

GynTect®

a DNA methylation marker panel-based diagnostic test shows very high specificity in the triage of cervical cancer screening samples

Schmitz M.¹, Eichelkraut K.¹, Schmidt D.¹, Zeiser I.², Dürst M.³, Ikenberg H.², Hansel A.¹

¹*oncgnostics GmbH, Jena Germany*

²*CytoMol, Frankfurt, Germany*

³*Department of Gynecology, Jena University Hospital, Jena, Germany*

Conflict of interest

M. Schmitz is employee and shareholder of the oncgnostics GmbH, a company that aims to commercialize DNA methylation markers.



Carcinogenesis of cervical carcinoma

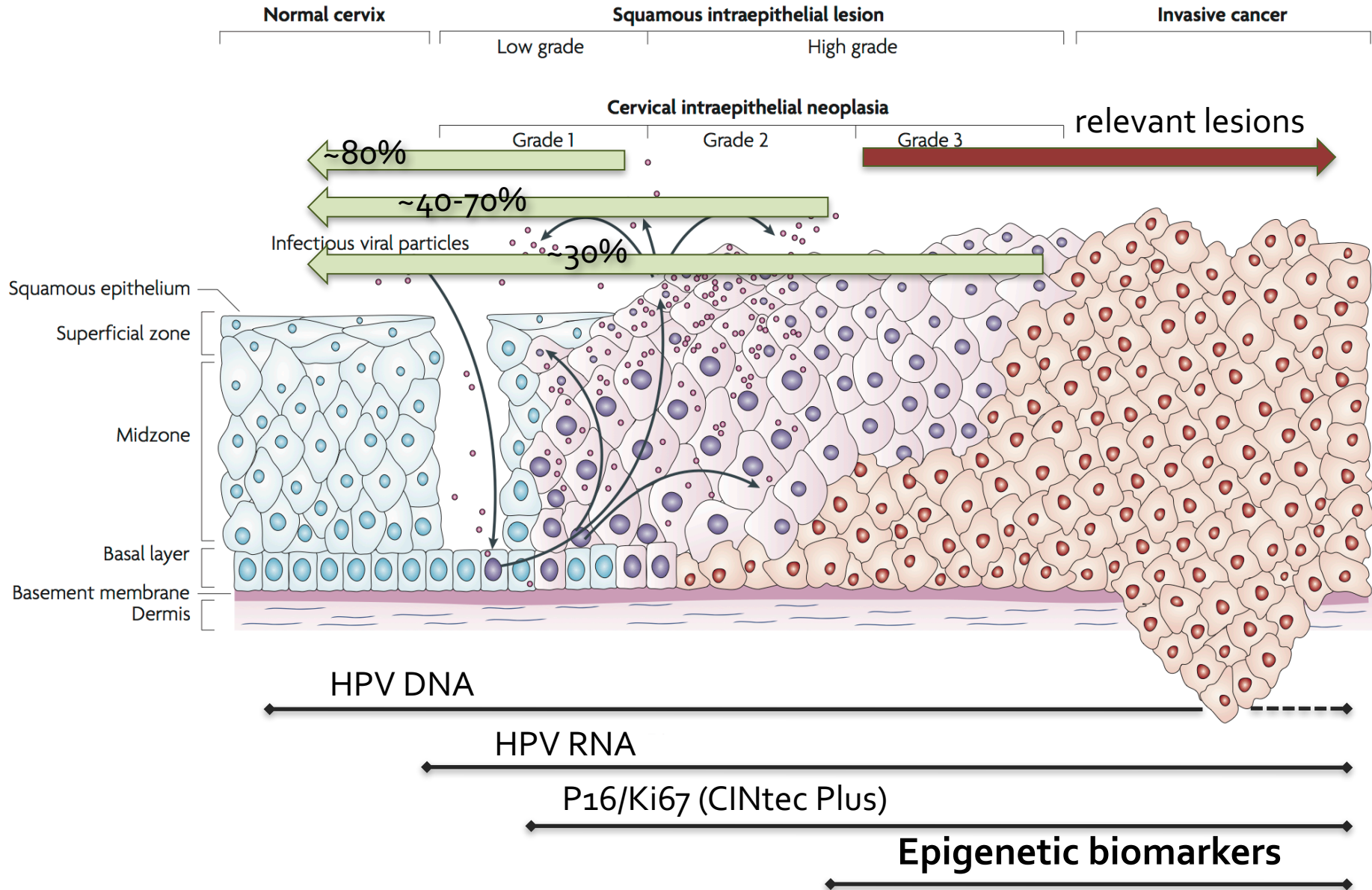
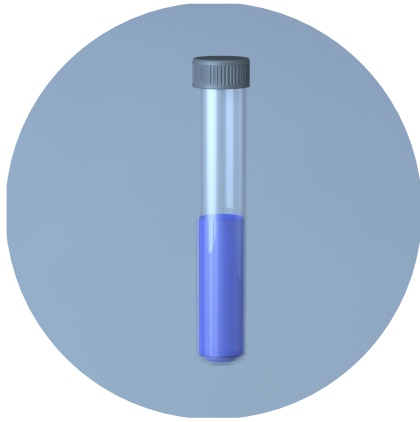
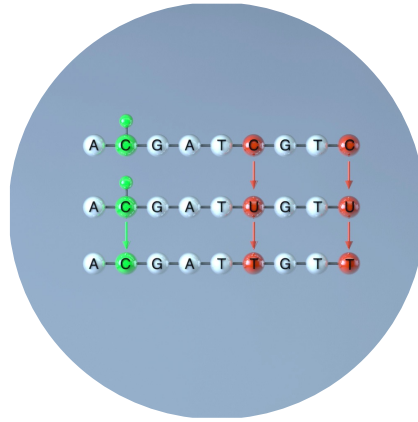


