

Hoofdsponsors



Bronzen sponsor



Andere sponsors



Resultaten EKE IHC 2023/1

De Wiest Bart

25/09/2023

OLV Ziekenhuis Aalst



EKE IHC 2023-1

Antistoffen: semi-kwantitatieve EKE

- ✓ ER: n=60
- ✓ Her2: n=57

Panel:

- ✓ Scoring 21/03/2023 (UZ Gent)
- ✓ Extra anonimisatie m.b.v. volgnummer
- ✓ Onafhankelijk, in consensus
- ✓ 2 pathologen



Procedure panelbeoordeling


- Literatuurstudie m.b.t. antilichaam: NordiQC website, datasheets, guidelines, ...
 - Wat moet / kan aankleuren?
 - Wat mag zeker niet aankleuren?
 - Vastleggen criteria aankleuring per AS
 - Beoordeling
 - Consensus binnen het panel
 - Reden voor afwijkend resultaat bij borderline/onvoldoende
 - Evt. aanbevelingen protocol
- eindbeoordeling



Antistof HER2

Samenstelling EQA blok

- Doel: evaluatie analytische accuraatheid Her2 analyse voor het aantonen en vaststellen van het eiwit expressie niveau in borstcarcinomen
- Hoe: 5 borstcarcinomen met dynamische en kritisch relevante expressieniveaus
- Weefsel

Biopten*		IHC	ISH (ratio)
1. Borstcarcinoom		1) 3+	1) Amplified (9.53)
2. Borstcarcinoom		2) 0	2) Not amplified (1.11)
3. Borstcarcinoom		3) 1-2+	3) Not amplified (1.08)
4. Borstcarcinoom		4) 1-2+	4) Not amplified (0.84)
5. Borstcarcinoom		5) 2+	5) Amplified (2.20)

- Cellijn: geen

Beoordelingscriteria HER2



Optimaal :

- de kleuring van biopt 5 (2+ amp) komt overeen met een score 2+
- de kleuring van biopt 3 komt overeen met een score 1+ of 2+
- geen of maximaal zwakke cytoplasmatische aankleuring die niet interfereert met de interpretatie van de membraire aankleuring

Goed :

- algemeen weinig intense membraire aankleuring
- of vals positieve aankleuring (bv. de kleuring van biopt 2 (0) komt overeen met een score 2+)
- of te zwakke tegenkleuring

Borderline :

- cytoplasmatische aankleuring die interfereert met de interpretatie van de membraire aankleuring
→ optimalisatie van het protocol is nodig

Onvoldoende :

- de kleuring van biopt 1 (3+) of 5 (2+ amp) komt overeen met een score 0 of 1+
→ optimalisatie van het protocol is dringend nodig



Protocol HER2

n= 57

Conc.: blijvende daling n=23 →19 →17

- Dako: polyclonaal: n=22 →18 →17
- CellMarque clone SP3 : n=1 → 0
- Leica/Novocastra: geen
- Enzo Lifesciences: geen

RTU: n=40

- Dako Herceptest (DG44): n=6
- Roche: rm 4B5: n=33
- Leica/Novocastra: clone CB11 : n=1

Protocol HER2

Polyclonaal conc. Dako

- Dako datasheet Autostainer
 - pH6: 1/600-1/800 ; 20min RT
 - pH9: 1/1000-1/1200 ; 20min RT
- op Autostainer: 4 → 3
 - Inc. tijd : 20-25min RT
 - Verdunningen:
 - 2019-1: **10** verdunningen: 1/150 - 1/800
 - 2022-1/3 : 3 verdunningen: 1/150 tot 1/300
 - 2023-1: idem
 - HIER
 - 2019-1: 2/14 pH9 → rest pH6
 - 2019-3: enkel pH6
 - 2020-1: 2/7 pH9 , rest pH6
 - 2020-3 : 3/7 pH9 , rest pH6
 - 2022-1/3: 1 pH6 en 2 pH9
 - 2023-1: idem

Protocol HER2

Polyclonaal conc. Dako

- op Omnis: 11
 - Verdunningen
 - 2019-1: 5 verdunningen 1/100 - 1/600 ; 2019-2: 6 verdunningen: 1/100 – 1/400
 - 2020-1: 7 verdunningen: 1/100 tot 1/1000 ; 1/4 gebruikt 1/200
 - 2020-3 : idem ; 1/3 gebruikt 1/200
 - 2021-1: idem, 1/100 tot 1/1000
 - 2022-3: 6 verdunningen: 1/100 tot 1/1000 (~30% gebruikt 1/200)
 - **2023-1: idem**
 - Inc.tijd : 12 - 30 min RT/32° C (82% gebruikt 20') ongewijzigd
 - HIER
 - 2019-1: enkel pH6 ; 2020-3: 70% pH6
 - 2022-1: 64% pH6 ; 2022-3: ongewijzigd
 - 2023-1: idem
- Dako AS op Roche stainers: 2 (ongewijzigd)
 - 1/200 32' bij 36° C of 1/400 20' bij 36° C UV ; HIER CC1 mild
- Dako AS op Bond III: 1 (ongewijzigd)
 - 1/500 15' bij RT ; HIER pH9 20'

Geen wijzigingen



Protocol HER2

Clone 4B5 RTU Ventana

- BMK Ultra UltraView
 - **25%** datasheet: AS12' ; CC1 mild = geen wijziging
 - AS: 12' - 32' bij 36° C (~25%: 12')
 - + amplifier (17% !): 4' - 16'
 - HIER: CC1 8' - 64' ! (~83% CC1 mild)
- BMK Ultra: optiView (n=1 → 0)

Herceptest/DG44 Dako RTU

allen optimal

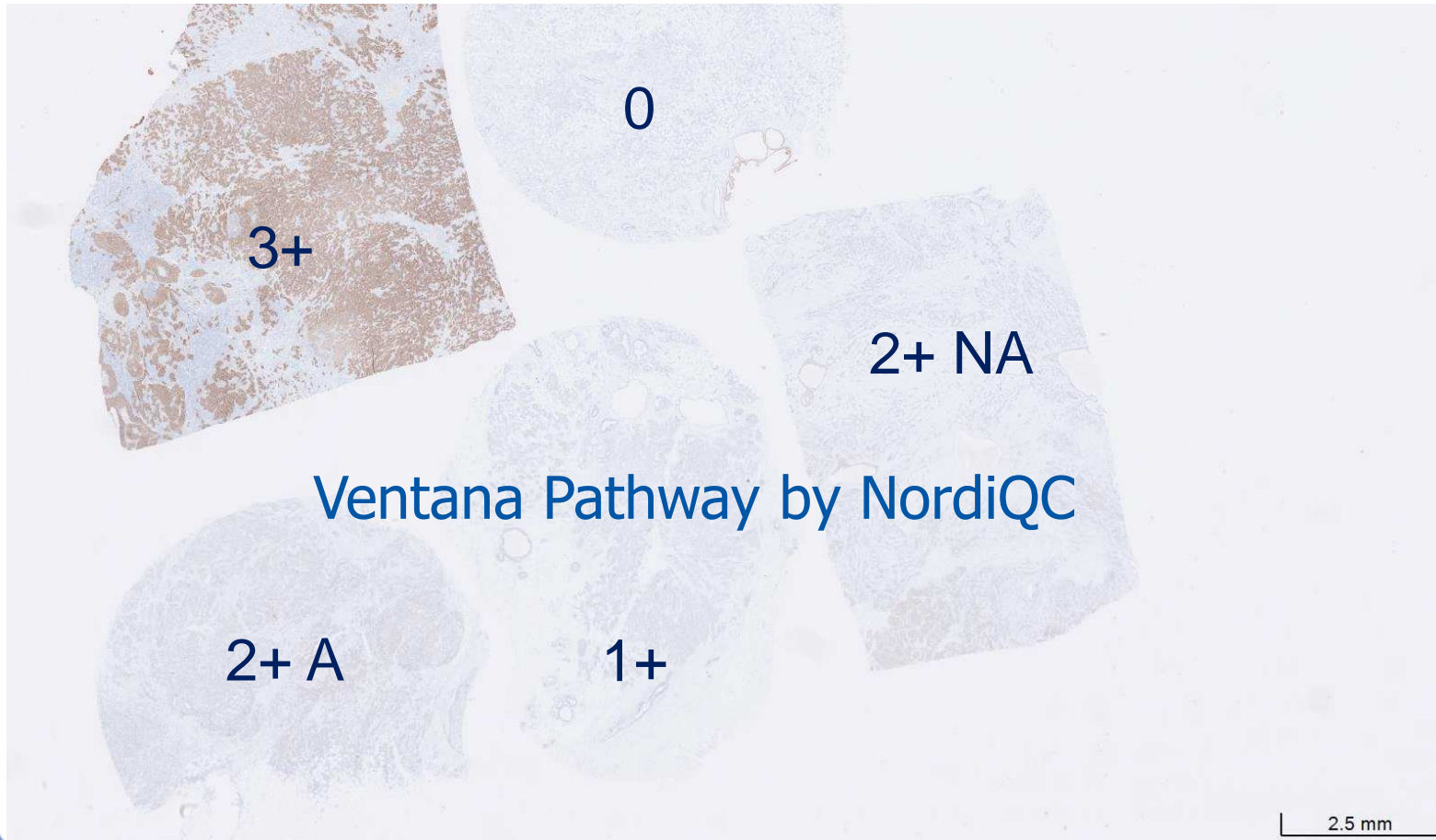
- 6 deelnemers Omnis platform
- Gestandaardiseerd: AS inc. enkel 10' bij 32° C ; HIER allen pH6 30'
→ ongewijzigd

Clone CB11 Leica

- RTU: Leica Bond III: AS inc. 15' RT; HIER pH9 20' ongewijzigd



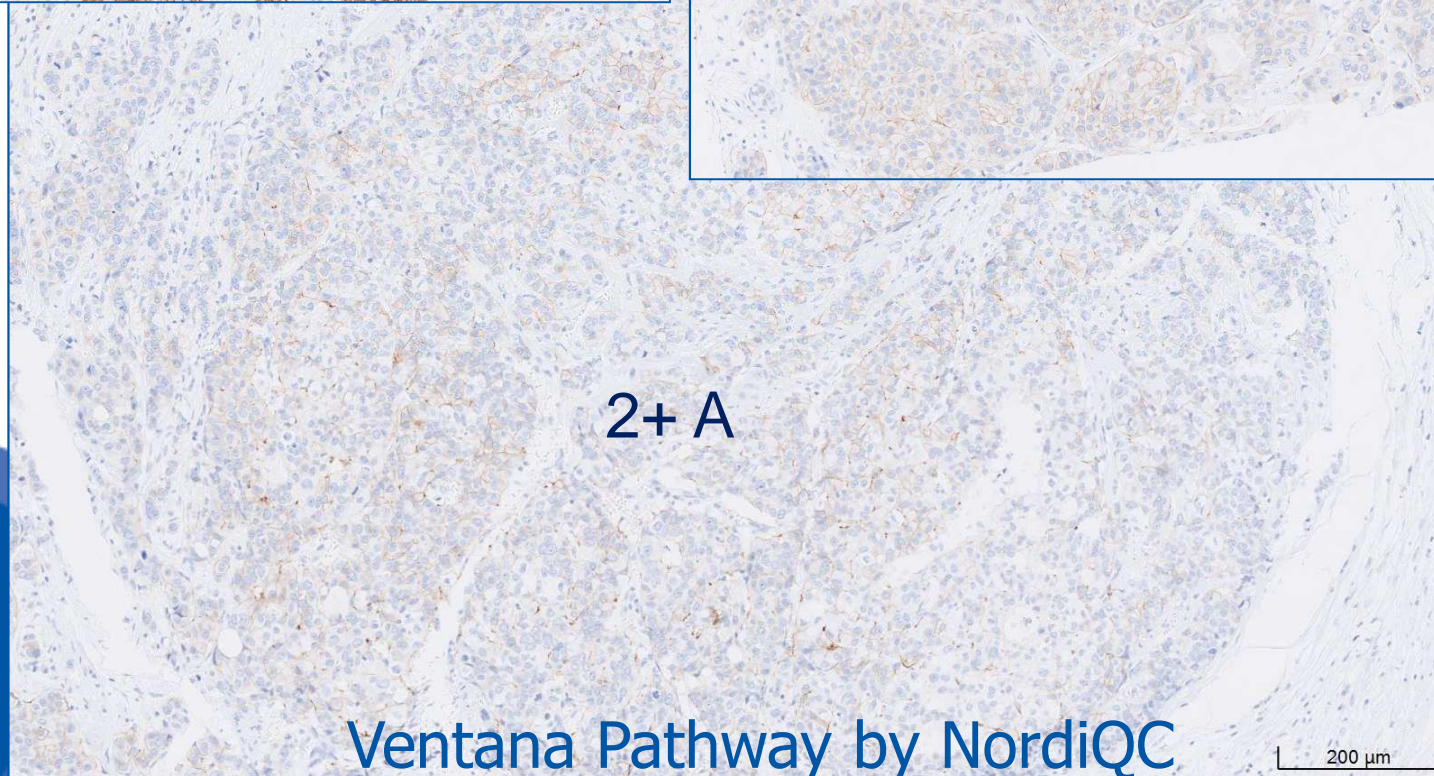
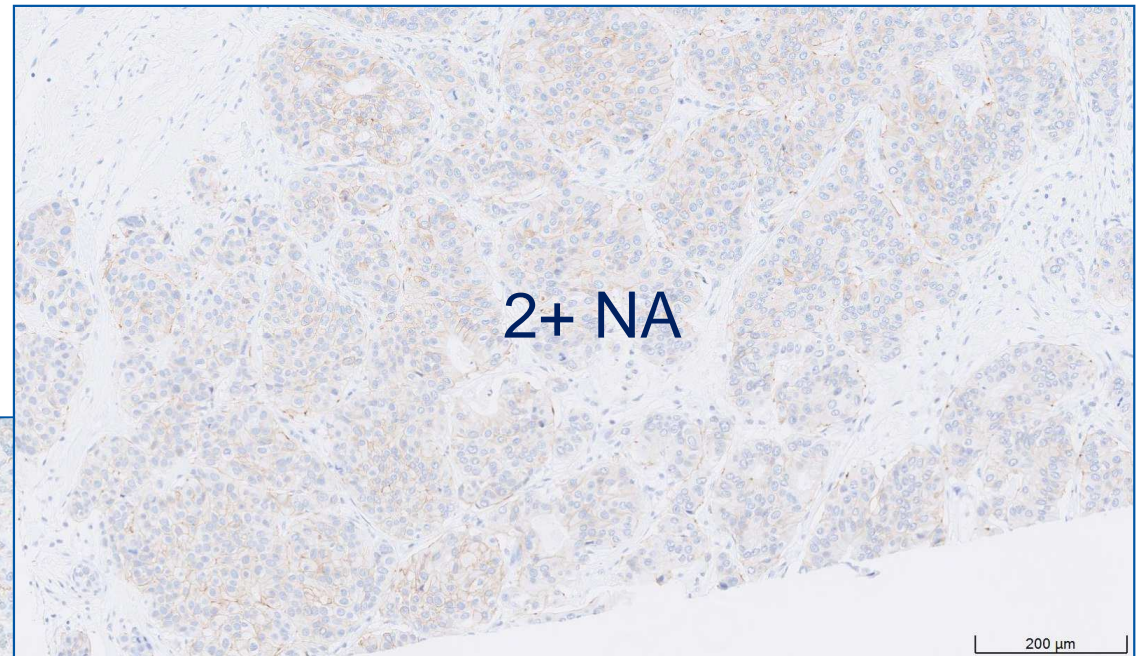
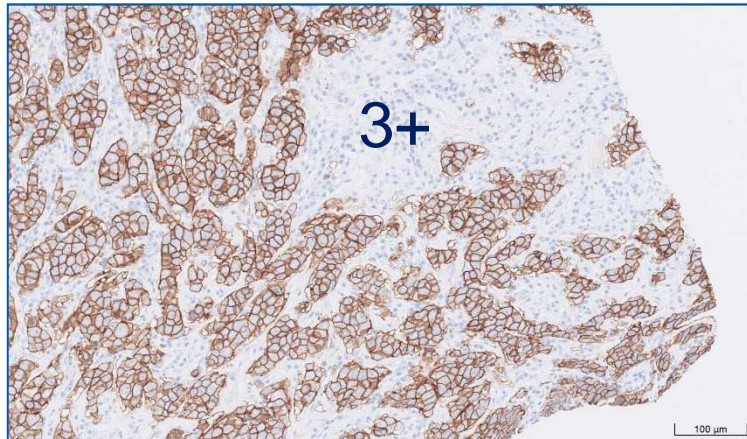
Antistof HER2 : overzicht



