HRP magenta	-	2	-	-	-	-
	18	FLEX+ DAB	-	7	11	-	38%	-
Dako/Agilent Omnis	9	FLEX+ HRP magenta	-	5	4	-	56%	-
	59	FLEX+ DAB	1	29	29	-	51%	2%
Leica Biosystems Bond⁴	8	Bond Refine Red	-	-	8	-	-	-
	30	Bond Refine DAB	-	2	28	-	7%	-
Ventana/Roche BenchMark⁵	56	OptiView DAB	1	8	47	-	16%	1%
	40	UltraView AP	-	7	32	1	17%	-
	41	UltraView DAB	-	-	41	-	-	-
Total	263		2	60	200	1		

MLA run 74 - IVD challenges



Dear all

As many of you already know - Epitomics have not applied for uplifting their IVD approved products to IVDR.

The consequence is that from May 25th, 2025, AH will not be able to buy IVD approved Epitomics clones via Cell Marque.

AH diagnostics was informed a few weeks ago, and we have worked hard on finding alternatives.

We have therefoer asked for a complete list of products which will remain available from Epitomics, but as RUO-only. This list is attached in this mail.

Unfortunately, some of our most used clones will not be available anymore – MART1, CK117, CK8, CMYC (see attached list).

790-2990 (LMPS) ⁴	110	ventana/roche	1	8	100	1	8%	1%
mAb clone								

Dear Valued Customer,

You receive this email as you have been purchasing **Optibodies** from Nordic Biosite recent years. Please forward this to end-users if not relevant to you.

Our CE-IVD product line **Optibodies** have been with us for almost 15 years now and we have been able to help many customers in the field of clinical pathology.

We are now reaching out to you as a customer to let you know that we are not pursuing IVDR-registration for these products and they will thus not be available as CE-marked after 2025-12-31.

mAb clone A103 PA0233/PA0044 (LMPS)⁴	13	Leica Biosystems	-	1	12	-	8%	0%
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rmAb clone EP43 8319-C010	3	Sakura Finetek	3	-	-	-	-	-
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Thank you for listening

MLA

(Melan-A)

Characteristics

Melan-A is a melanocyte differentiation antigen, recognized by autologous cytotoxic T lymphocytes. Melan-A is also called MART-1 (melanoma antigen recognized by T cells). The Melan-A/MART-1 gene encodes this protein, 20-22 kDa, associated with endoplasmic reticulum and melanosomes. The function of the protein is unknown. Melan-A is expressed in all normal melanocytes and melanocyte cell lines. Using the monoclonal antibody A-103, staining is also seen in steroid hormone producing cells: adrenal cortex, granulosa and theca cells of the ovary and Leydig cells of the testis. This is due to cross reaction (as the Melan-A gene is not detected in these cells).

Neoplasms

Melan A is expressed in 80-100% of malignant melanomas, including all primary cutaneous malignant melanomas and mucosal melanomas. In metastatic melanomas the staining may be patchy and somewhat less often positive than in the corresponding primary tumours. In desmoplastic melanoma the staining reaction is frequently patchy or negative. Cutaneous naevi (intra-dermal, compound, junctional) are Melan-A positive as are Spitz naevus, blue naevus etc. Melan-A is also demonstrated in other tumours of melanocytic origin or differentiation (i.e., melanosome producing), such as clear cell sarcoma, melanotic neurofibroma, melanotic schwannoma and other melanotic neural crest derived tumours, as well as in so-called PEComas (perivascular epithelioid cell tumour) derived from modified smooth muscle cells in the so-called tuberous sclerosis complex: angiomyolipoma, lymphangiomyoma(-tosis), and pulmonary sugar tumour. Using the antibody A-103,

Protocols

[Recommended protocols](#)

Assessments

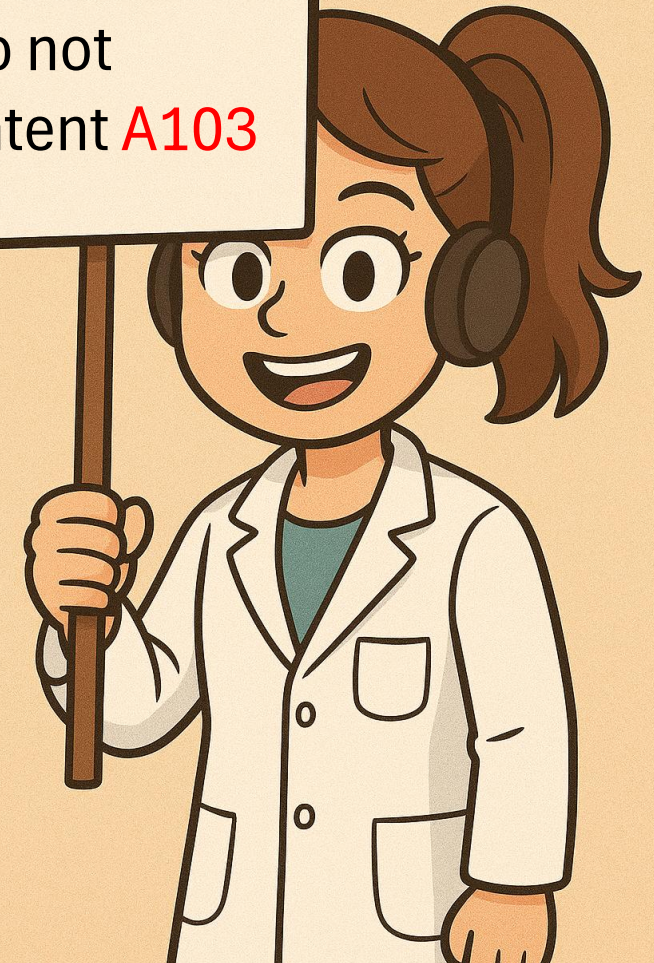
[Run 74](#)
[Run 60](#)
[Run 56](#)
[Run 49](#)
[Run 42](#)
[Run 31](#)
[Run 24](#)
[Run 20](#)
[Run 16](#)
[Run 07](#)

Podcasts

[MLA run 74 podcast](#)

AI-generated by NordiQC

Please
Do not
patent **A103**



Also available for **P53**: <https://nordiqc.org/downloads/documents/231.mp3>