Figure: The natural history of cervical HPV infection: unresolved issues. Nat Rev Cancer. 2007 Jan;7(1):11-22.

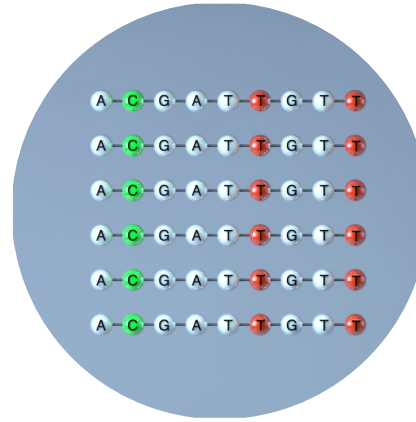
Workflow of GynTect



Patient sample:
PreservCyt
ThinPrep Media



Chemical treatment:
Bisulfite treatment for
fixation of DNA
methylation



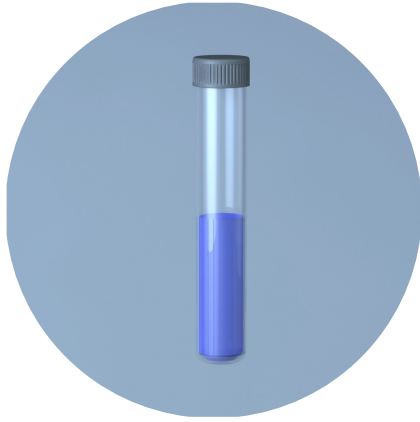
Analytical PCR:
detection of 6
markers via real-time
PCR



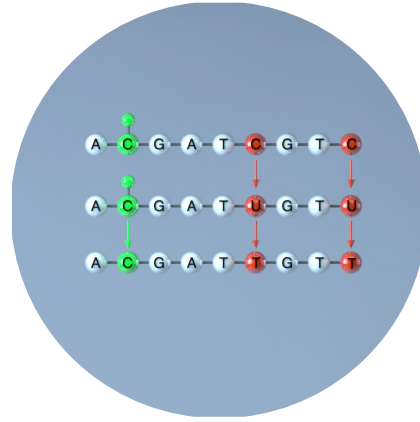
Data analysis:
Positive if at least a
proportion of
markers is positive



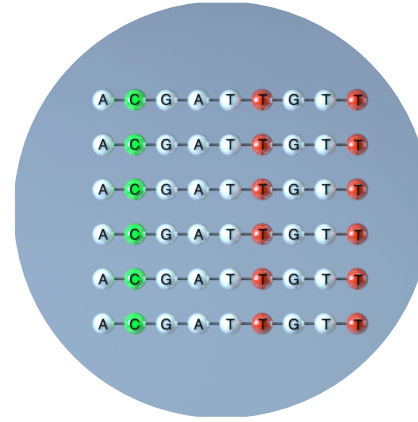
Workflow of GynTect



Patient sample:
PreservCyt
ThinPrep Media



Chemical treatment:
Bisulfite treatment for
fixation of DNA
methylation



Analytical PCR:
detection of 6
markers via real-time
PCR



Data analysis:
Positive if at least a
proportion of
markers is positive

Six biomarker	Quality control marker
ASTN1	IDS-M
DLX1	ACHE
ITGA4	
RXFP3	
SOX17	
ZNF671	