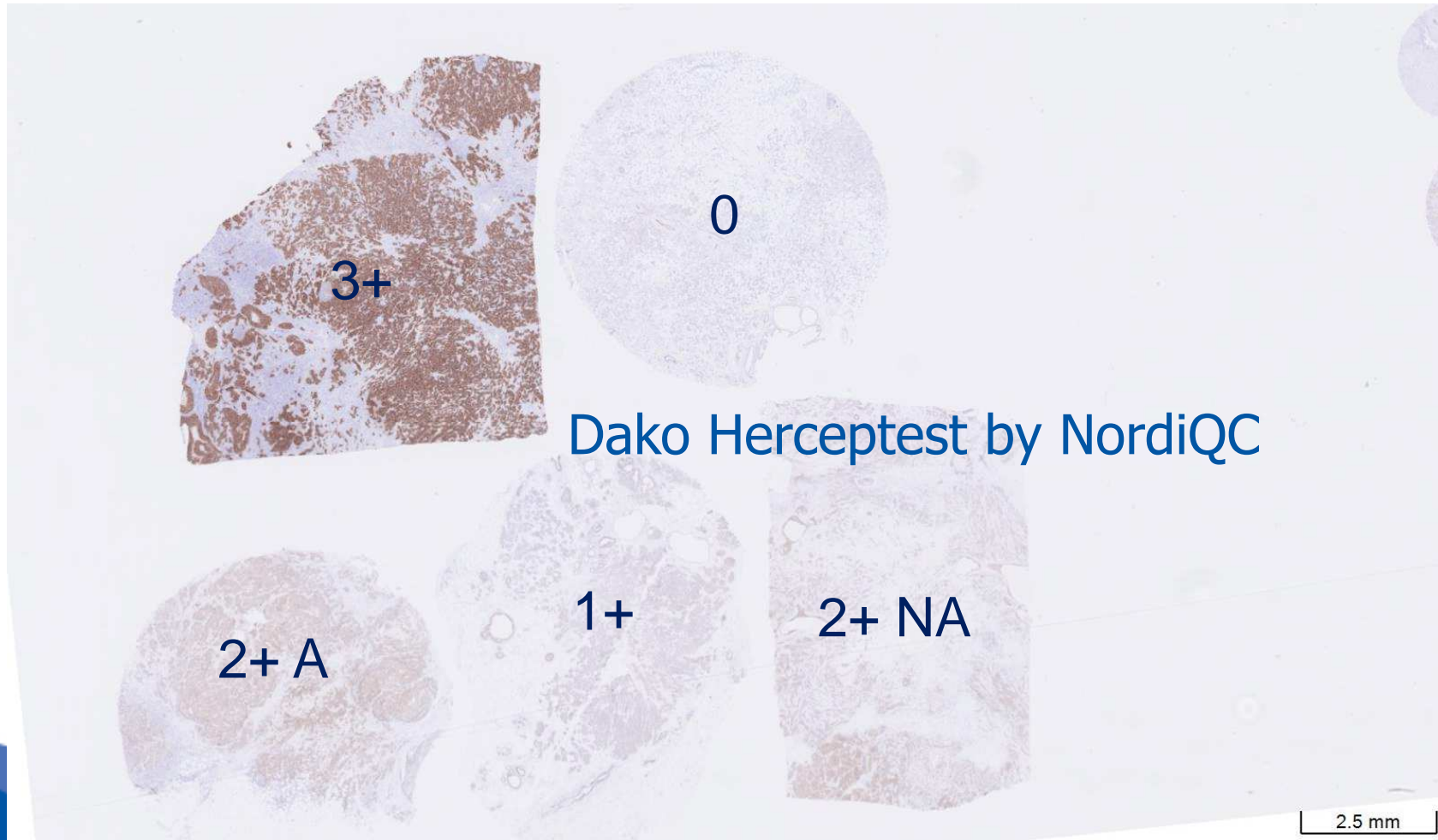
Expected result



Antistof HER2 : overzicht

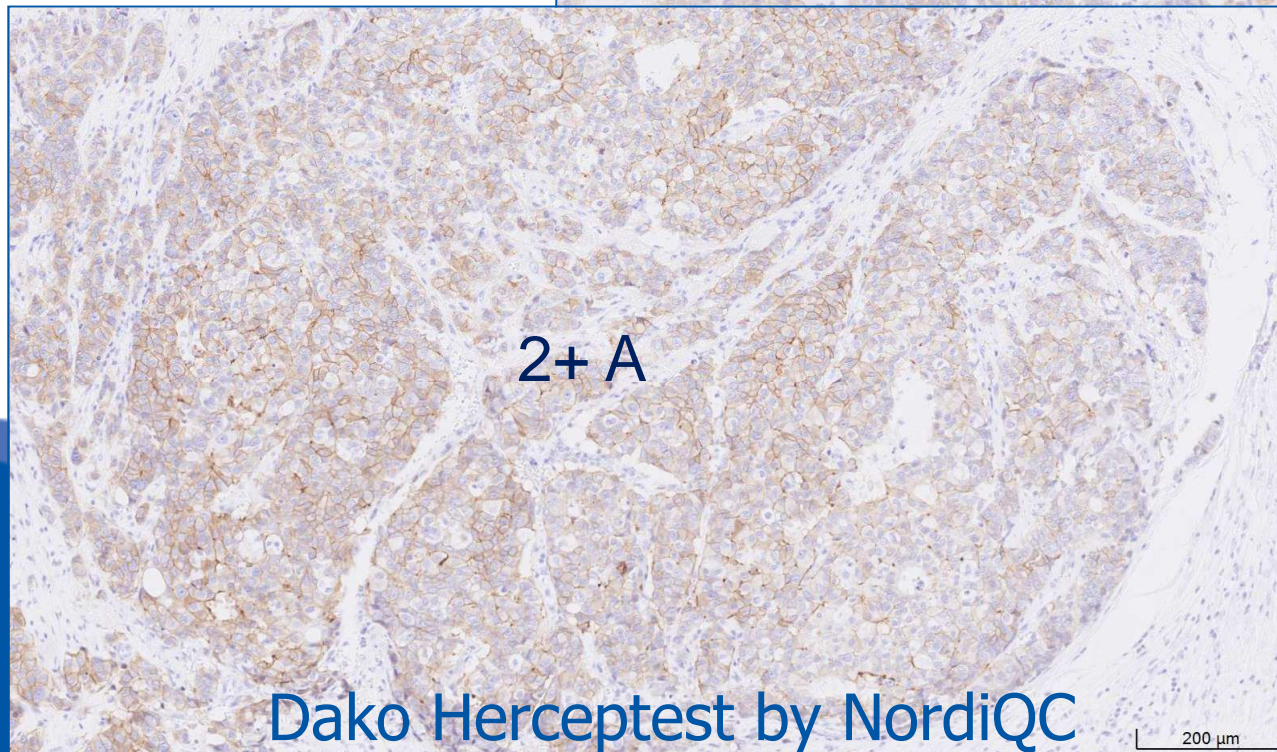
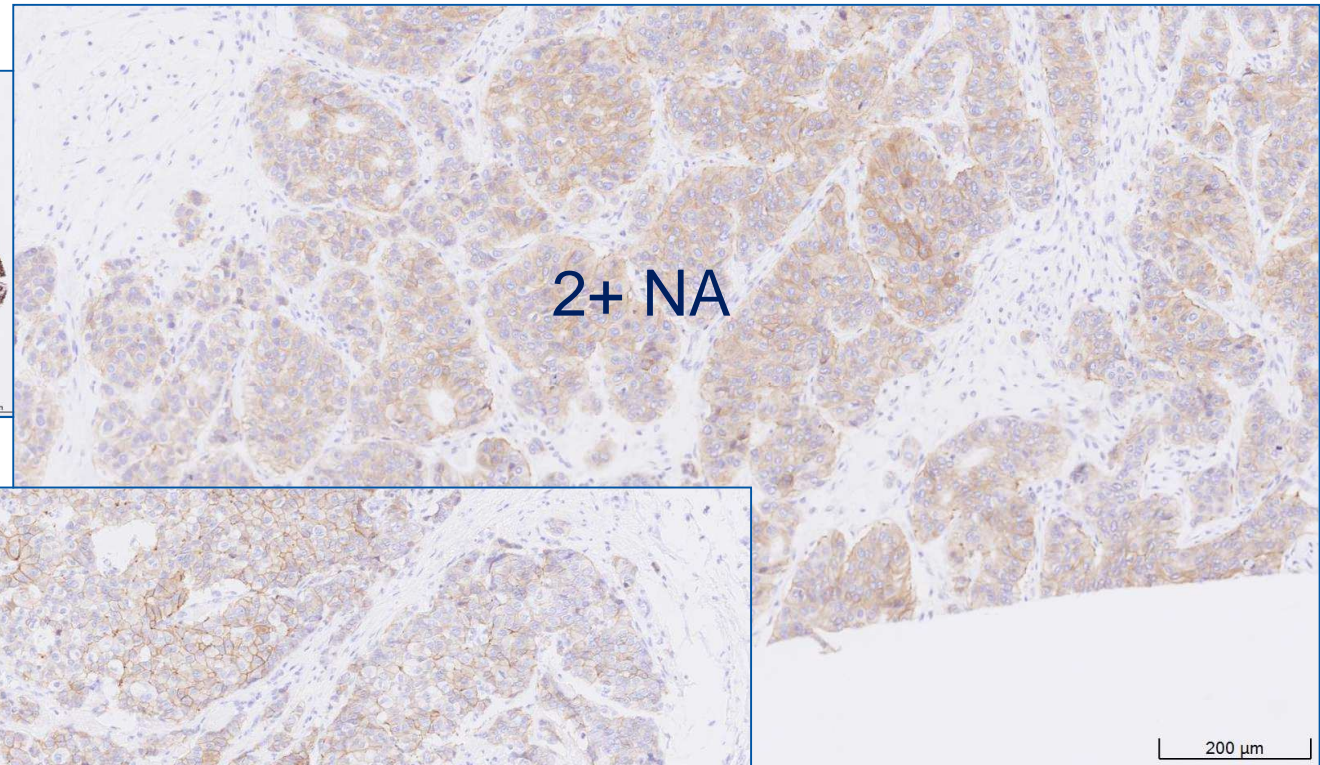
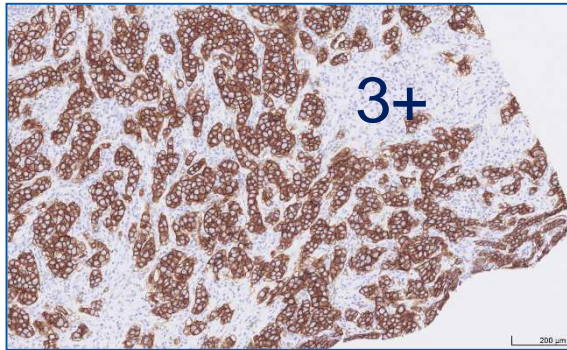


Antistof HER2 : overzicht

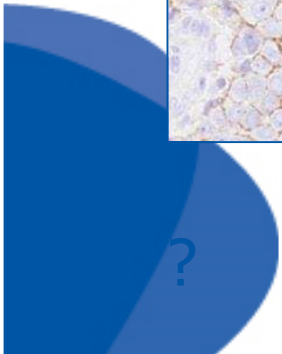
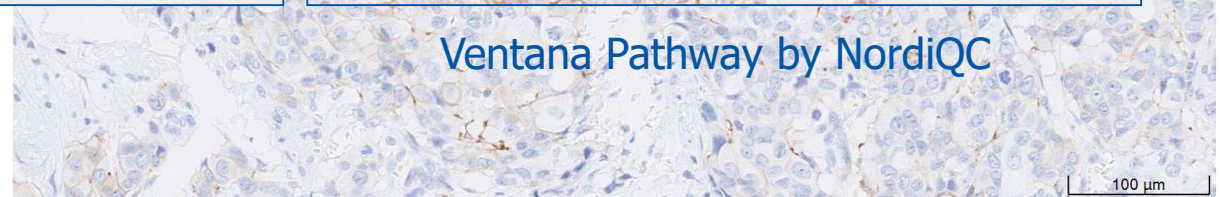
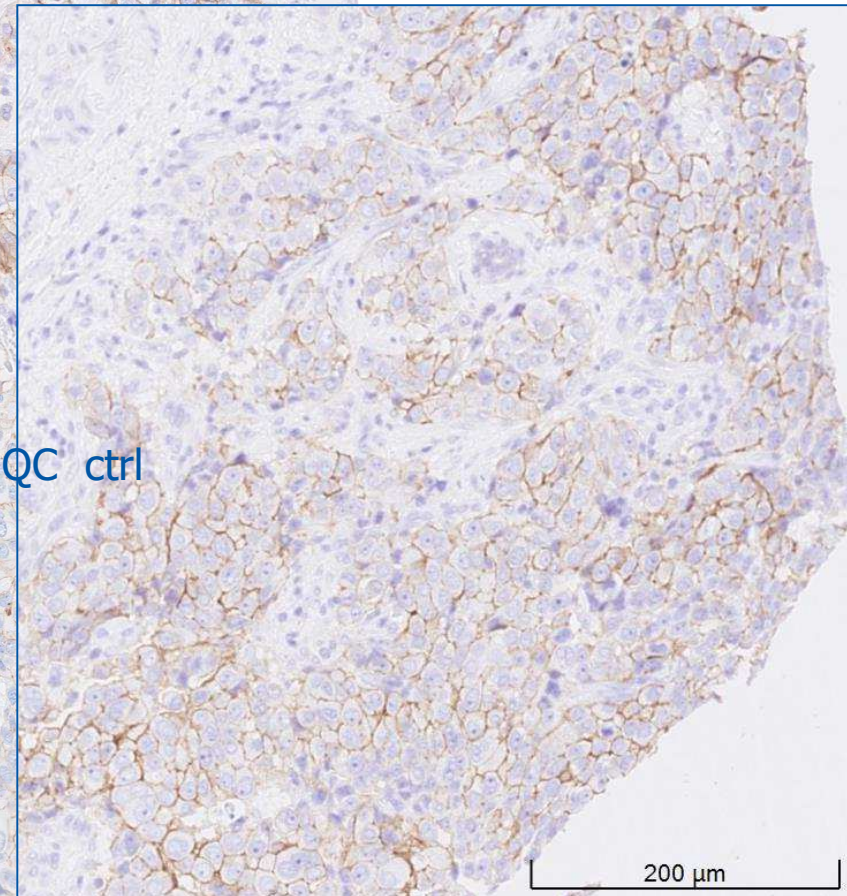
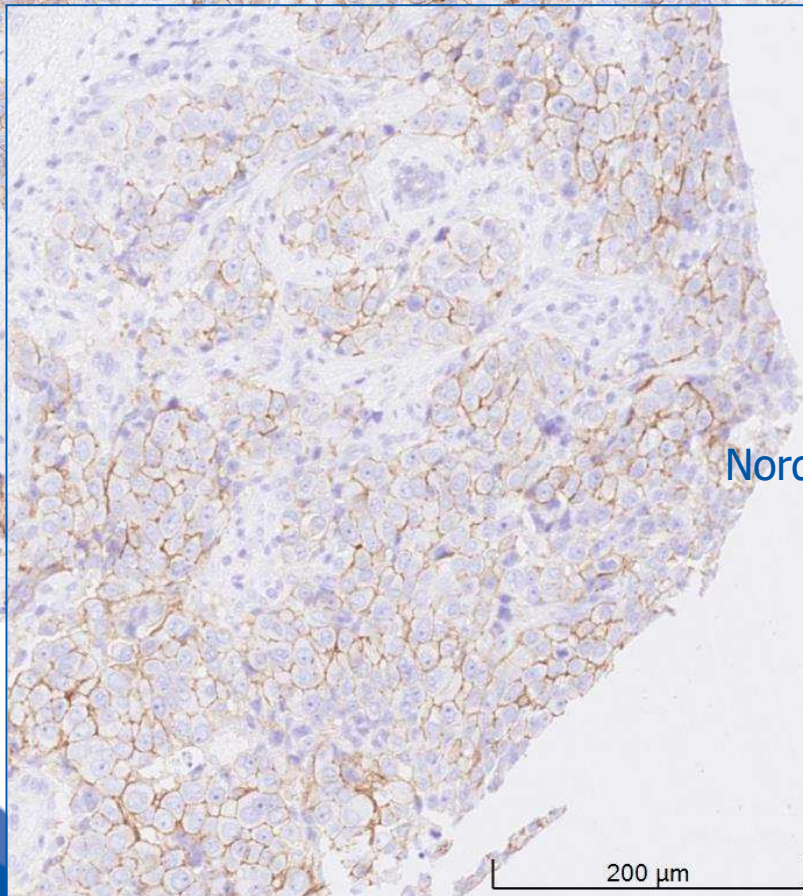
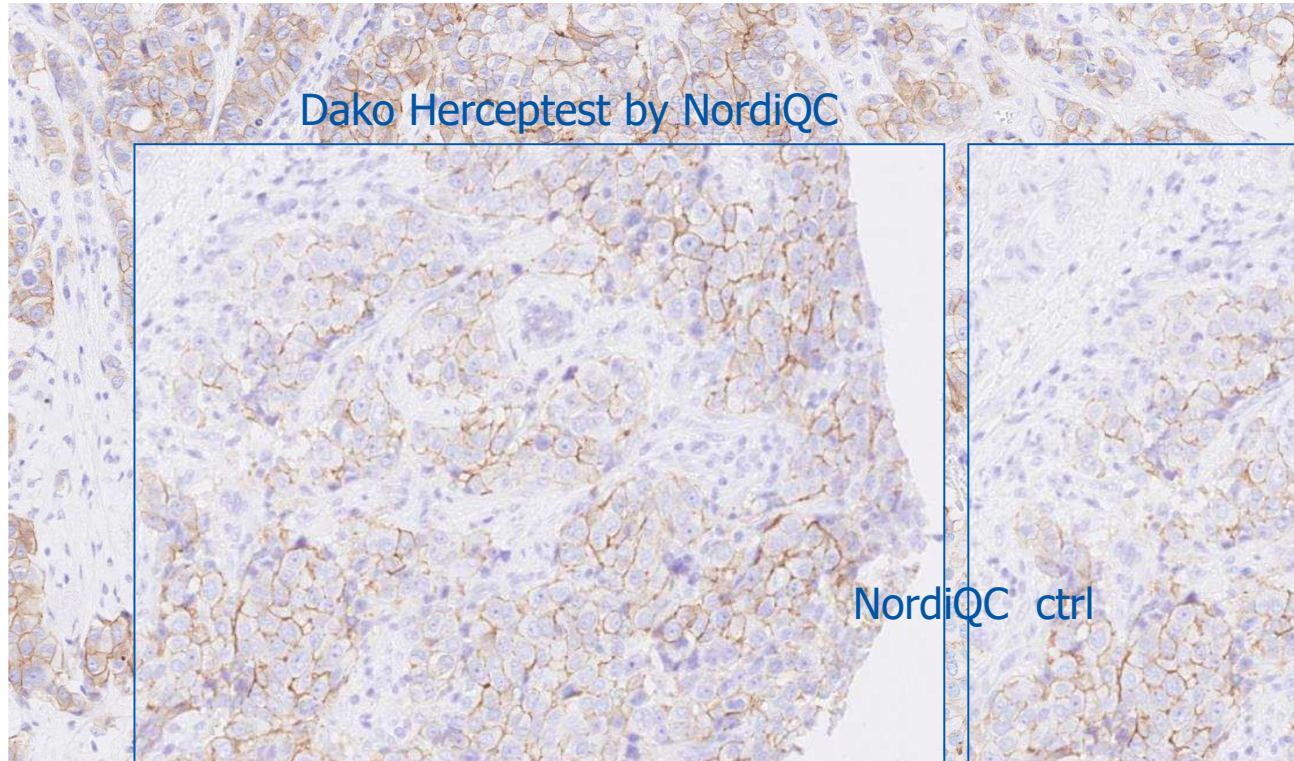


Expected result

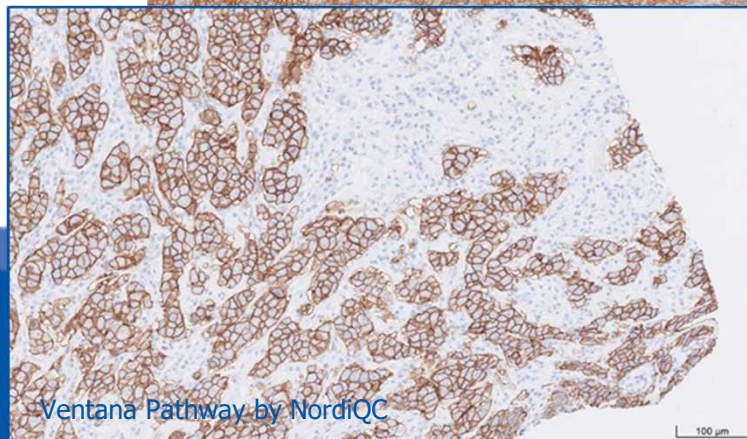
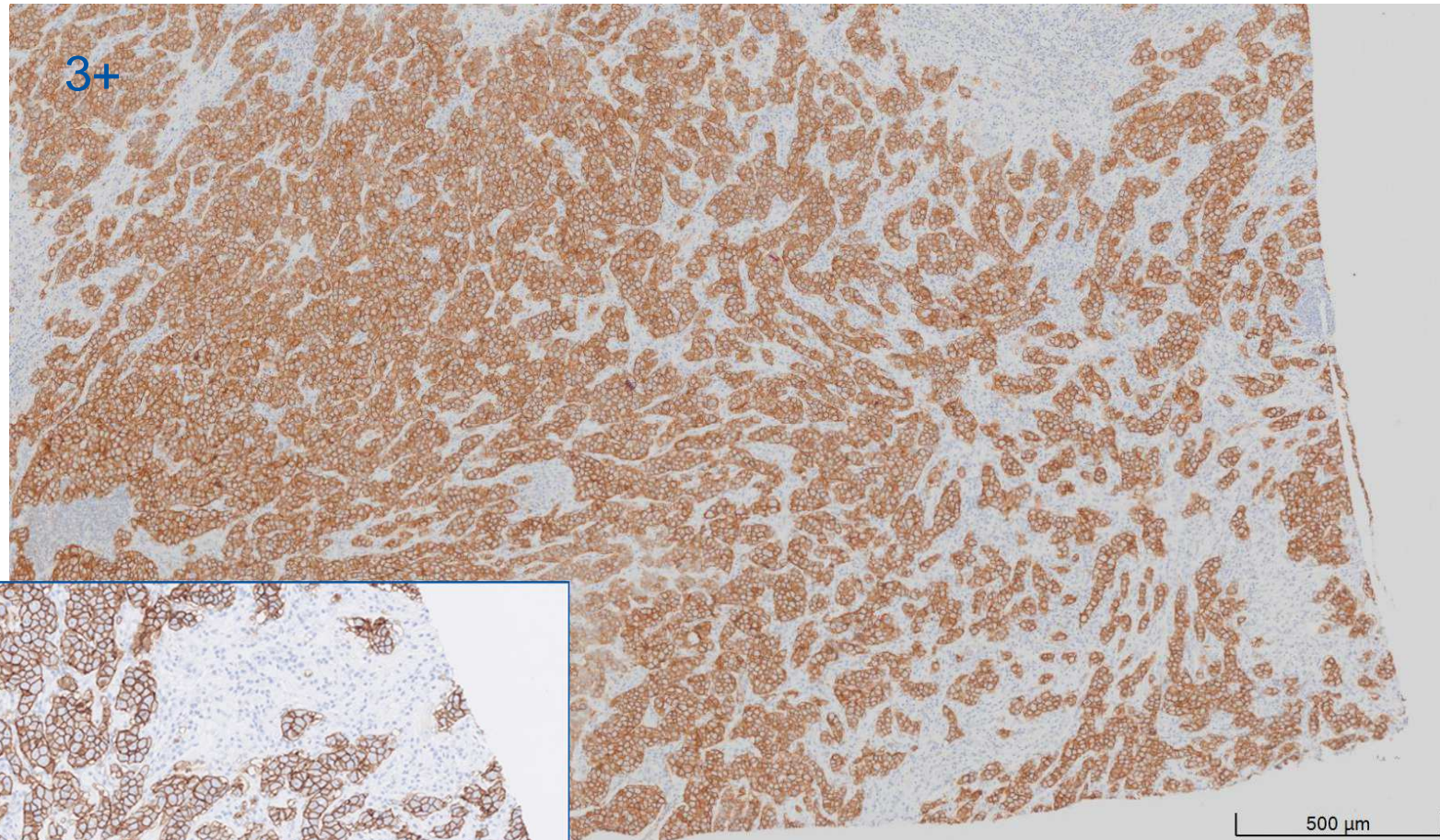
Antistof HER2 : overzicht



Antistof HER2 : overzicht



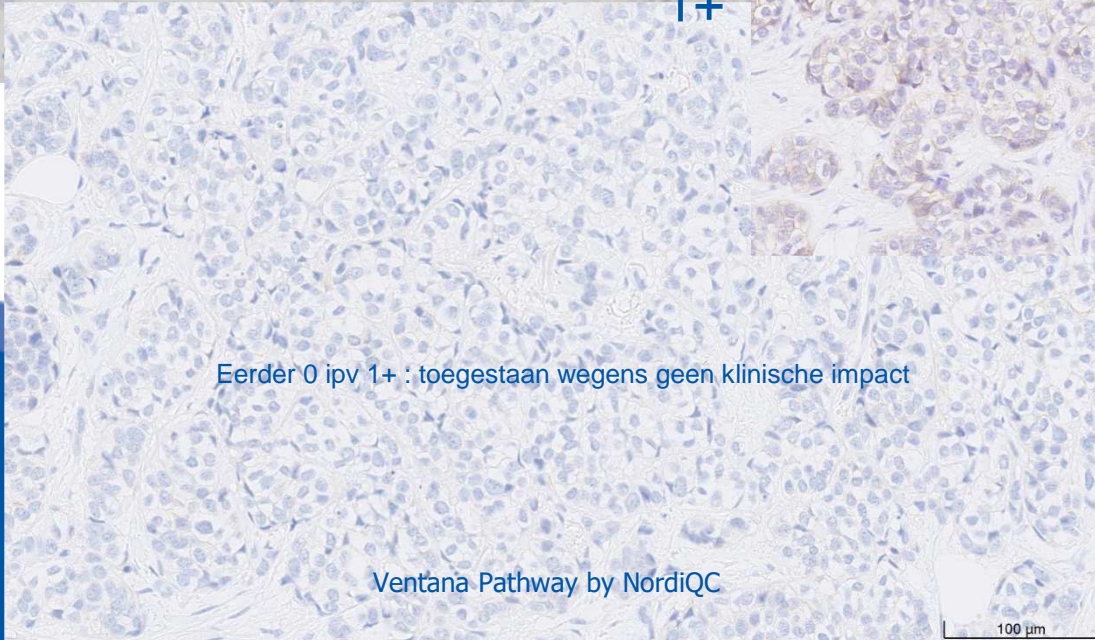
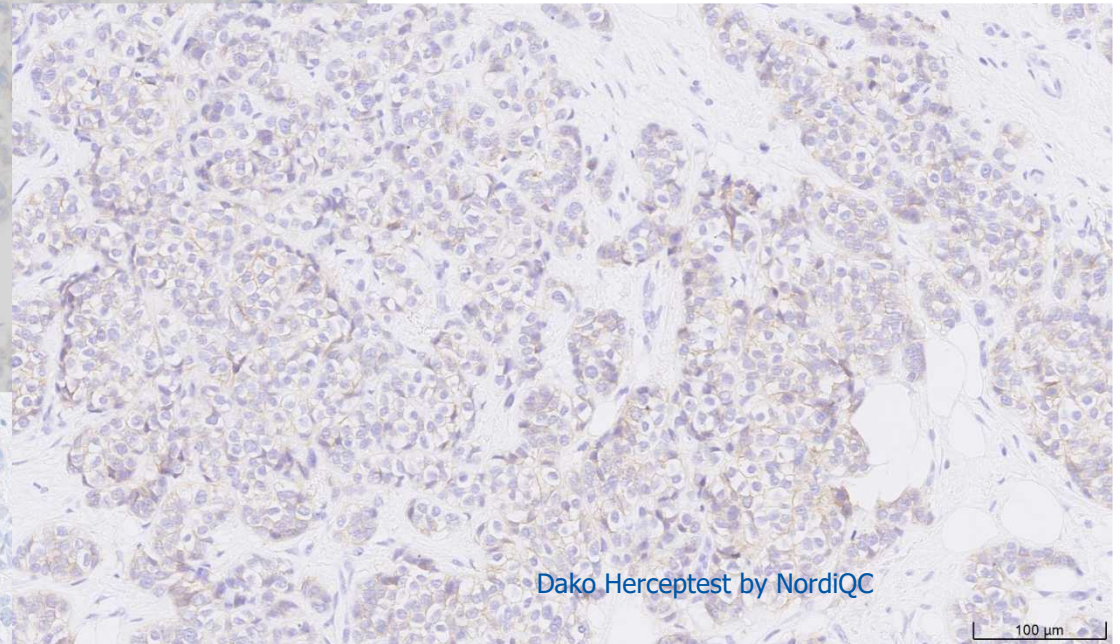
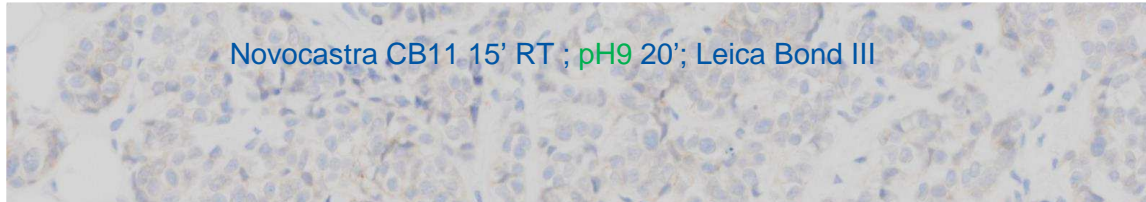
Antistof HER2



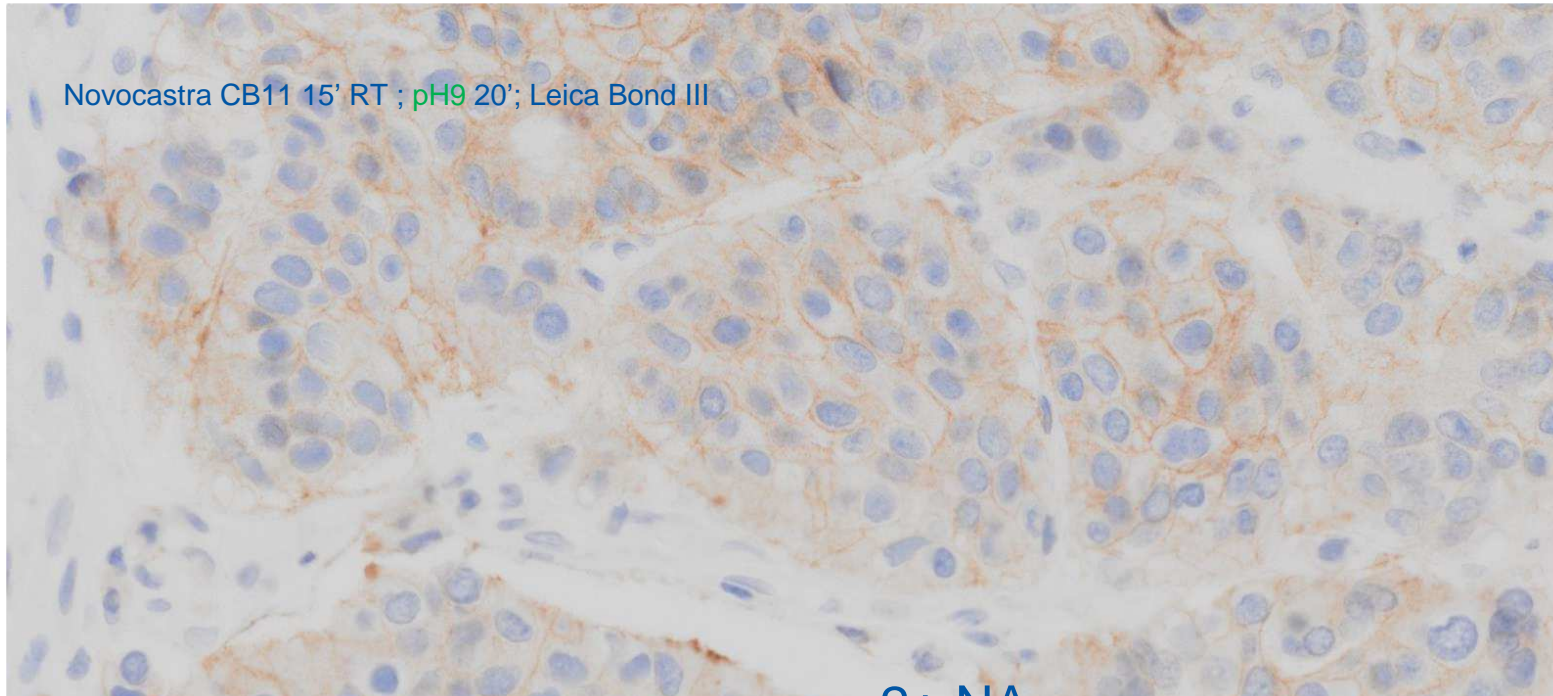
Novocastra CB11 15' RT ; pH9 20'; Leica Bond III



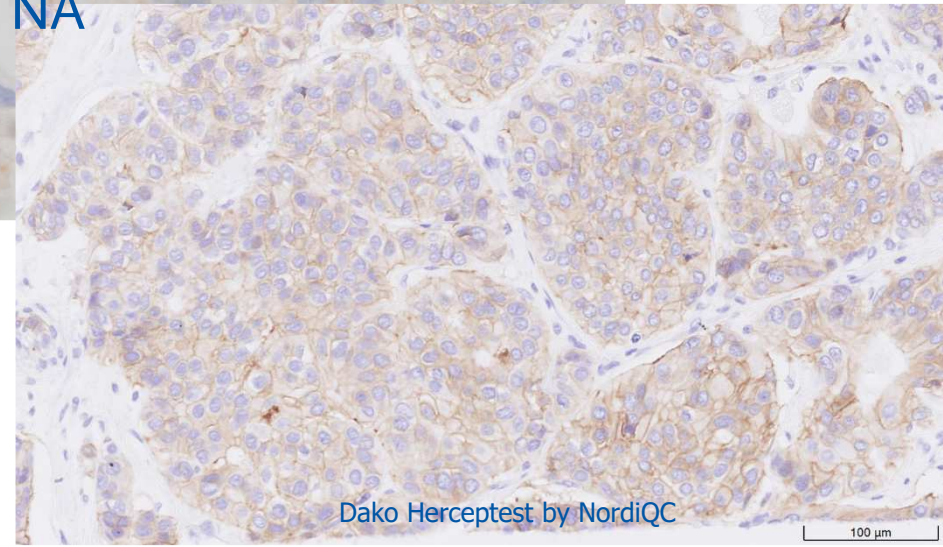
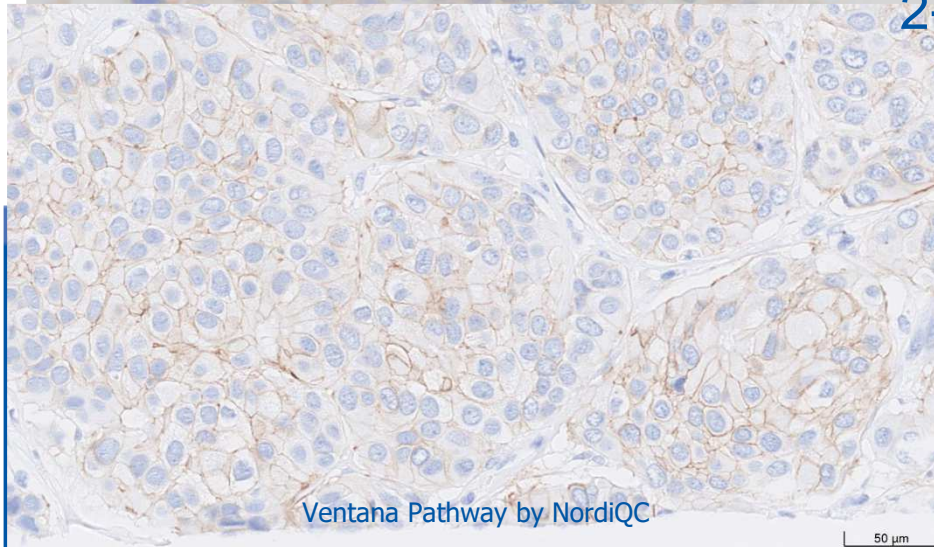
Antistof HER2



Antistof HER2

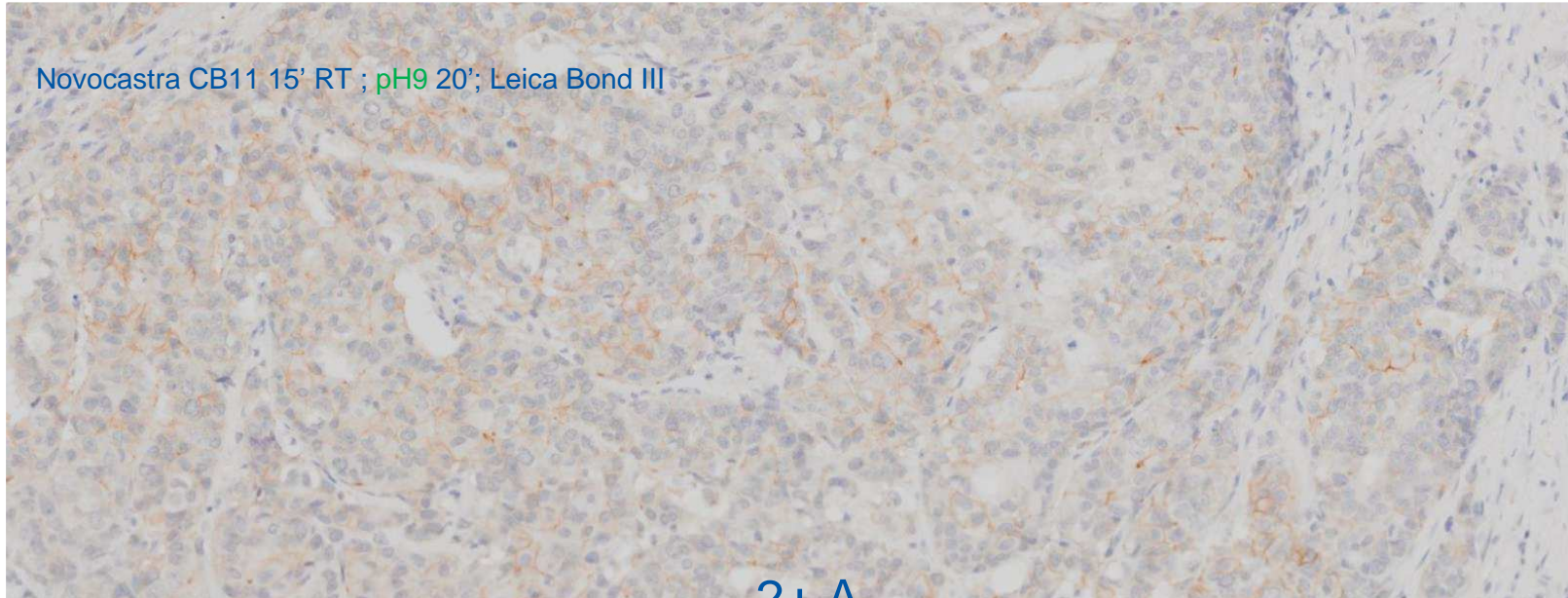


2+ NA

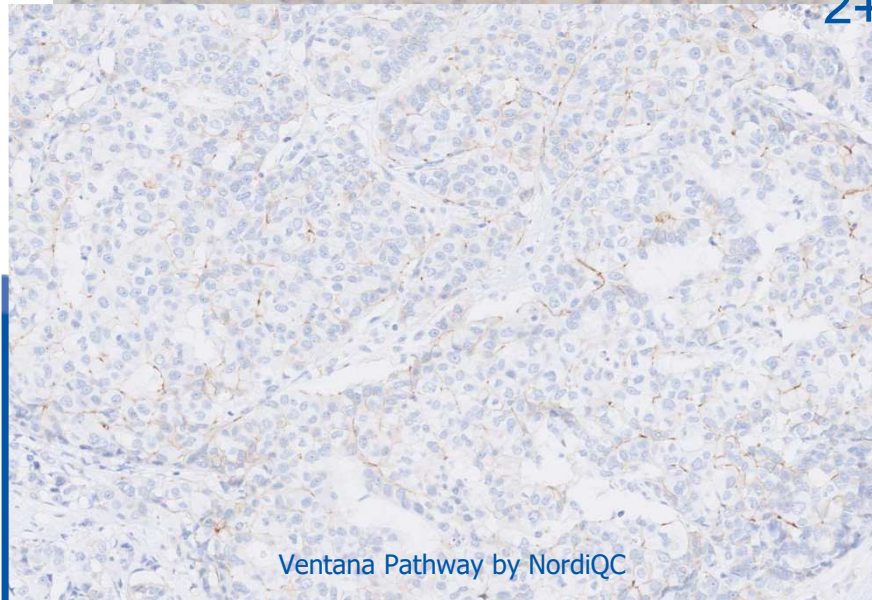


Antistof HER2

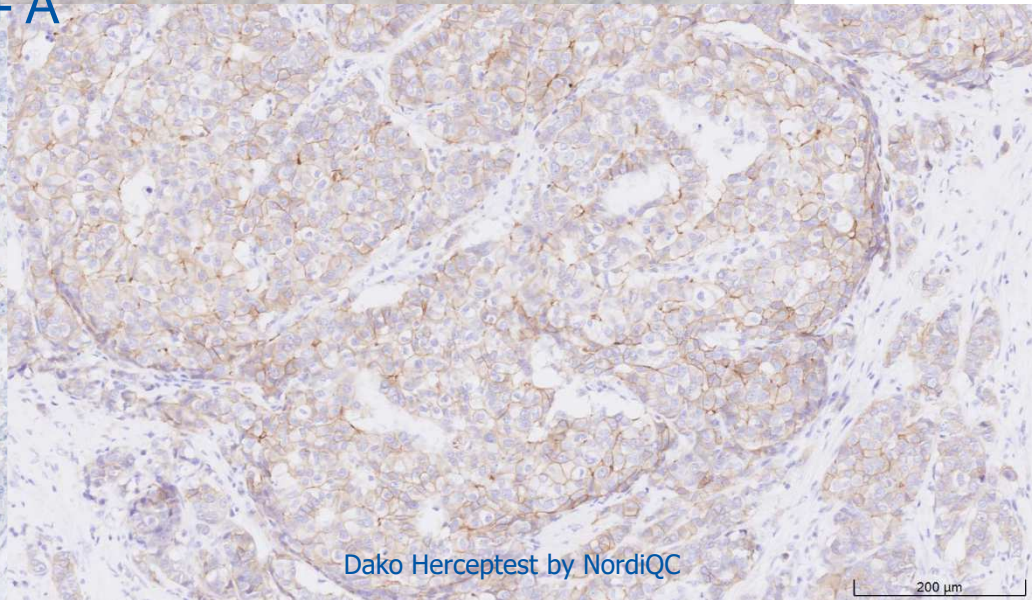
Novocastra CB11 15' RT ; pH9 20'; Leica Bond III



2+ A



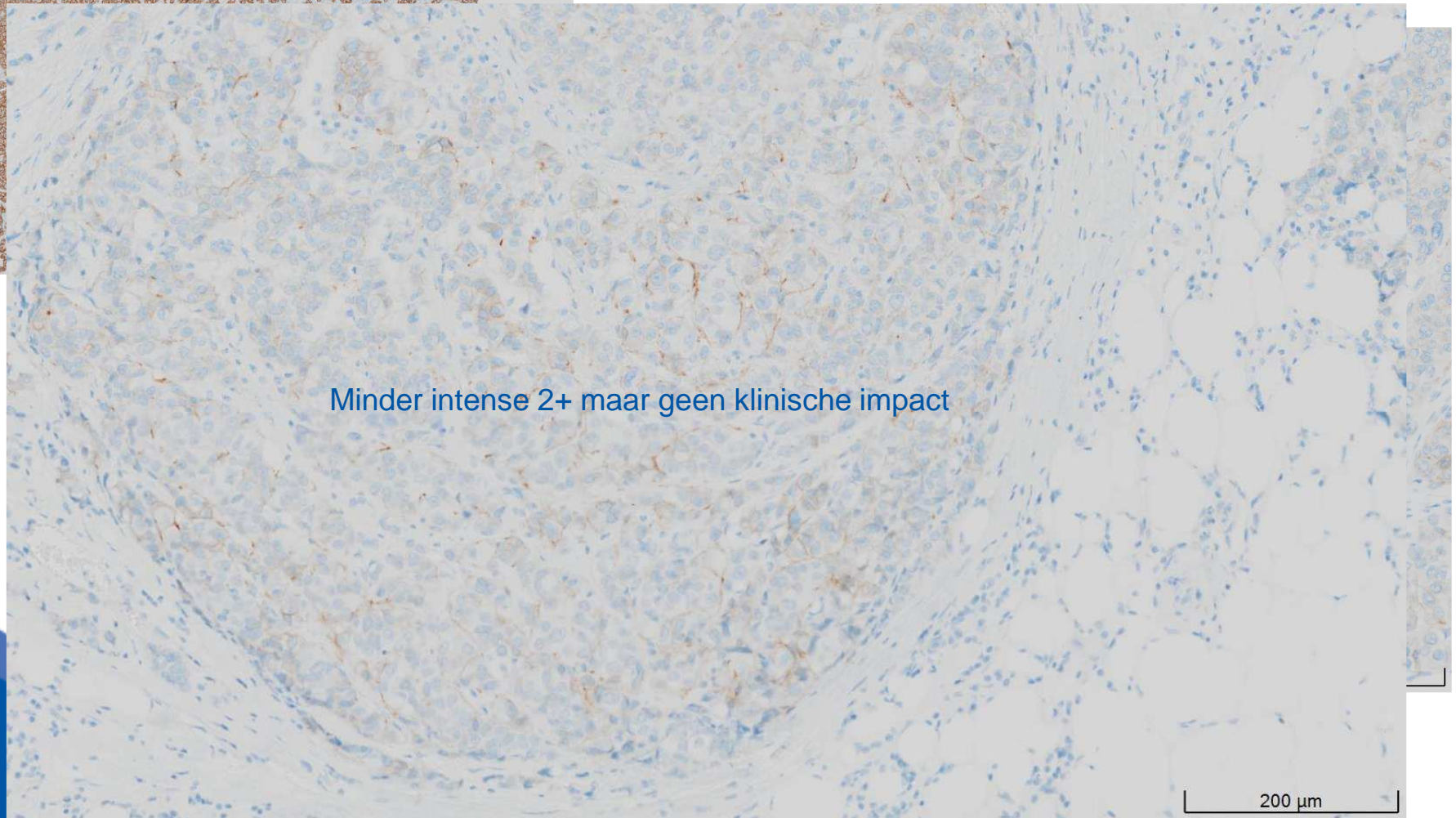
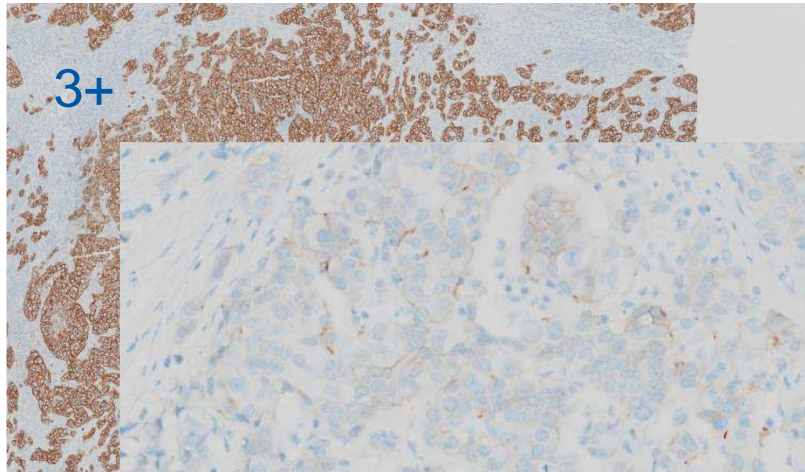
Ventana Pathway by NordiQC



Dako Herceptest by NordiQC

200 μm

Antistof HER2



Resultaatbespreking HER2

Algemeen resultaat

n=57		2023-1		2022-3		2022-1		2020-3		2020-1		NQC run B35	
	<i>n</i>	<i>%</i>	<i>suff.</i>	<i>%</i>	<i>suff.</i>	<i>%</i>	<i>suff.</i>	<i>%</i>	<i>suff.</i>	<i>n</i>	<i>suff.</i>	<i>n=324</i>	<i>suff.</i>
optimaal	57	100%		63%		88%		62,5%		86 %		66%	
goed	0	0%	100%	20%	83%	12%	100%	3 %	67%	4%	90%	24%	90%
borderline	0	0%	-	0		-		8 %		2%		6%	
onvoldoende	0	0%	-	17%		-		26,5%		7%		4%	

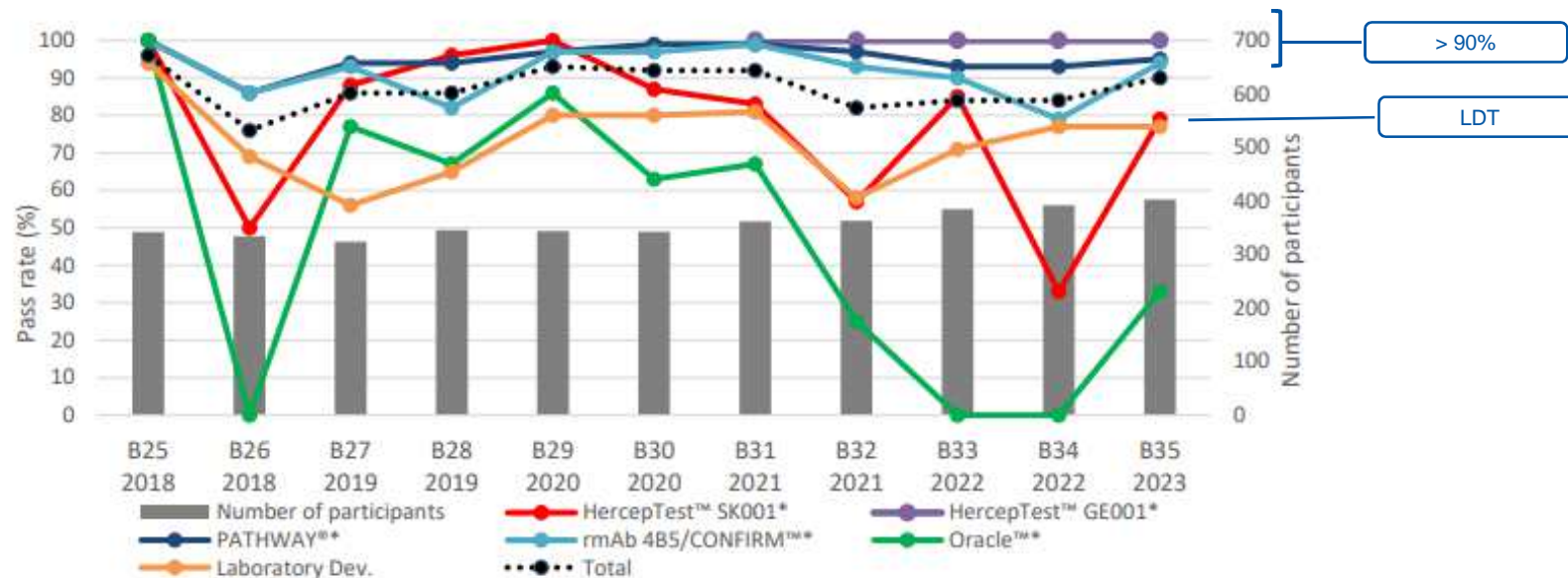


Resultaatbespreking HER2

Algemeen

The historical pass rates of the NordiQC HER2 IHC assessments are illustrated in Graph 1 below.

Graph 1. Pass rates of the HER2 IHC assessments in the NordiQC breast cancer module 2018-2023



* pass rates using vendor recommended protocol settings

Resultaatbespreking HER2

Opgesplitst per clone : conc.

n=17	<i>polyclonal Dako 2023-1</i>	suff 2023-1	<i>polyclonal Dako 2022-3</i>	suff 2022-3	<i>polyclonal Dako 2022-1</i>	suff 2022-1	<i>polyclonal Dako 2020-3</i>	suff 2020-3	<i>polyclonal Dako 2020-1</i>	suff 2020-1	2019-3	suff 2019-3						
			n=18		n=18		n=22			n=21								
optimaal	17	100%	11	61%	13	72%	21	95%	18	85%	6	26%						
goed	0	-	4	22%	5	28%	0	-	1	5%	9	39%						
borderline	0	-	0	-	0	-	0	-	1	5%	0	-						
onvoldoende	0	-	3	17%	0	-	1	5%	1	5%	8	35%						
Totaal suff	<table border="1" style="width:100%; text-align:center;"> <tr> <td>100%</td> <td>83%</td> <td>100%</td> <td>95%</td> <td>90%</td> <td>65%</td> </tr> </table>												100%	83%	100%	95%	90%	65%
100%	83%	100%	95%	90%	65%													
<i>NQC B35 2023</i>	<i>87% geslaagd 43% optimaal</i>																	

Eerdere NQC runs: B33 86% suff. / 61% optimaal
 B32 86% suff. / 42% optimaal
 B31 88% suff. / 56% optimaal
 B30 95% suff. / 77% optimaal
 B29 85% suff. / 44% optimaal



Resultaatbespreking HER2

Opgesplitst per clone: RTU

n=6	Herceptest Dako (DG44)						
	2023-1	2022-3	2022-1	2020-3	2020-1	2019-3	2019-1
optimaal	6	5	6	2	1	1	0
goed	0	1	0	0	0	0	0
borderline	0	0	0	0	0	0	0
onvoldoende	0	0	0	0	0	0	1
Totaal suff	100%	100%	100%	2/2	1/1	1/1	0/1
<i>NQC B35 2023</i>	Poly (VRPS) 79% suff. ; 14% optimaal >< LMPS 60% suff. ; 20% optimaal rm DG44 (enkel VRPS) 100% suff. ; 72% optimaal >< LMPS: 1/2 suff.						

VRPS = vendor recommended protocol settings
 LMPS = lab modified protocol settings



Resultaatbespreking HER2

Opgesplitst per clone: RTU


n=1	CB11 Leica Novocastra						
	2023-1	2022-3	2022-1	2020-3	2020-1	2019-3	2019-1
optimaal	1	0	1	0	1	0	0
goed	0	1	0	1	0	1	0
borderline	0	0	0	0	0	0	1
onvoldoende	0	0	0	0	0	0	0
Totaal suff	1/1	1/1	1/1	1/1	1/1	1/1	0/1
<i>NQC B35 2023</i>	<i>VRPS 1/3 suff. ; LMPS 1/4 geslaagd ; 0 optimaal</i>						

VRPS = vendor recommended protocol settings
LMPS = lab modified protocol settings



Resultaatbespreking HER2

Opgesplitst per clone: RTU

n=33		4B5 / Pathway Ventana					
	2023-1	2022-3	2022-1	2020-3	2020-1	2019-3	2019-1
optimaal	33	21	32	36	40	26	27
goed	0	6	2	3	0	11	7
borderline	0	0	0	0	0	1	3
onvoldoende	0	7	0	0	0	0	0
Totaal suff	100%	79%	100%	100%	100%	86%	92%
<i>NQC B35 2023</i>	<div style="display: flex; align-items: center;"> <div style="margin-right: 10px;">  </div> <div> <p><i>Pathway® VRPS 95% suff. ; 64% optimaal <-> LMPS 96% suff. ; 80% optimaal</i></p> <p><i>4B5 VRPS 94% suff. ; 73% optimaal <-> LMPS 99% suff. ; 78% optimaal</i></p> </div> </div>						

VRPS = vendor recommended protocol settings
 LMPS = lab modified protocol settings



Resultaatbespreking HER2

Besluit:

- 100% deelnemers geslaagd ; 100% optimaal
- = 2+ amplified core: alle labo's OK
- Per AS, per toesteltype: protocol spreidingen geen impact op resultaat



Resultaatbespreking HER2



Besluit:

- Vraag naar beoordeling Her 2 kleuring
 - Globaal OK, geen overinterpretatie (bv. 3+ ipv 2+), maar
 - 2+ ampl. core:**
 - 3 deelnemers hebben – hoewel aankleuringspatroon OK was – deze foutief geïnterpreteerd als 1+ → bemerking in individueel rapport

Antwoorden	Biopt 1	Biopt 2	Biopt 3	Biopt 4	Biopt 5
Verwacht resultaat	3+/A*	0/NA*	1-2+/NA	1-2+/NA	2+/A
0	-	84%	-	18%	-
1+	-	16%	11%	70%	8%
2+	-	-	89%	12%	95%
3+	100%	-	-	-	-

(*) A = amplified, NA = not amplified

Her2 low?

Bron: Sciensano globaal rapport

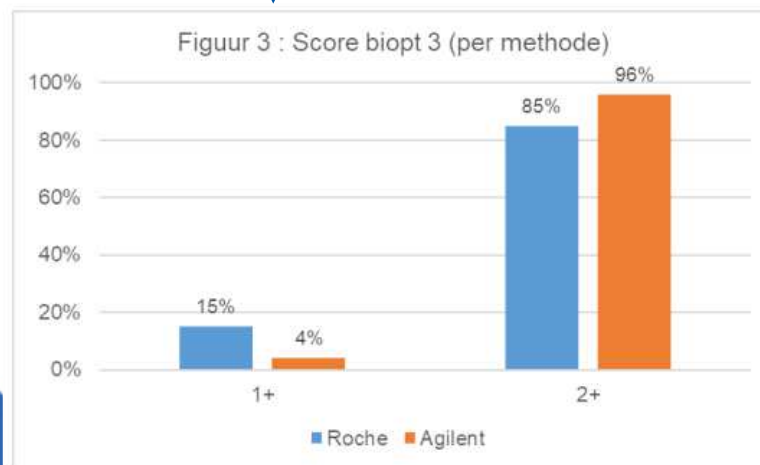
Resultaatbespreking HER2

Besluit:

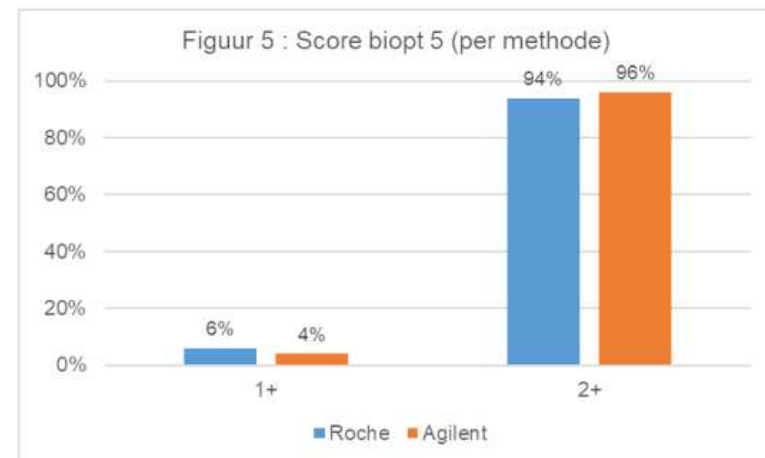
- Vraag naar beoordeling Her 2 kleuring
 - 2+ cores:
 - Amp. / Niet-ampl. per methode

Initieel 2+ non ampl

Antwoorden	Roche (N)	Agilent (N)	Leica (N)
0	0	0	0
1+	5	1	0
2+	28	22	1
3+	0	0	0



Initieel 2+ non ampl



Initieel 2+ ampl

lop in Zorg.

Resultaatbespreking HER2

Besluit:

- Gebruik controles:
 - Verplichting EKE, conform dagelijks gebruik
 - Controle: **98% OK** (2022-2: 97% ; 2022-1: 93% ; 2020-3 98% ; 2020-1: 92% ; 2019-2: 98,5% ; 2019-1: 55%)
 - Conformiteit?
 - Perfecte controle = dynamic range
 - 0, 1+ en/of 2+ (voorkeur amplified), 3+
 - **100% conform** (2022-2: 96% ; 2022-1: 100% ; 2020-3: 94% ; 2020-1: 93% conform ; 2019-3: 83%)



Controleweefsel aanwezig?	Conform de richtlijnen*?	Richtlijnen*
Ja / Neen	Conform / Niet conform	Er dient minstens een sterk positieve (3+) en een negatieve (1+ en/of 0) controle als dagelijks controlemateriaal te worden gebruikt. Zwak positieve (2+) controles zijn sterk aanbevolen.

(*) - Praktijkrichtlijn voor de erkende laboratoria voor pathologische anatomie, versie 2.1, 12/10/2022
- Update of the Belgian guidelines for HER2 testing in breast cancer
Lambein K., Guiot Y., Galant C., Salgado R., Colpaert C.
Belg J Med Oncol 2014;8(4):109-15

Controls

Inclusion of 2+ tumours with and without HER-2 gene amplification in the control material for both EQA and internal quality control is essential to evaluate precision and performance stability of the IHC HER-2 assay. (bron NordiQC)





Protocol ER

n= 59

Conc.: n=3 → 1

- Dako: rm clone EP1: n=1
- Cell Marque: rm clone SP1: n=2 → 0
- Leica Novocastra: geen

RTU: n=58

- Dako: rm clone EP1 : n=21
- Roche/Cell Marque: rm clone SP1 : n=35
- Leica Novocastra: mm clone 6F11: n=2



Protocol ER

Conc. AS

- EP1 Dako
 - Omnis
 - 1/50 20' bij 32° C ; pH9 30' Flex+ met linker 10'

RTU clone 6F11 (Leica)

- 2022-1: Bond III: 15' RT ; HIER pH6 of pH9 20'
- 2023-1: Bond III: 15' RT ; HIER enkel pH9 20-30'



Protocol ER

RTU clone SP1 (Ventana/Cell Marque)

Protocol:

- UView: 34
 - Datasheet 2013: HIER 60' , AS 16' → 21%
 - AS 16' – 40' bij 36° C (38% 16' AS)
 - HIER CC1 8' – 64' (56% → 44% 'standard' CC1)
 - +/- 4' tot 16' amp (~20%)
- optiView: 1→2
 - geen datasheet beschikbaar
 - AS 16-24' bij 36° C
 - geen amplifier
 - CC1 56-64'



Protocol ER

RTU clone EP1 (Dako)

Protocol:

- Autostainer (4→3)
 - Datasheet: 20'RT ; pH9 tijd?

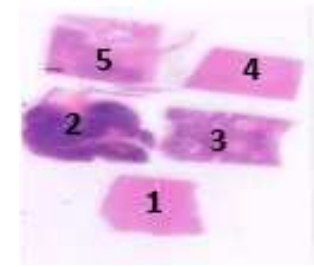
 - AS: 20-25-40' bij RT → 50% datasheet
 - Envision Flex+ ; 2/3 linker 15'
 - HIER: pH9 10'

- Omnis (18)
 - 20' - 27'30" bij RT
 - 10' bij 32° C
 - 89% gebruikt 10' bij 32° C = datasheet? (laatste 2 EKE's ~60% en 83%)
 - 17% inc. bij RT
 - Envision Flex+ ; 2x linker 5'
 - HIER: pH 9 30'



Scoringscriteria ER

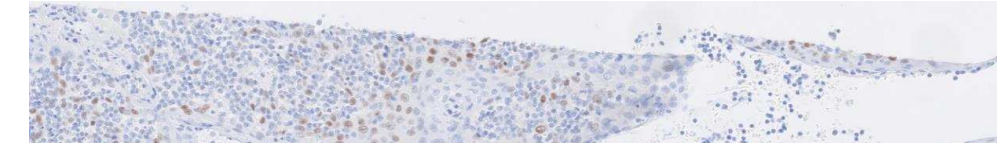
Aankleuringspatroon: nucleair



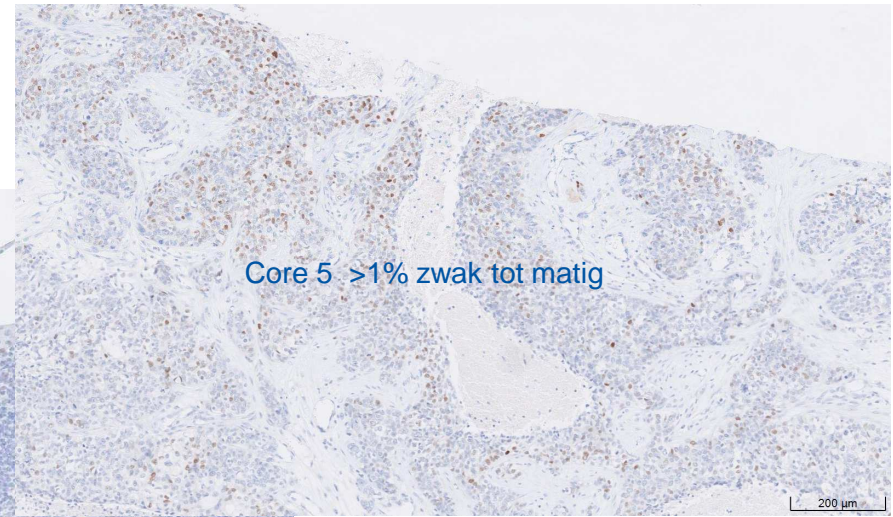
- Cervix : matig tot sterke aankleuring van bijna alle columnair epitheel, basaal squameus epitheel en de meeste stromale cellen (uitgezonderd endotheliale en lymfoïde cellen)
- Tonsil : minstens zwak tot matige aankleuring in verspreide folliculaire dendritische cellen/T-cellen en plaveiselcelepitheel
- Borstcarcinoom core 3 : sterke aankleuring in 90-100% van de tumorale cellen
- Borstcarcinoom core 4 : geen / max. zwakke aankleuring in <1% van de tumorale cellen
- Borstcarcinoom core 5: zwak / matige aankleuring in >1% van de tumorale cellen (klinische cut off)



Antistof ER



Tonsil : minstens zwak tot matige nucleaire aankleuring in verspreide folliculaire dendritische cellen/T-cellen en plaveiselcellepitheel

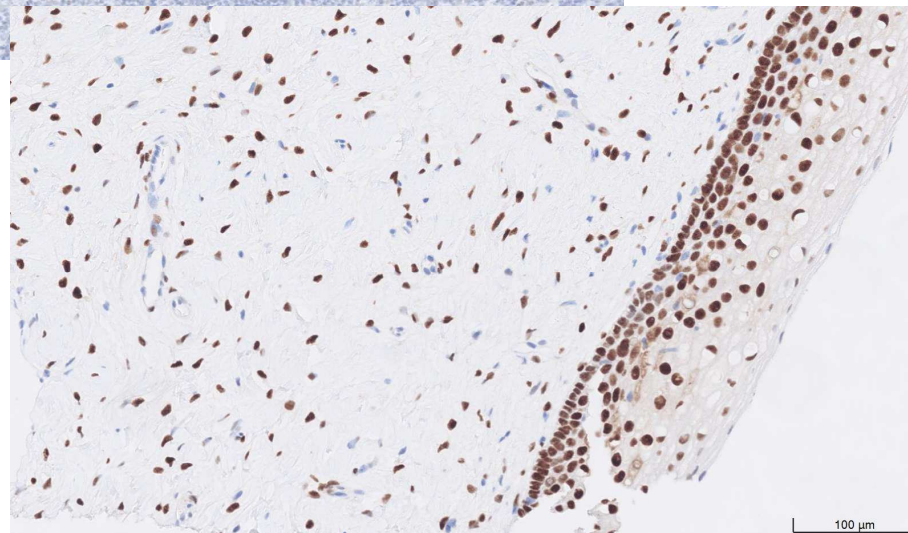
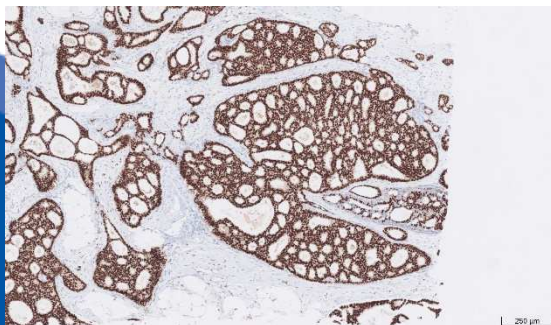


Core 5 >1% zwak tot matig

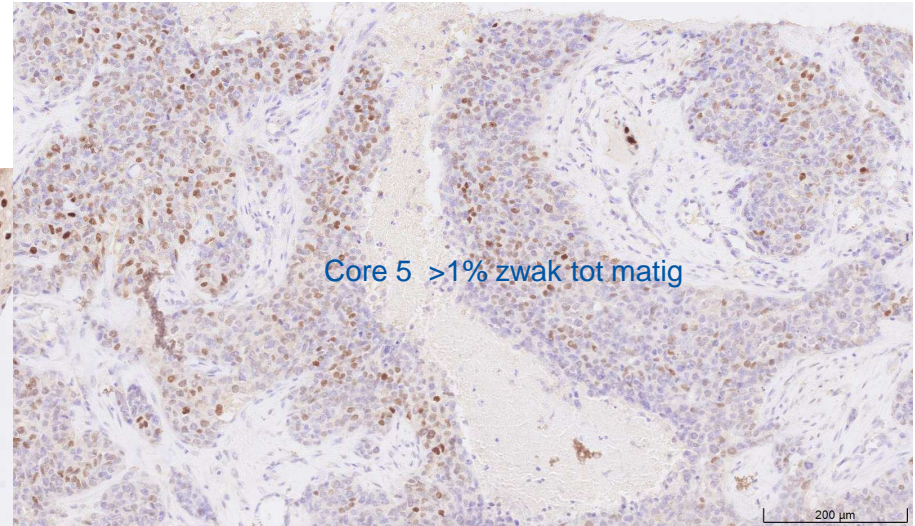
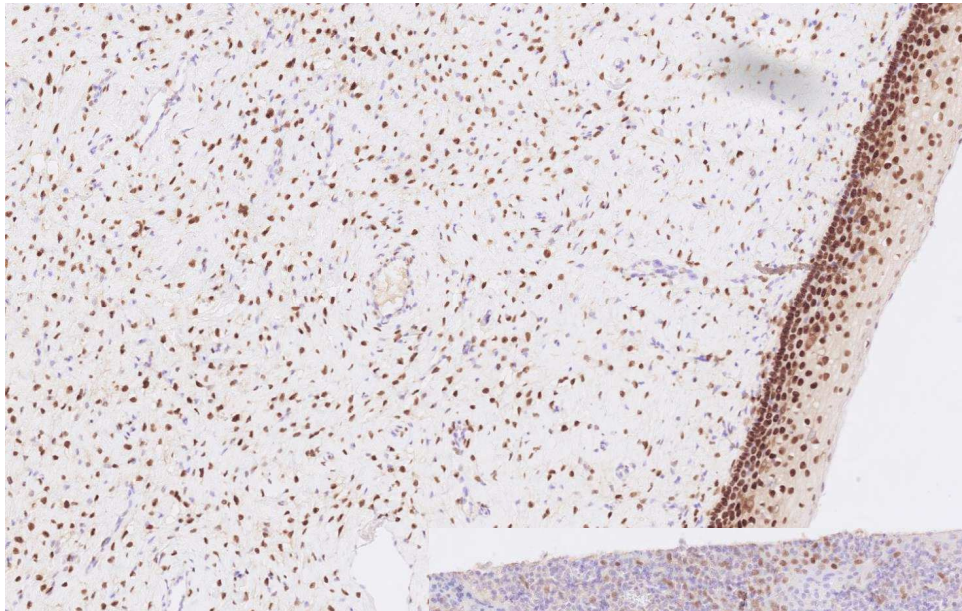


Ventana SP1 by NordiQC

Expected result



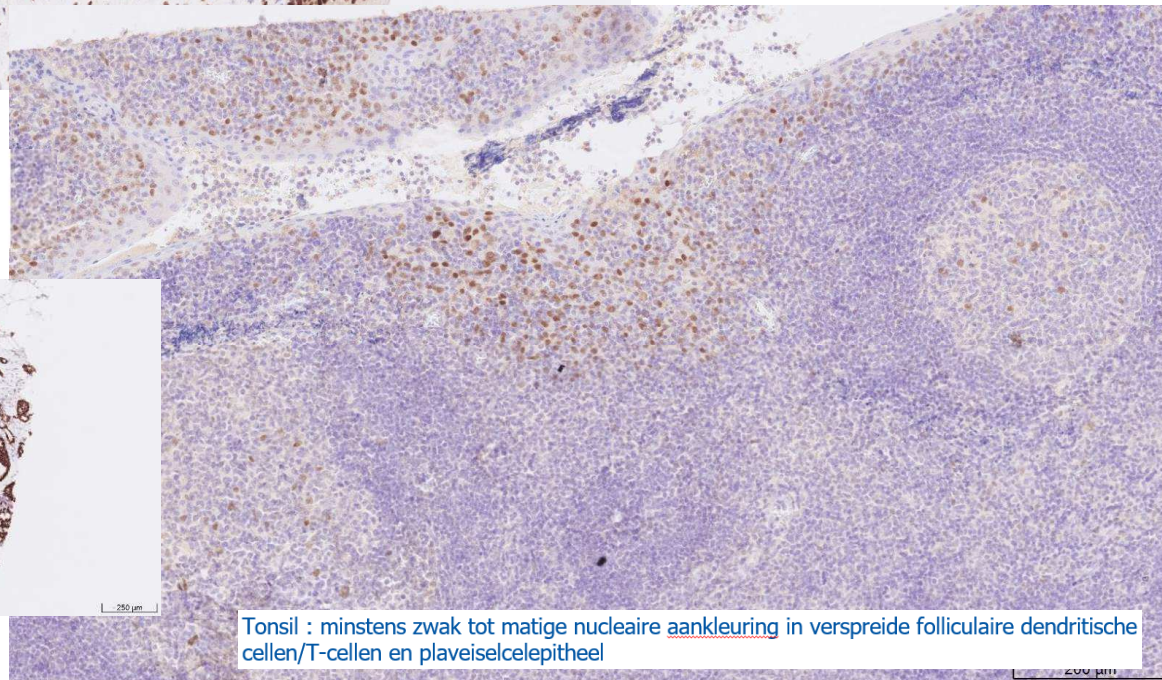
Antistof ER



Core 5 >1% zwak tot matig

Dako EP1 by NordiQC

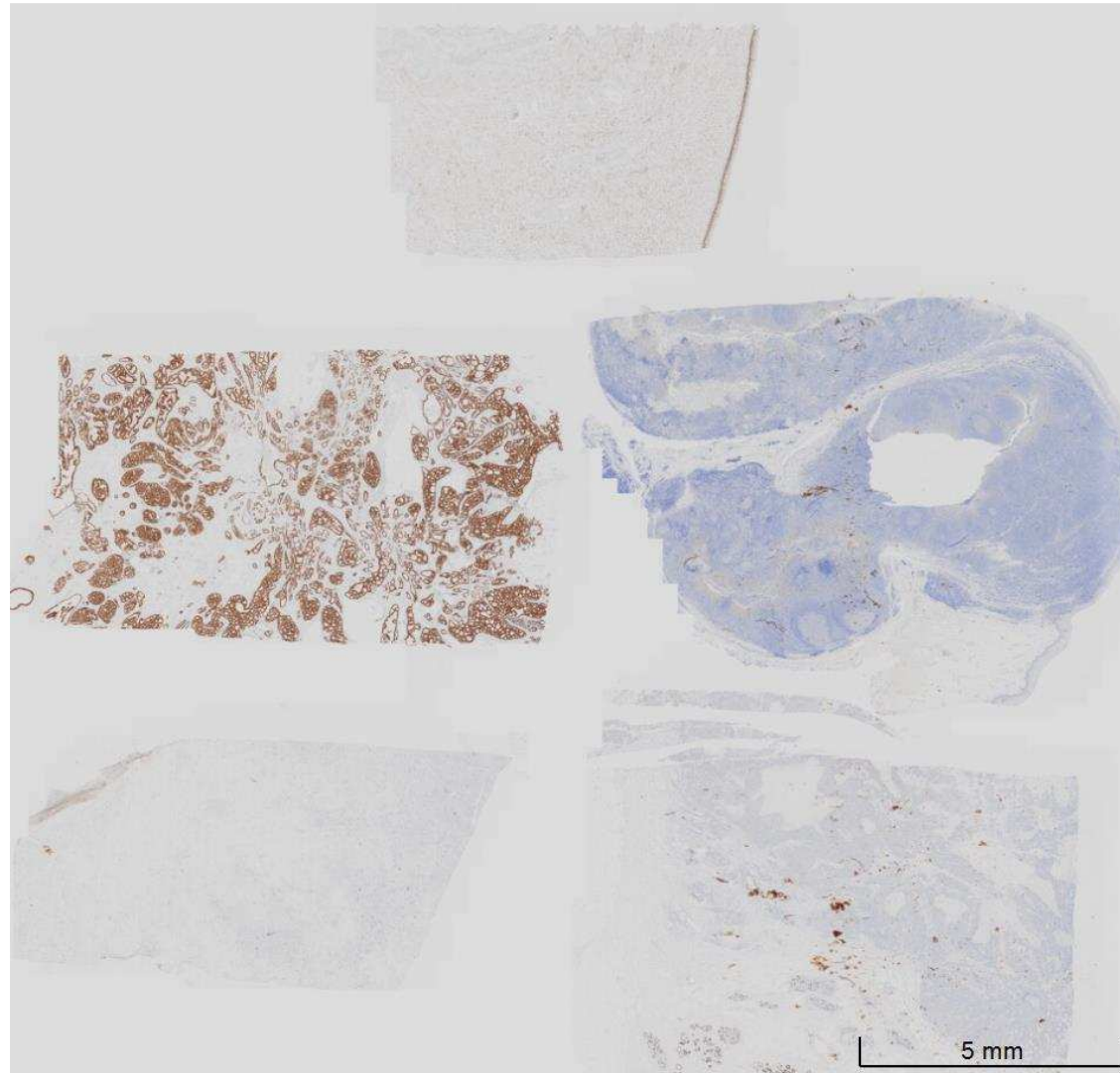
Expected result



Tonsil : minstens zwak tot matige nucleaire aankleuring in verspreide folliculaire dendritische cellen/T-cellen en plaveiselcellepitheel

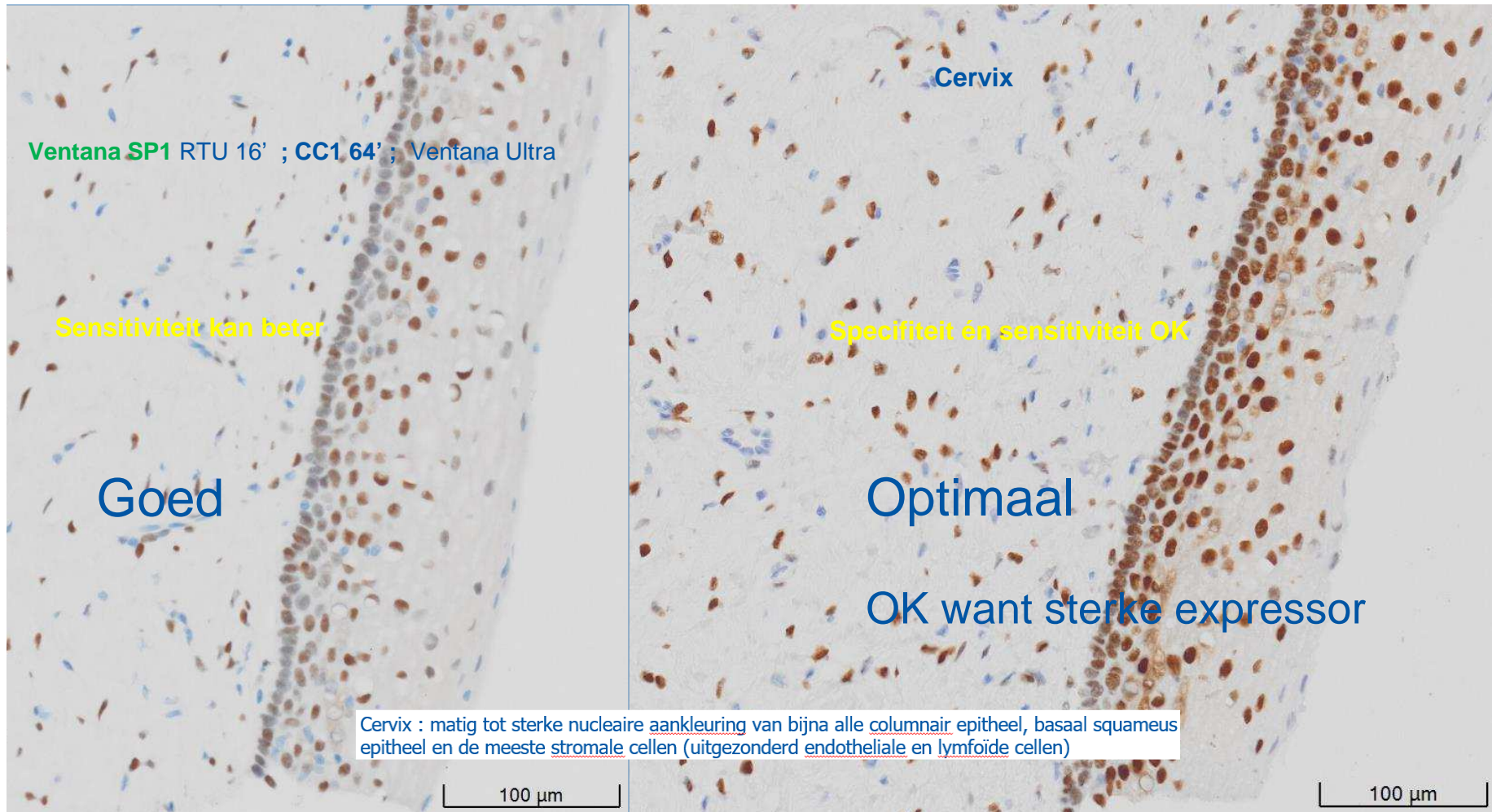


Antistof ER



Dako EP1 1/50 20' 32° C+linker 10' ; pH9 30' ; Dako Omnis

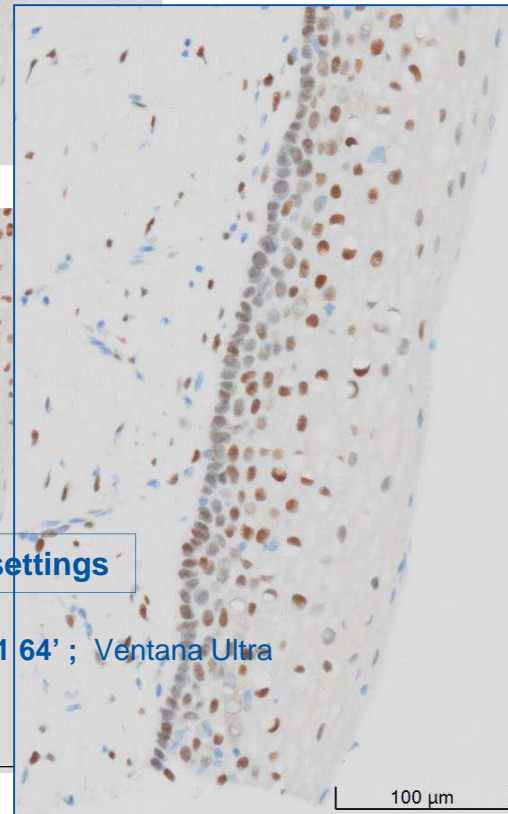
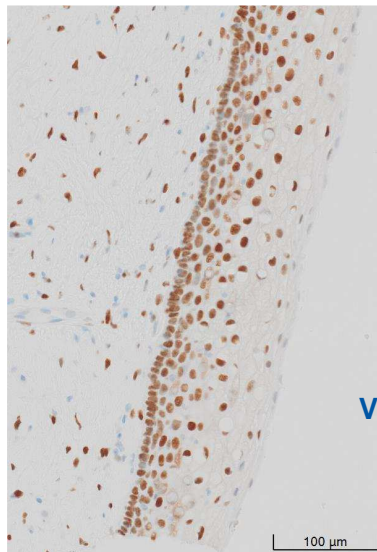
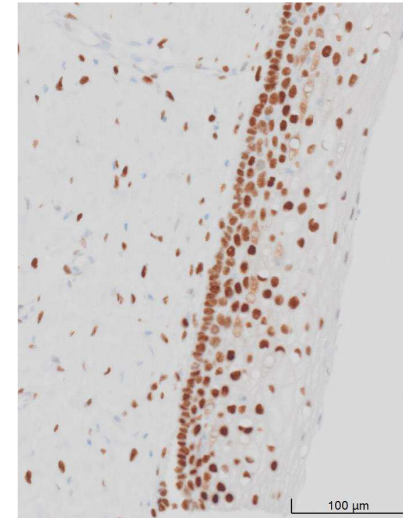
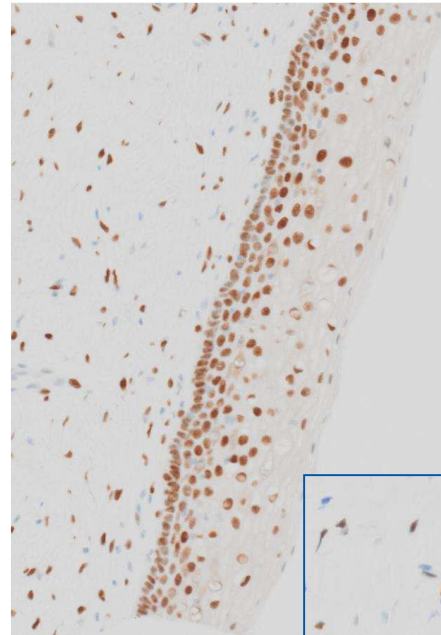
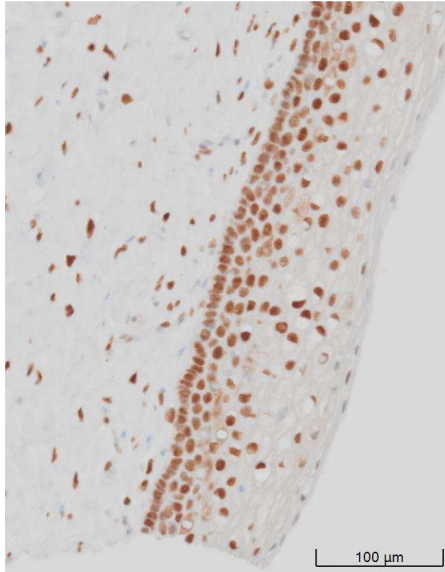
Antistof ER



Dako EP1 1/50 20' 32° C +linker 10' ; pH9 30' ; Dako Omnis



Antistof ER

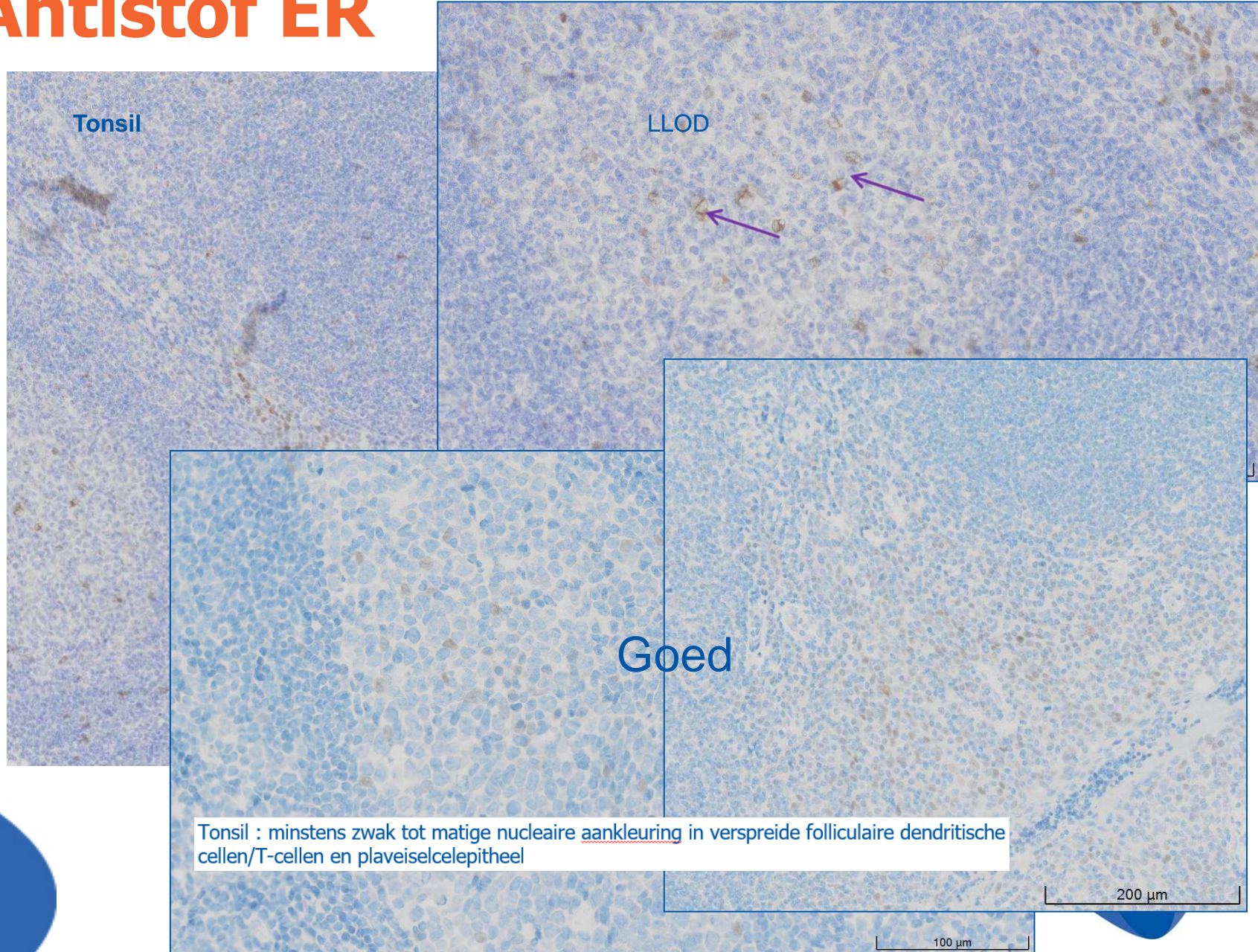


Same protocol settings

Ventana SP1 RTU 16' ; CC1 64' ; Ventana Ultra



Antistof ER



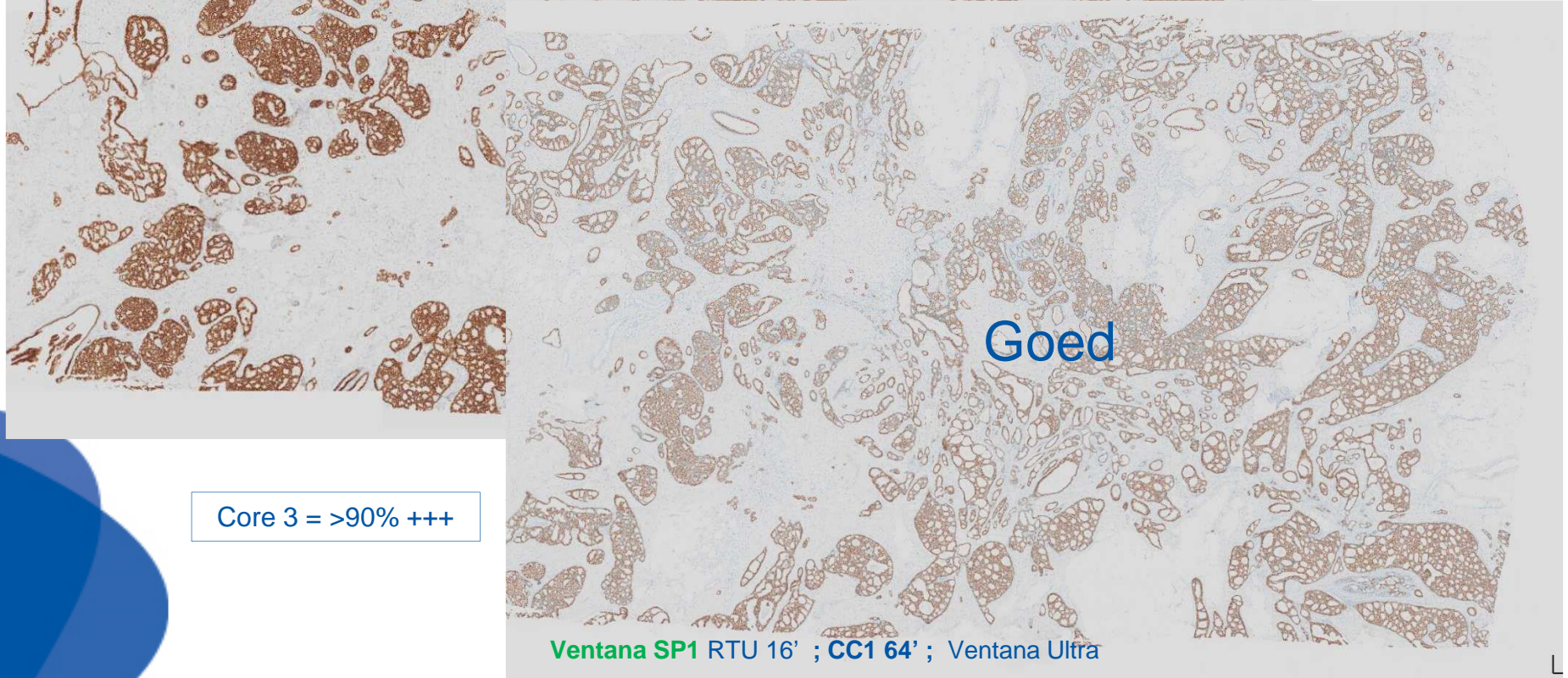
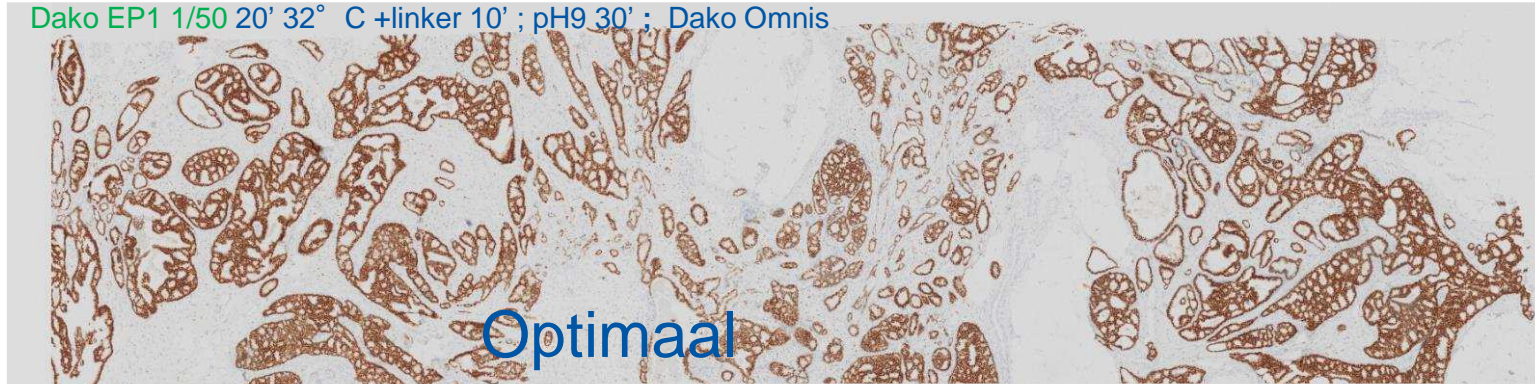
Tonsil : minstens zwak tot matige nucleaire aankleuring in verspreide folliculaire dendritische cellen/T-cellen en plaveiselcelepitheel

100 μm

200 μm

Antistof ER

Dako EP1 1/50 20' 32° C +linker 10' ; pH9 30' ; Dako Omnis

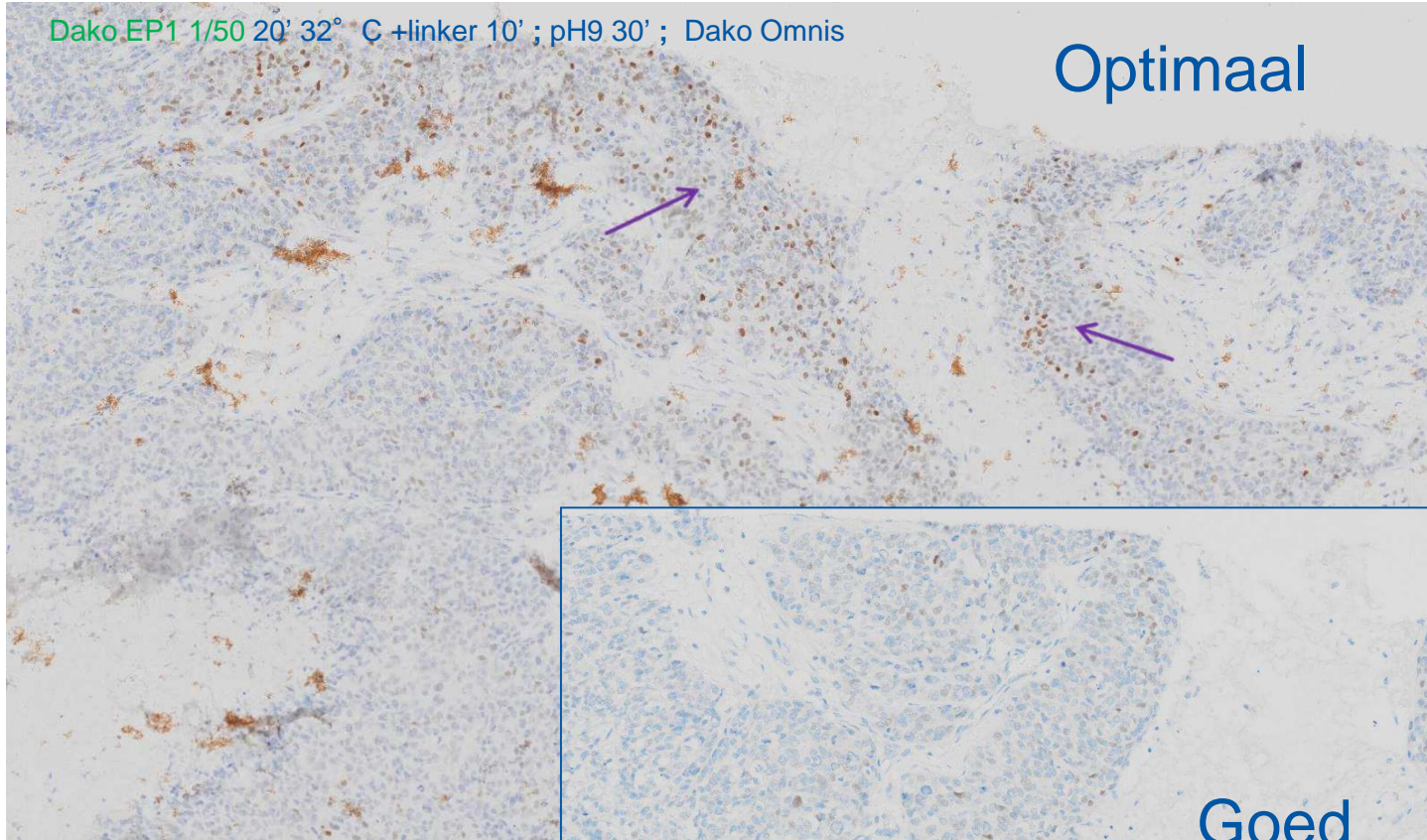


Core 3 = >90% +++

Antistof ER

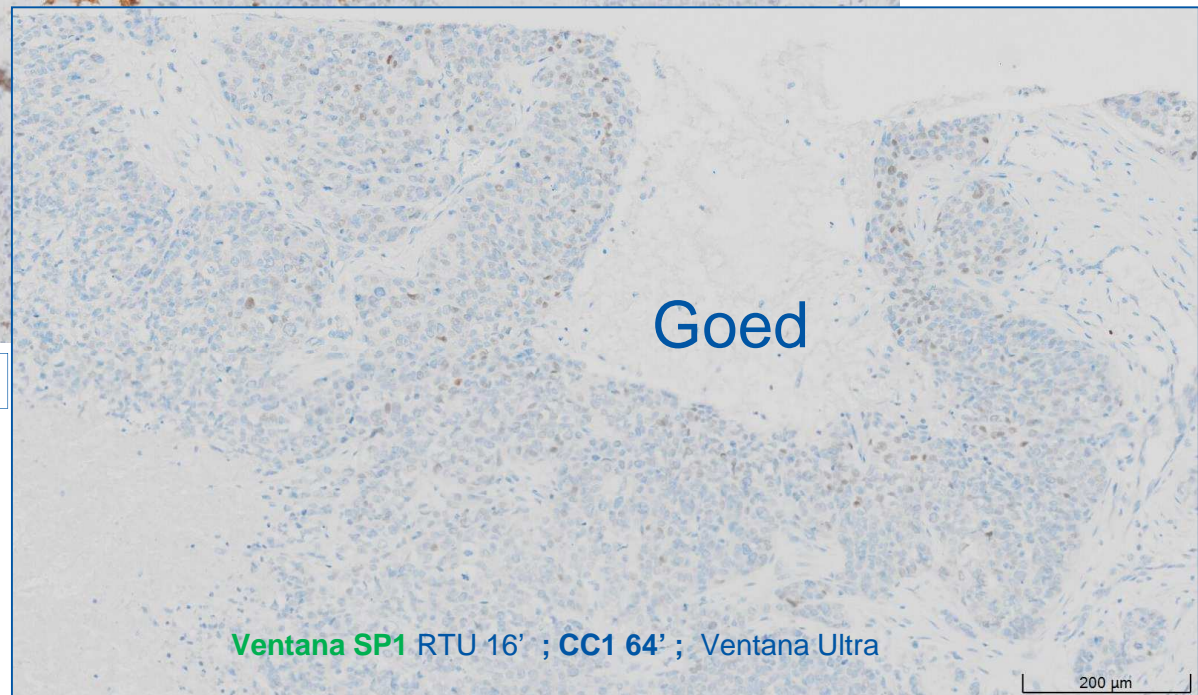
Dako EP1 1/50 20' 32° C +linker 10' ; pH9 30' ; Dako Omnis

Optimaal



Core 5 overview= >1% zwak tot matig

Goed



Ventana SP1 RTU 16' ; CC1 64' ; Ventana Ultra

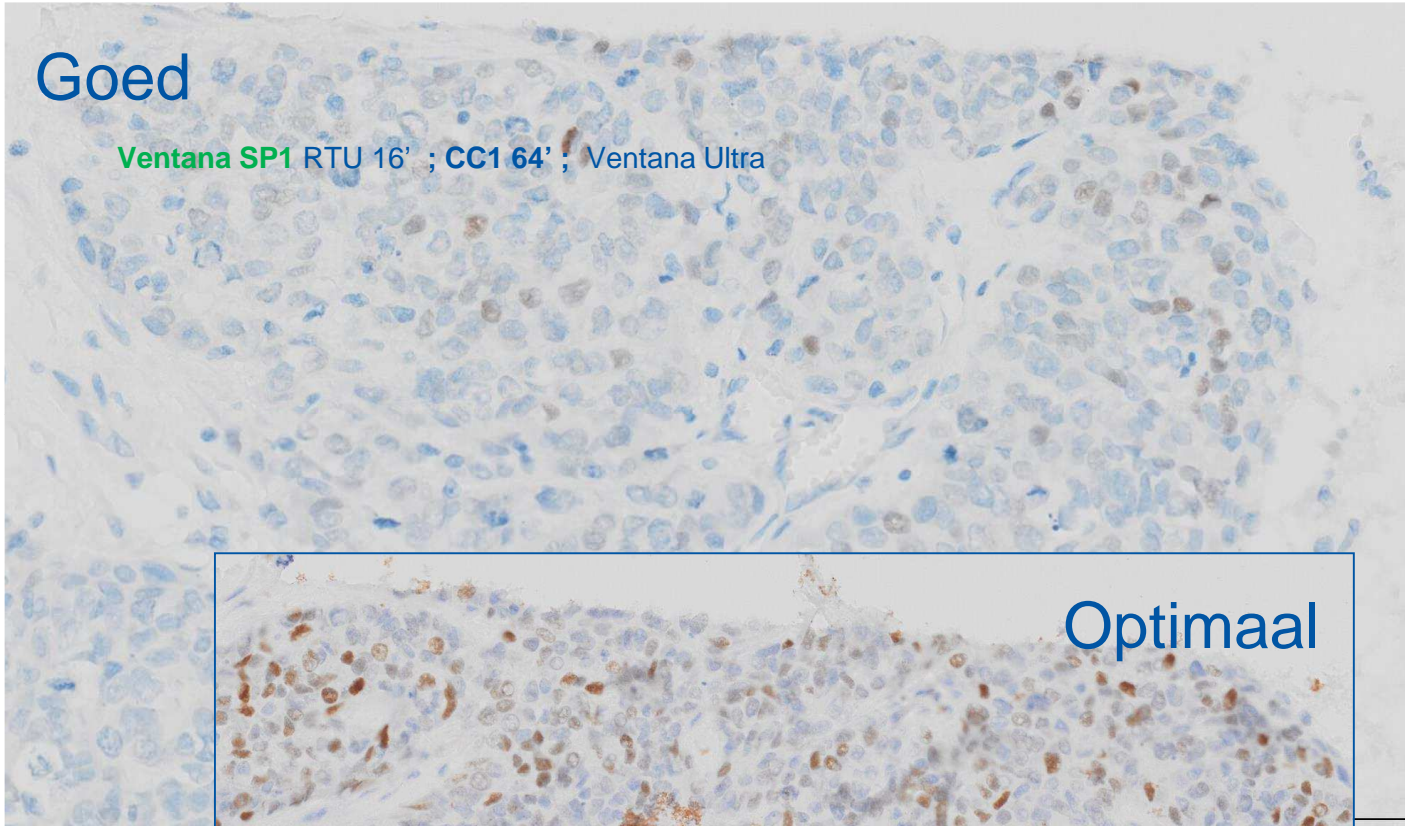
200 µm

Antistof ER

Core 5 detail = >1% zwak tot matig

Goed

Ventana SP1 RTU 16' ; CC1 64' ; Ventana Ultra



Optimaal

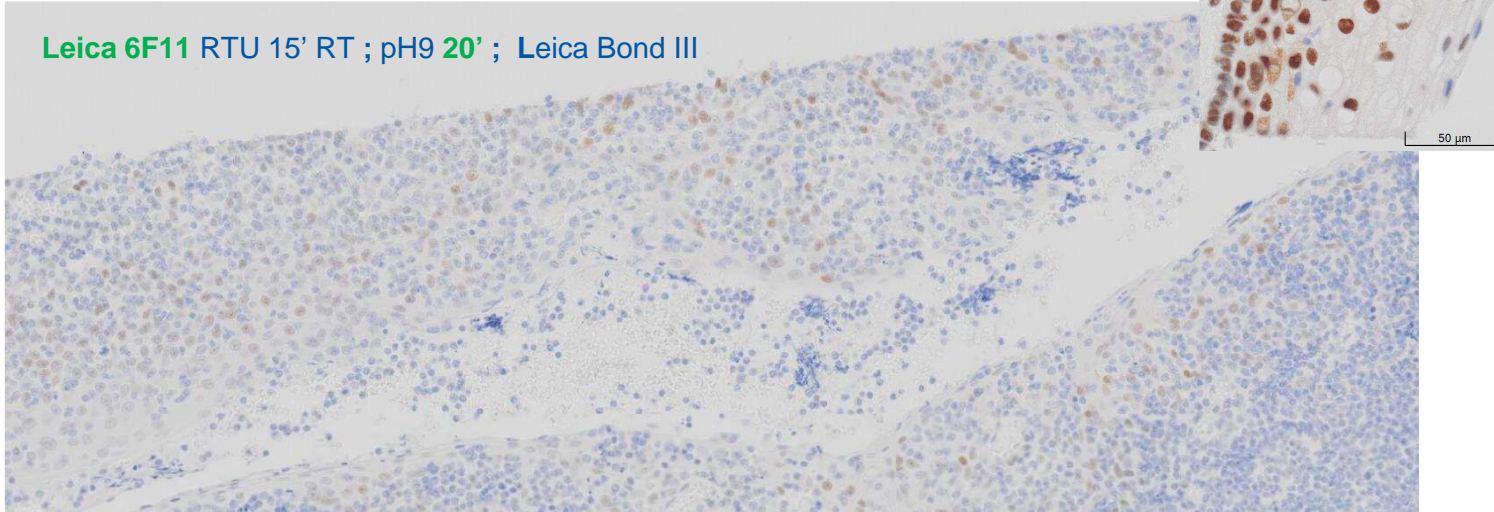
Dako EP1 1/50 20' 32° C; pH9 30' ; Dako Omnis

100 µm



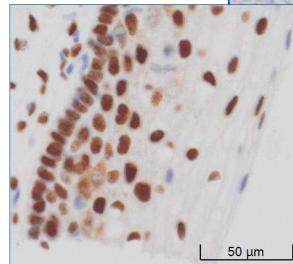
Antistof ER

Leica 6F11 RTU 15' RT ; pH9 20' ; Leica Bond III



Optimaal

Sensitiviteit beter

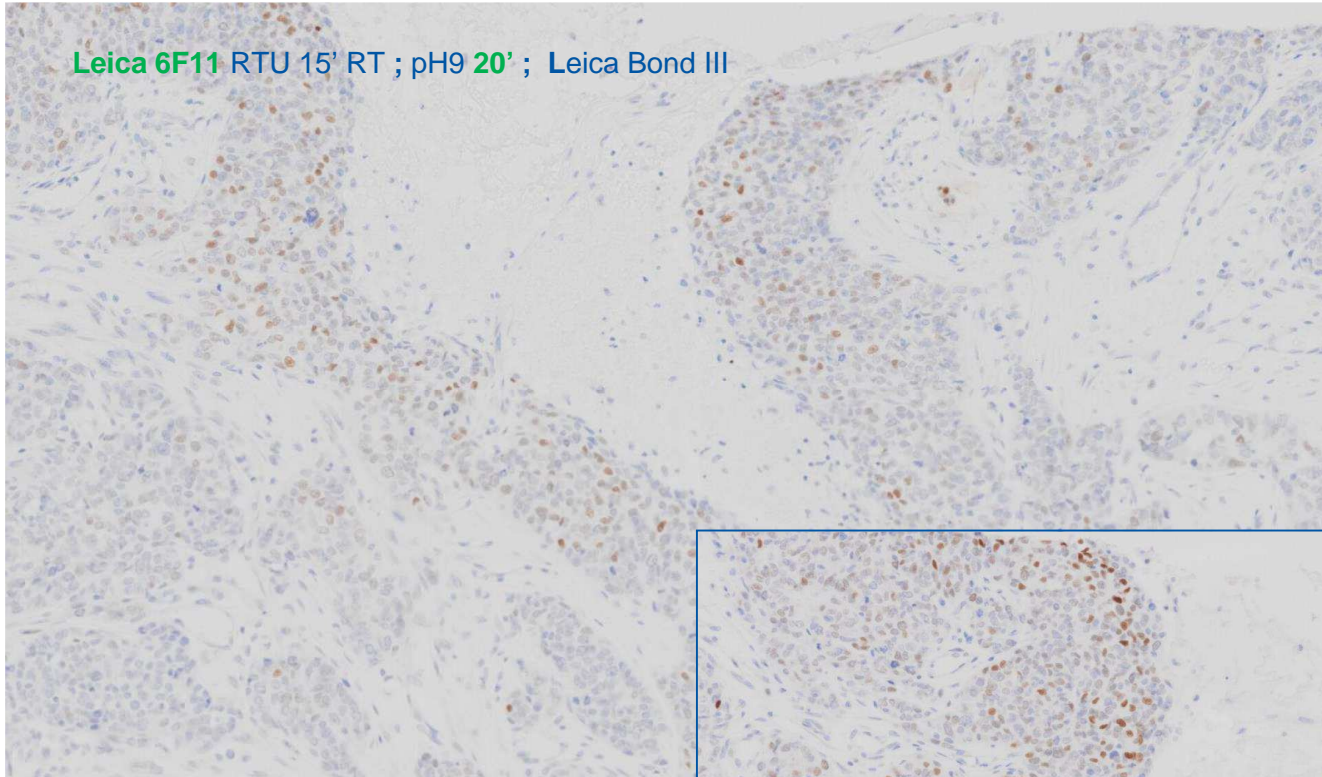


Leica 6F11 RTU 15' RT ; pH9 30' ; Leica Bond III

200 μm

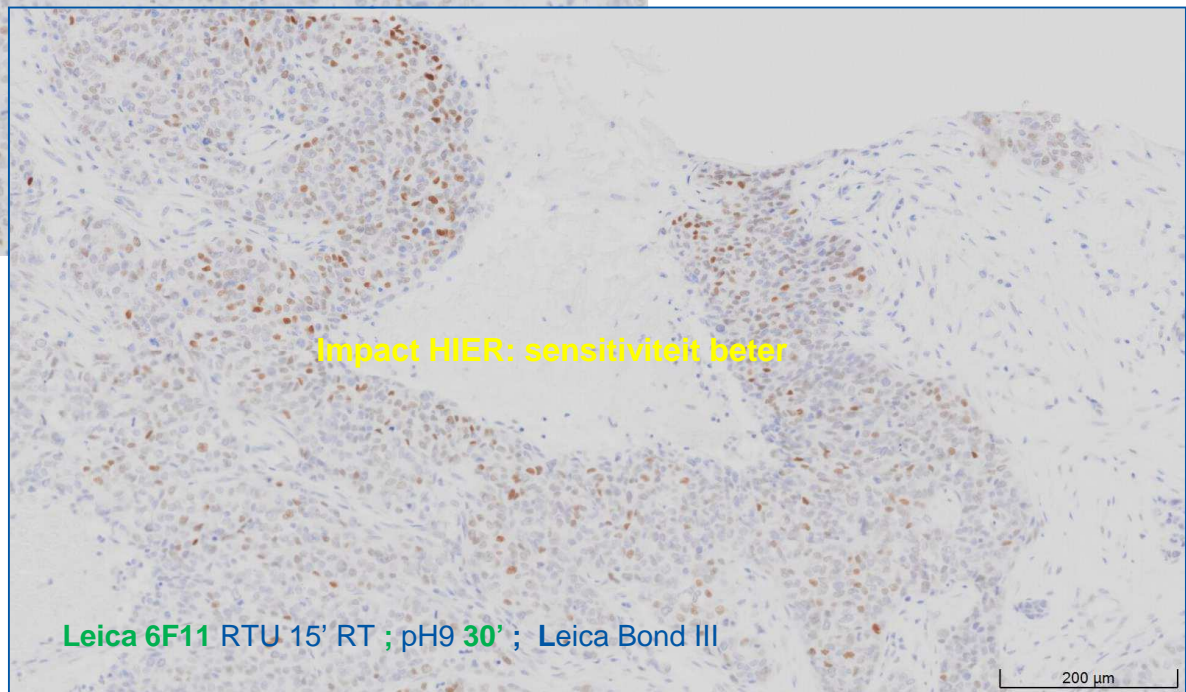


Antistof ER



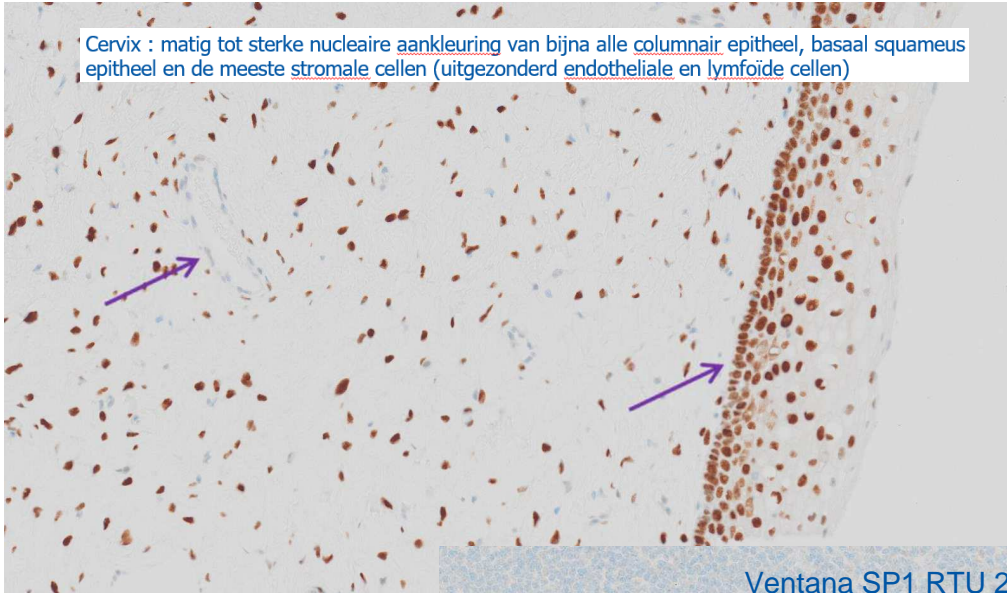
Core 5 = >1% zwak tot matig

Optimaal



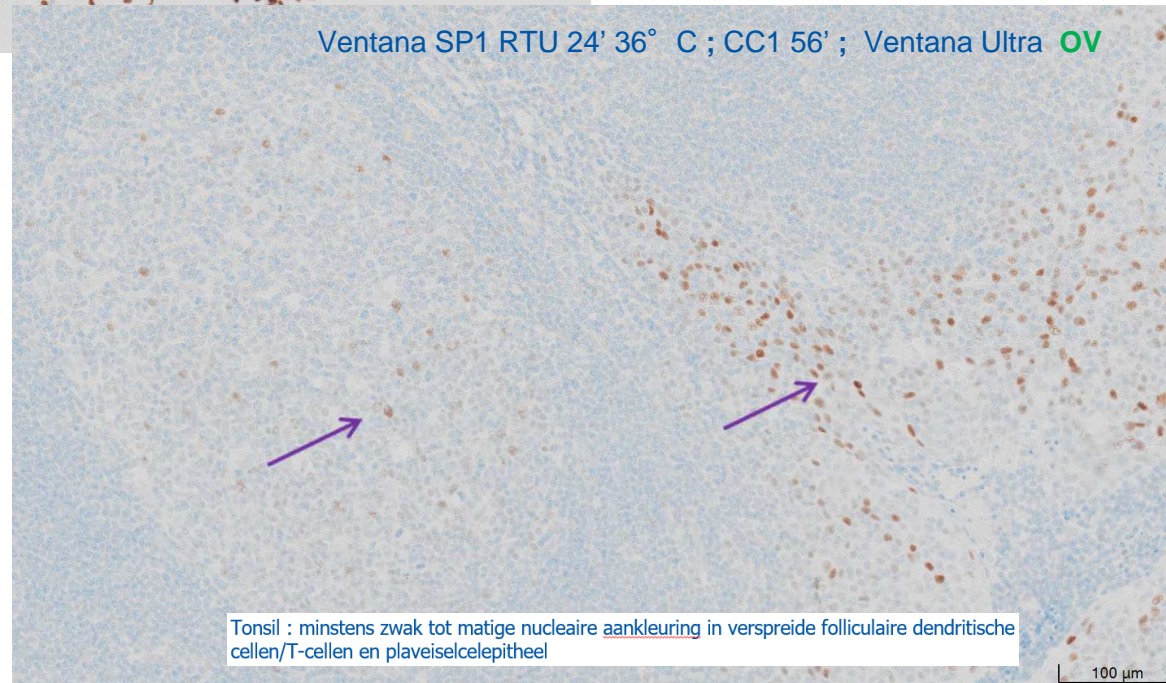
Antistof ER

Cervix : matig tot sterke nucleaire aankleuring van bijna alle columnair epitheel, basaal squameus epitheel en de meeste stromale cellen (uitgezonderd endotheliale en lymfoïde cellen)



Optimaal

Ventana SP1 RTU 24' 36° C ; CC1 56' ; Ventana Ultra **OV**

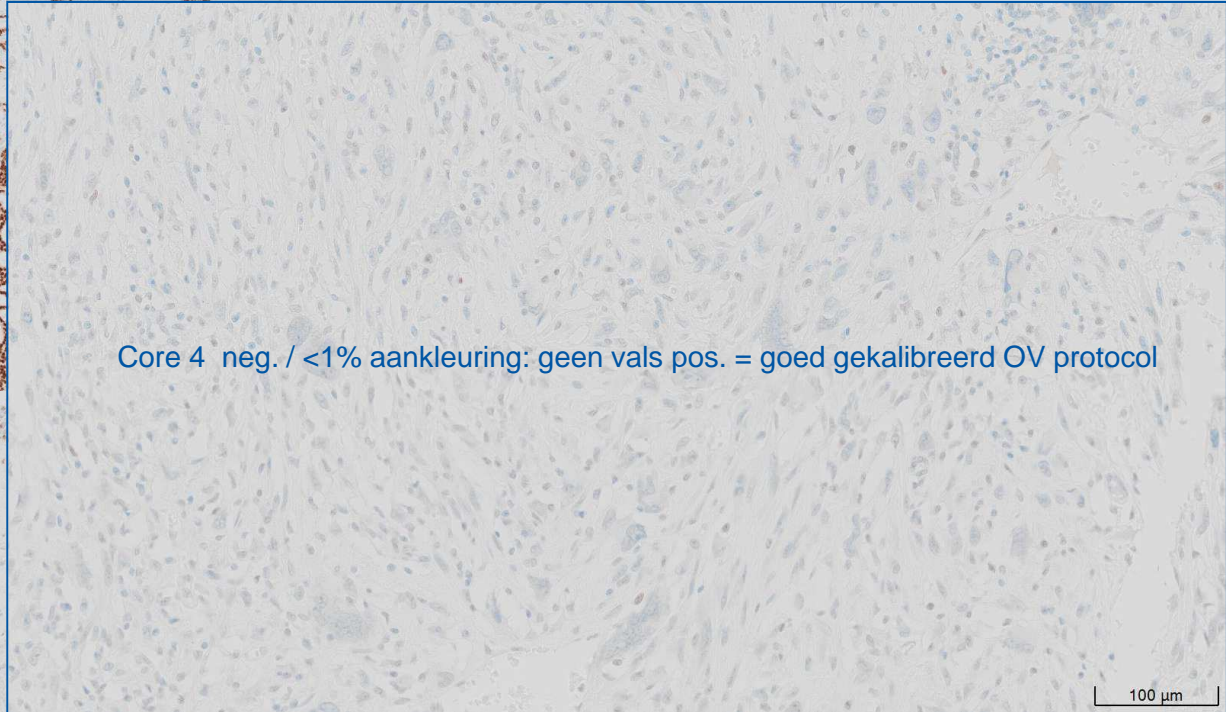
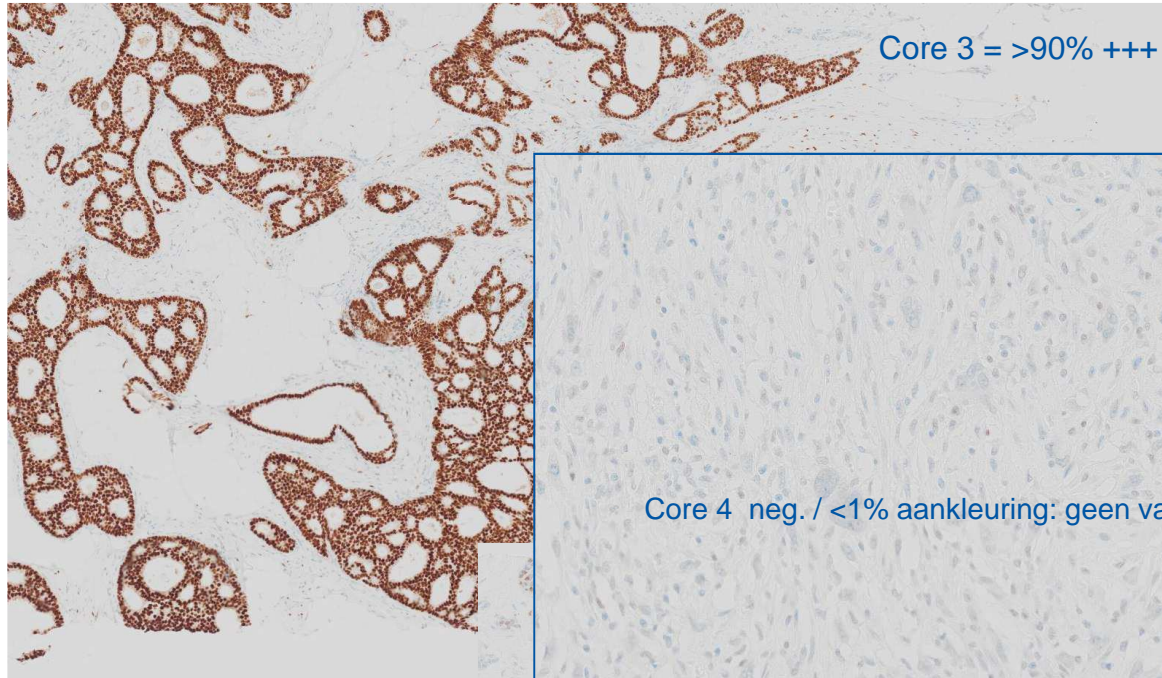


Tonsil : minstens zwak tot matige nucleaire aankleuring in verspreide folliculaire dendritische cellen/T-cellen en plaveiselcelepithel



100 μm

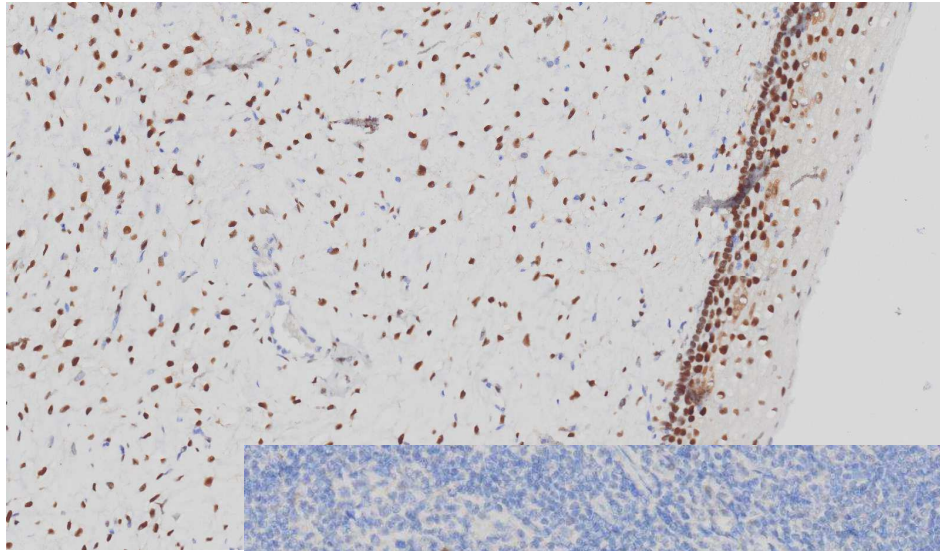
Antistof ER



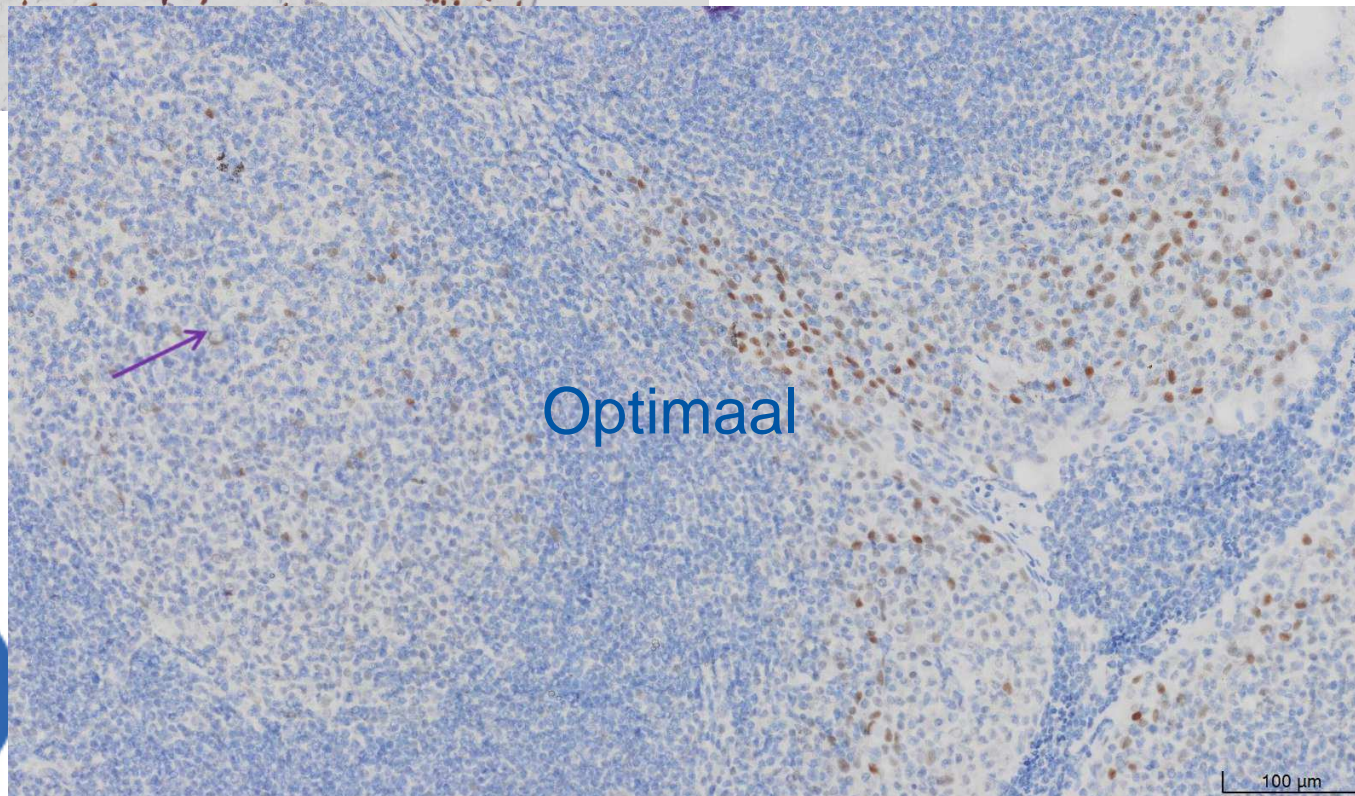
Optimaal



Antistof ER



Dako EP1 RTU 20' RT ; pH9 30' ; Dako Omnis

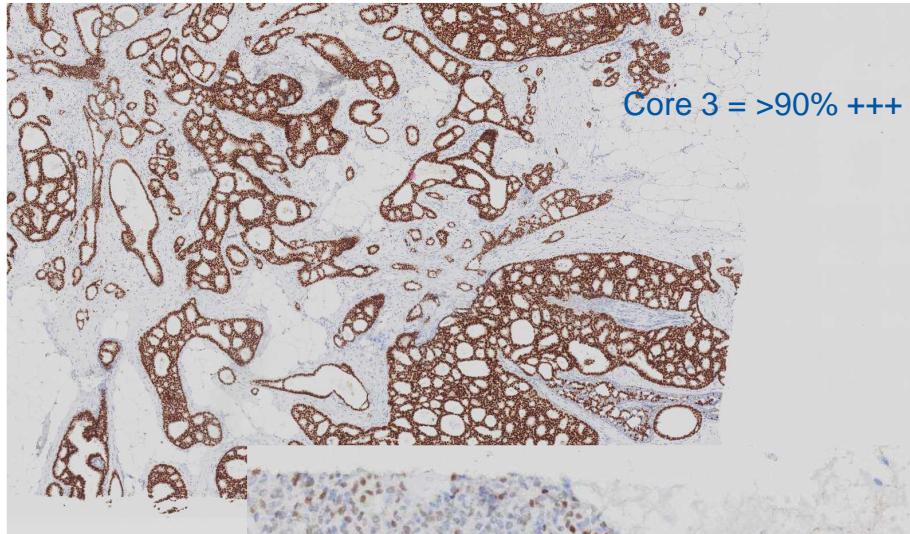


Optimaal

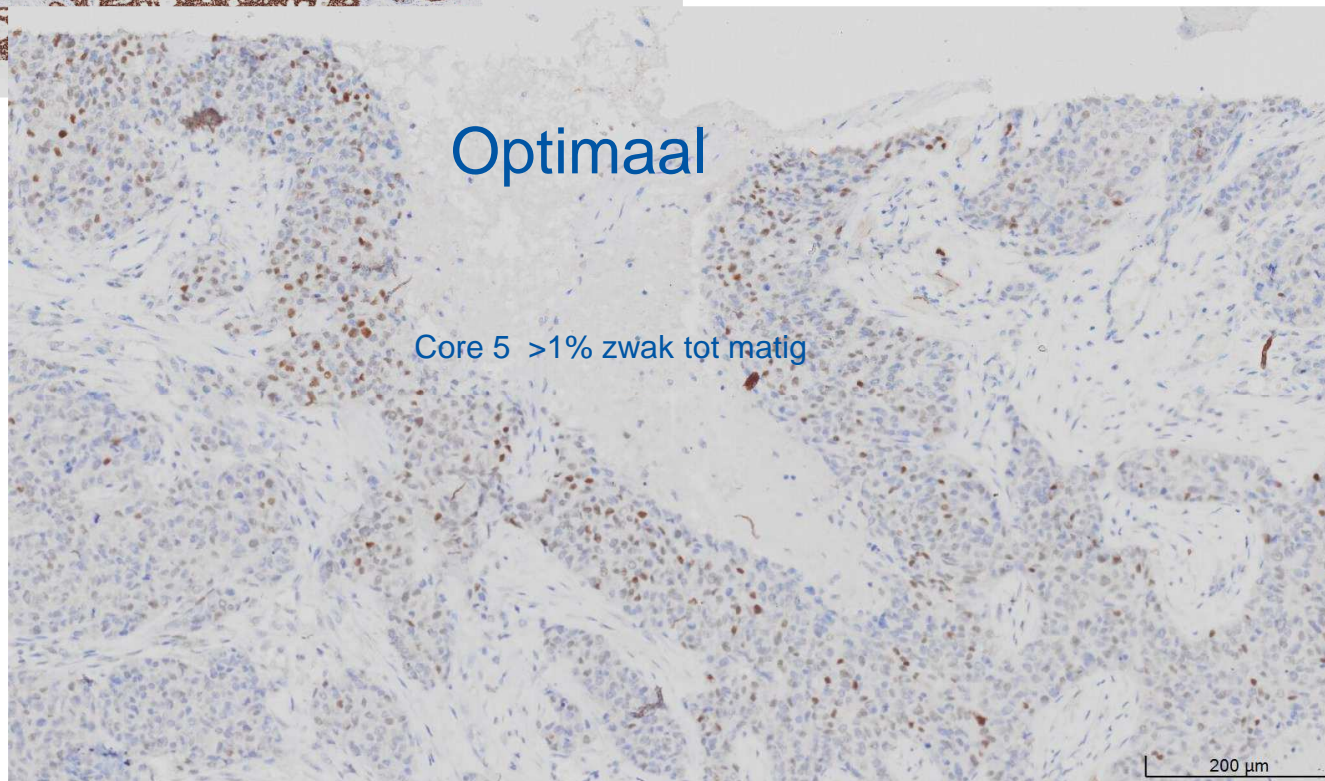


100 µm

Antistof ER



Dako EP1 RTU 20' RT ; pH9 30' ; Dako Omnis

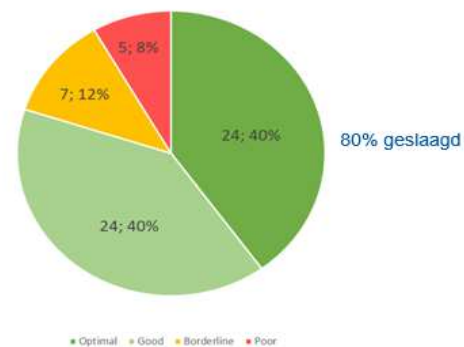


Resultaatbespreking ER

Algemeen

n=59	EKE2023-1		EKE2022-1		EKE2020-1		EKE 2019-3		NQC 2023 B35		
	n	%	suff.	%	suff	%	suff	%	suff	%	suff
optimaal	58	98,3%	100%	90,3%	94%	32%	81%	27%	79%	58%	91%
goed	1	1,7%		3,3%		49%		52 %		33%	
borderline	0	0	0	3,3%	0%	14 %	7%				
onvoldoende	0	0	0	3,3%	19%	7%	2%				

NordiQC run B31 - ER
Belgium laboratories



Resultaatbespreking ER

Opgesplitst per clone:

	EP1 Dako conc.	EP1 Dako RTU	% suff	SP1 Ventana/ C. Marque RTU	% suff	6F11 Leica RTU	% suff
		n=21		n=35		n=2	
optimaal	1	21	100%	34	97%	2	-
goed	0	0	0%	1	3%	0	-
borderline	0	0	0%	0	0%	0	-
onvoldoende	0	0	0%	0	0%	0	-
Totaal suff	1/1	100%		100%		2/2	
<i>EKE2019-1</i>	<i>0/1</i>	<i>100%</i>		<i>72%</i>		<i>0/1</i>	
<i>EKE2020-1</i>	<i>1/1</i>	<i>79%</i>		<i>72%</i>		<i>1/1</i>	
<i>EKE2022-1</i>	<i>1/1</i>	<i>94%</i>		<i>92%</i>		<i>1/1</i>	
<i>NQC 2023</i>	<i>73%*</i>	<i>90-98%**</i>		<i>92-100%***</i>		<i>63%****</i>	

* NordiQC: waarvan 45% optimaal

** NordiQC: Autostainer: waarvan 24% optimaal LMPS ; Omnis waarvan VRPS 69%, LMPS 48%optimaal

*** NordiQC: waarvan resp. 60-67% optimaal

**** NordiQC: waarvan 24% optimaal LMPS



Resultaatbespreking ER

Besluit:

Suff. 100 %

- Algemene score in stijgende lijn, beter dan alle voorgaande EKE
- Slechts 1 deelnemer 'goed':
 - algemeen matige aankleuring
 - ook in eigen ctrl (bevatte enkel sterke expressor) → advies in indiv. rapport
- Suff. resultaat te behalen bij alle gebruikte clones/stainers
 - SP1 en EP1 clones: beiden hoog slaagpercentage (>97%)
 - 6F11: optimaal vs NordiQC iets minder performant (slechts 24% optimaal)
- AS:
 - Slechts 1 conc. AS, geen conc. SP1 (C.Marque) meer
 - 37% Dako clone EP1 , 59% Ventana/C.Marque clone SP1
 - Dako platformen:
 - Omnis: sterk gestandaardiseerd, 100% optimaal resultaat
 - Autostainer: meer spreiding in protocols (AS) → geen impact op resultaat: allen optimaal
 - Ventana platformen:
 - 44% gebruikt datasheet HIER (60') = daling, vs 56% EKE2022, 40% EKE2020, 12% EKE2019
 - 38% gebruikt datasheet AS tijd (16') en 20% ampl.
 - Slechts 2 deelnemers gebruiken 3 stap optiView detectie (datasheet = ultraView)
→ geen impact op resultaat
- Extra controlecoupe: 83% (EKE2022: 69% ; EKE2020: 66% ; EKE2019: 55%)



Resultaatbespreking ER

Besluit:

Suff. 100%

- Leica 6F11 RTU:
 - HIER pH6 (BERS1) = datasheet setting
 - 2019-1 : 1 deelnemer: onvoldoende o.w.v. HIER pH6 → 2020-1 HIER pH9 = geslaagd
 - Update EKE 2022: pH6 = borderline (vals negatief) vs pH9 optimaal
 - Update EKE 2023: geen pH6 meer = enkel optimaal resultaat



NordiQC 2019:

'The Leica RTU system PA009/PA0151 (6F11) for BOND gave an overall pass rate of 62%.

Optimal results were only obtained by laboratory modified protocol settings using HIER in BERS2 (pH9) for 20 min. as opposed to performing HIER in BERS1 (pH6) for 20 min. as recommended by Leica. '

NordiQC 2023:

The Leica RTU system PA0009/PA0151 for BOND based on mAb 6F11, was used by 5% (21 of 422) of the participants and gave an overall pass rate of 67%. In this assessment, VRPS based on HIER in BERS1 (low pH) for 20 min., 15 min. incubation of the primary Ab and Bond Refine as detection system was used by two participants, with both achieving sufficient results. **Laboratories using a protocol modification increasing analytical sensitivity by using HIER in BERS2 (high pH) for 20 min. obtained a pass rate of 89% (8 of 9), 67% optimal (6/9).** Extension of the primary antibody incubation time in conjunction with HIER in BERS1 (low pH) was performed by two laboratories, neither of which obtained satisfactory results. However, 4 instances of false positive staining of the negative tumour (breast carcinoma no. 5) were seen with high pH retrieval, as previously also noted in run B28 and sporadically in subsequent runs. This was linked to extended retrieval in BERS2 with or without extension of primary antibody incubation time.



Resultaatbespreking ER




Besluit:

- Aanbevolen controle: NordiQC

Recommended controls

ER - Estrogen Receptor

cellen)

Control type	Positive tissue control High expression level	Positive tissue control Low expression levels	Negative tissue control
Tissue	Cervix	Tonsil	Tonsil
Description	Virtually all squamous epithelial cells, columnar epithelial cells and stromal cells (except lymphocytes and endothelial cells) must show a moderate to strong nuclear staining reaction.	The vast majority of squamous epithelial cells and dispersed follicular dendritic cells / T-cells within the germinal centers must show an at least weak, distinct nuclear staining reaction.	No staining reaction in mantle zone and germinal center B-cells should be seen.
Example	 Click to enlarge	 Click to enlarge	 Click to enlarge

NIEUW NORDIQC

CD30

Tonsil

[See controls](#)

CD31

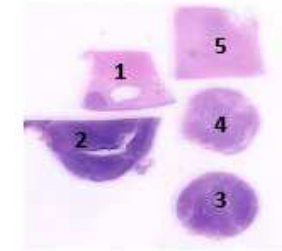
Appendix/colon, Liver, Tonsil

[See controls](#)



Reassessment PR

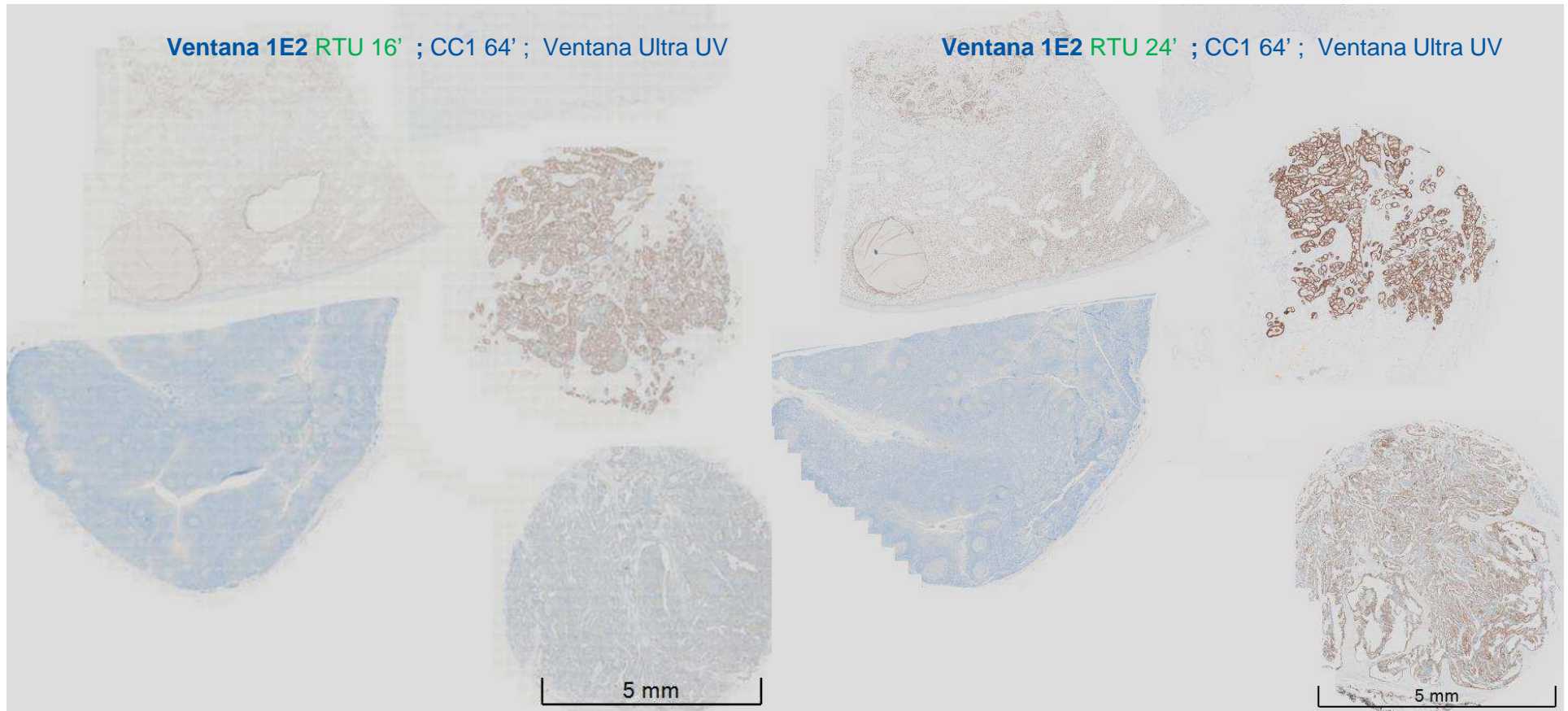
- 1 Cervix: normaal
- 2 Tonsil
- 3 Borst Ca
- 4 Borst Ca
- 5 Borst Ca
- 6 Borst Ca



Aankleuringspatroon: nucleair

- Normale cervix: matig/sterke aankleuring bijna alle columnair epitheel en de meeste stromale cellen, minstens zwakke aankleuring basaal squameus epitheel. Uitz. endotheel en lymfoïde cellen
- Normale tonsil : geen aankleuring (controle specificiteit)
- Borst carcinoom (core 3) : aankleuring in minderheid (30%) van de tumorale cellen (controle analytische sensitiviteit)
- Borst carcinoom (core 4): sterke aankleuring in ~90% van de tumorale cellen
- Borst carcinoom (core 5) : geen aankleuring van de tumorale cellen

Reassessment PR

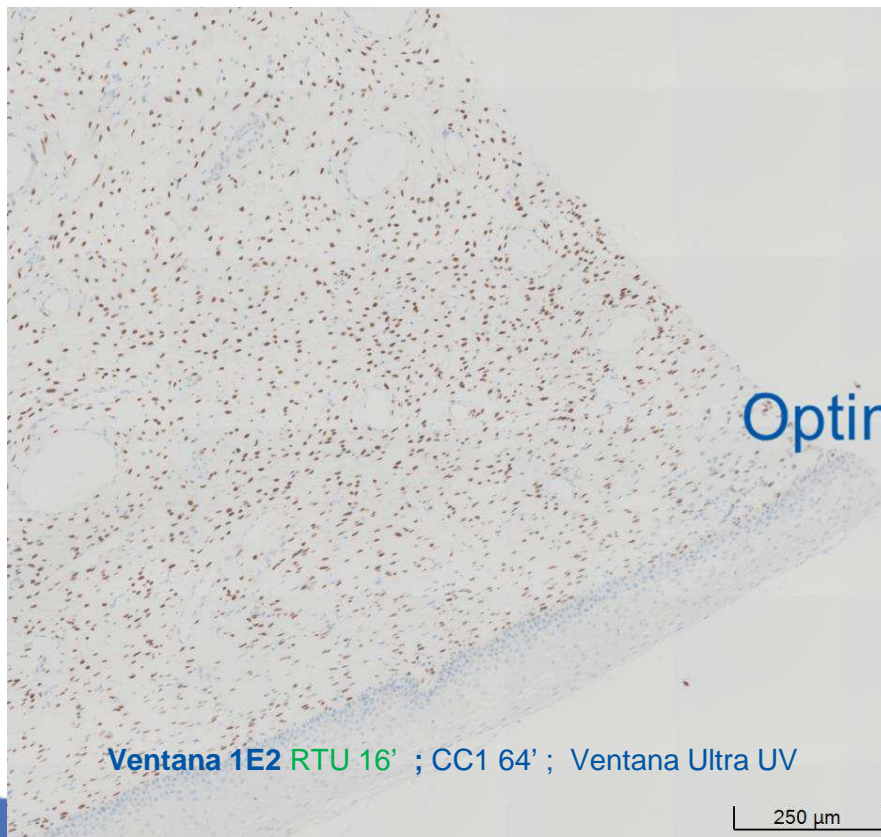


voor

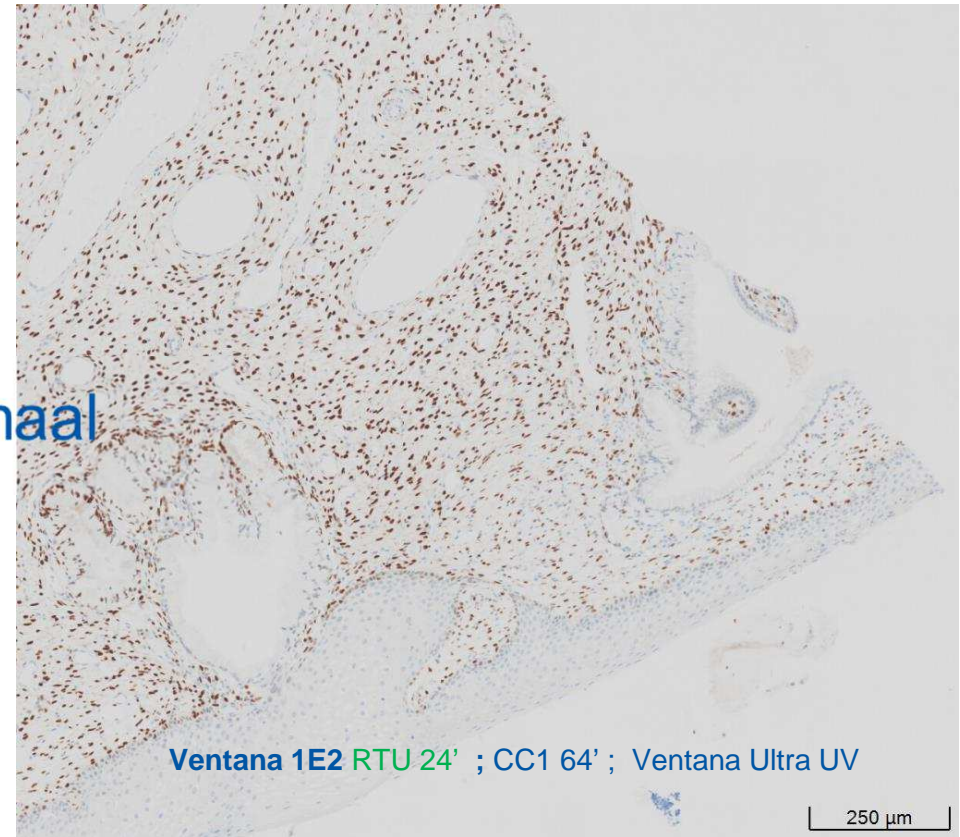
na



Reassessment PR



Optimaal



voor

na



Reassessment PR

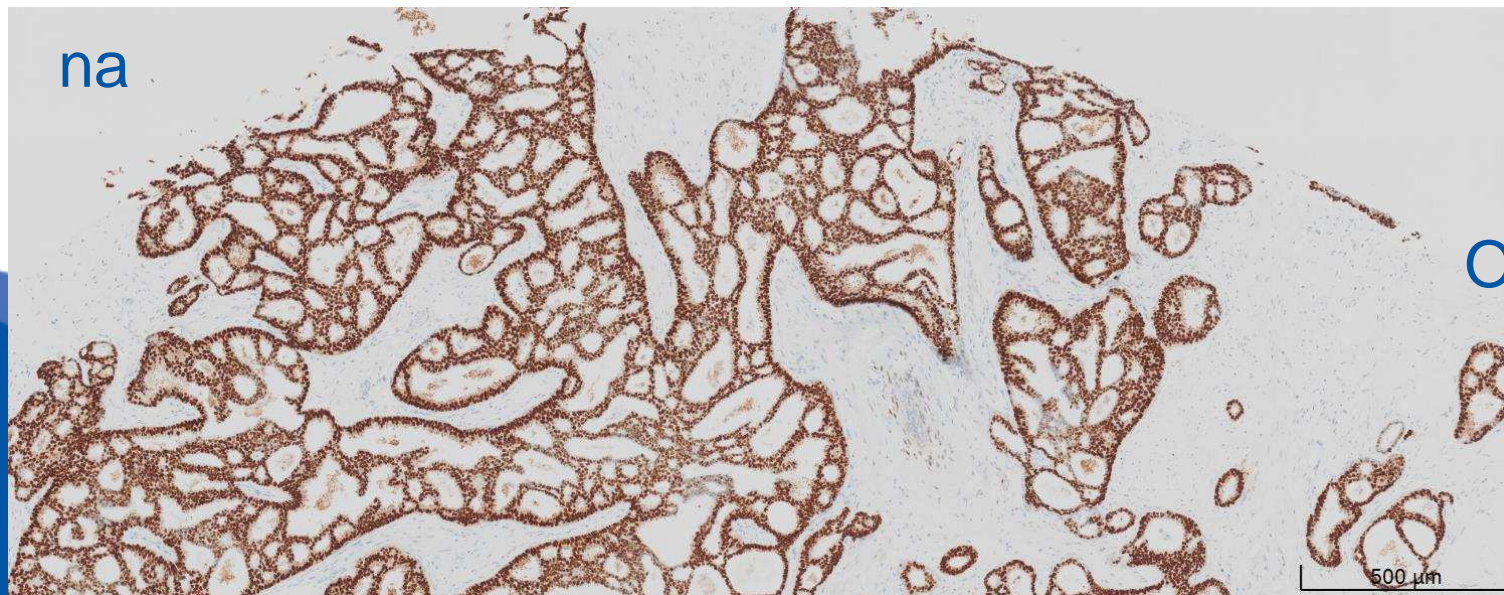
voor

Zwakkere, heterogene aankleuring

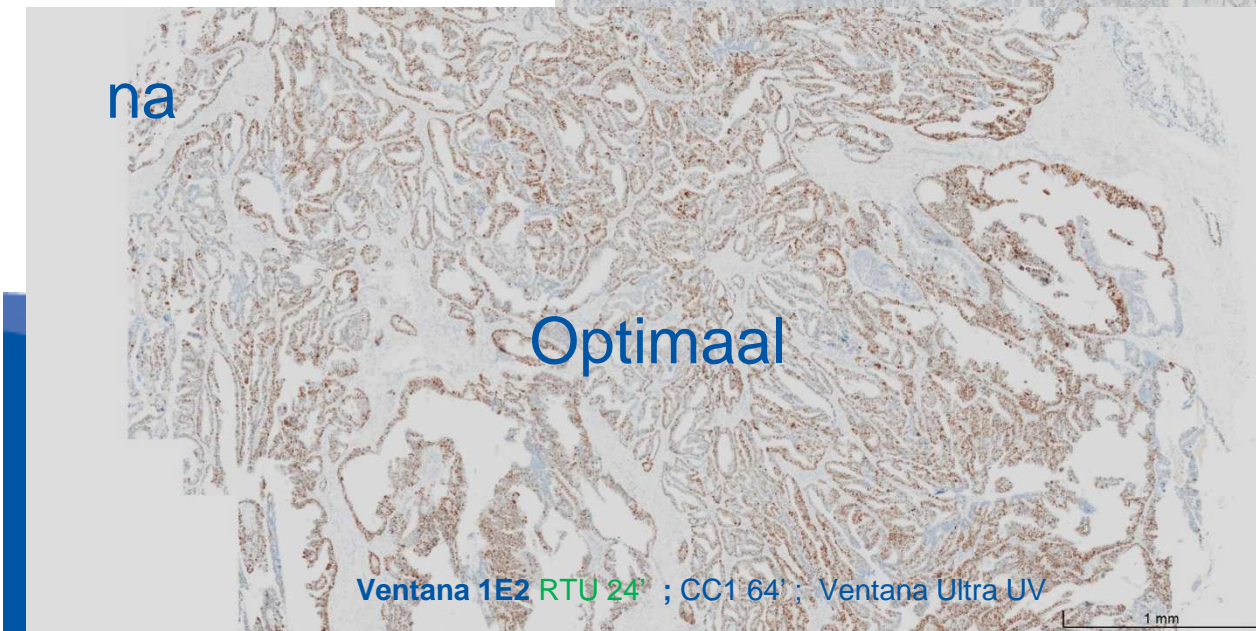
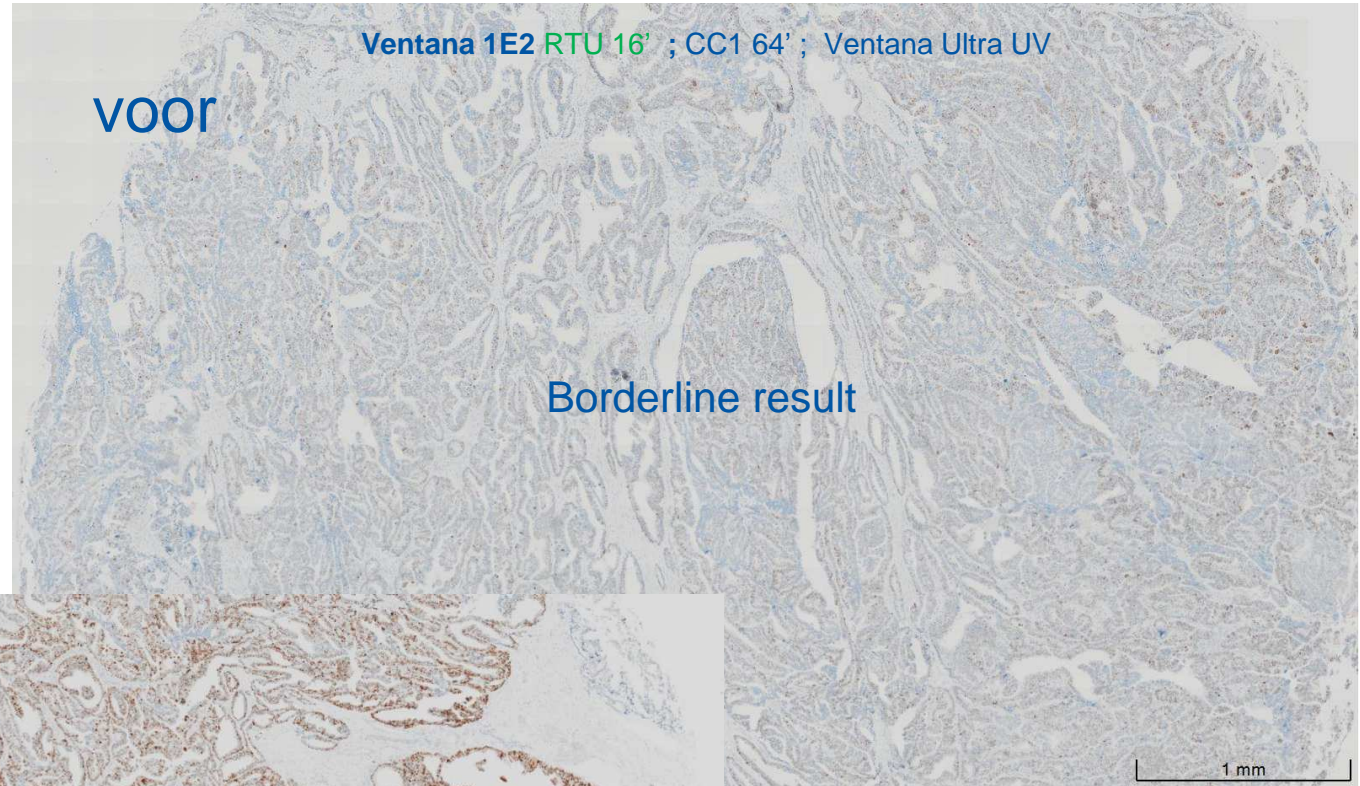


na

Optimaal



Reassessment PR



Resultaatbespreking besluit

geslaagd		2023-1	2022-3	2022-1	2020-3	2020-1	2019	NordiQC	
PR		-	98% (100%*)	-	87% (93,5%*)	-	92%*	91%	2022
HER2	✓	100%	83%	100%	98%	96,5%	86%	90%	2023
ER	✓	100%	-	94%	-	81 % (88%*)	84 %	91%	2023

* Na reassessment



Hoofdsponsors



Bronzen sponsor



Andere sponsors