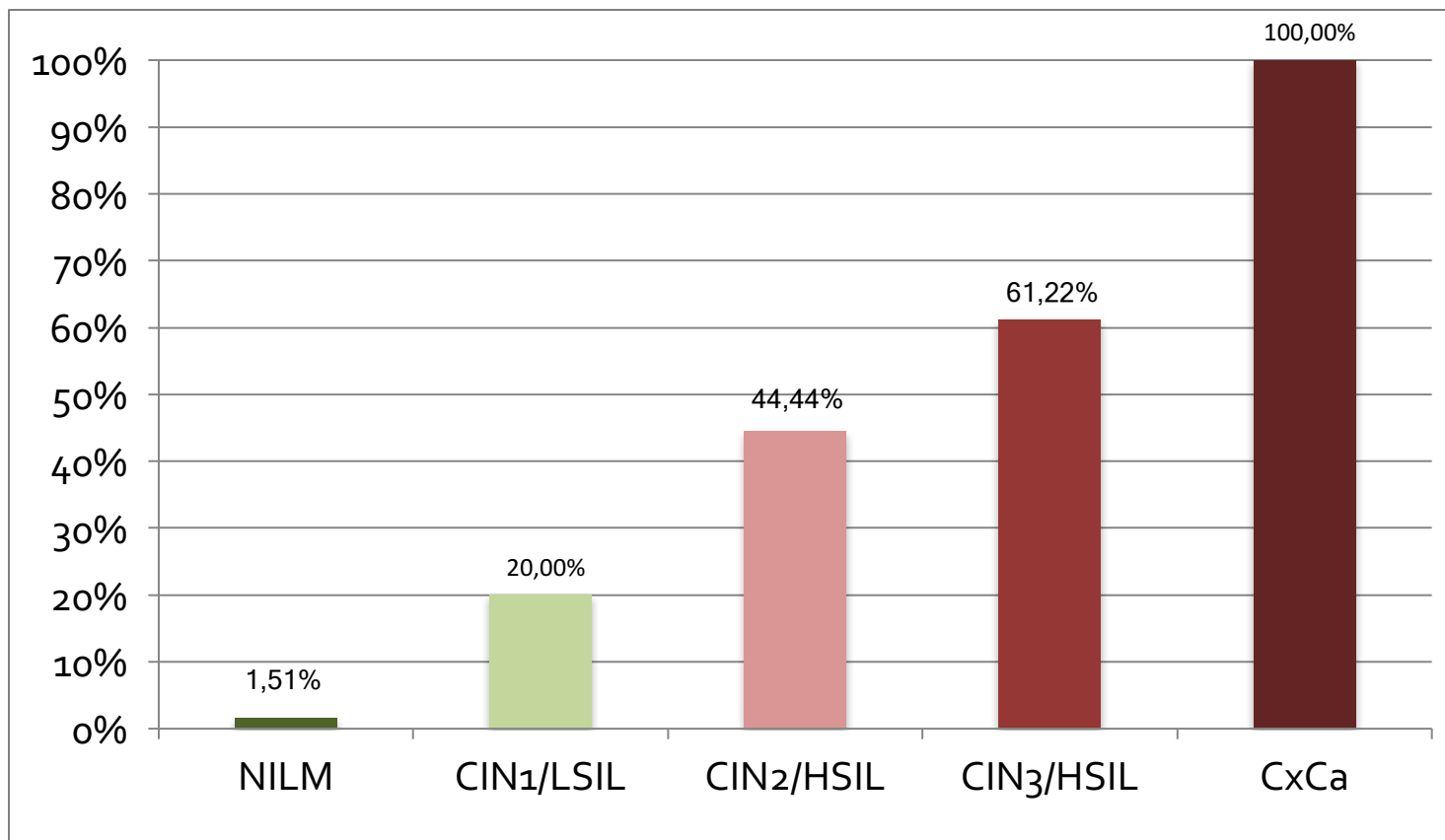
Comparative study: GynTect | cobas HPV | CINtec Plus

Samples from CytoMol lab, Frankfurt

status	number of patients
NILM	201
CIN ₁	5
CIN ₂	19
CIN ₃	50
CxCa	5
total	280

- Cytology-based screening, retrospective study
- All CINs histopathologically confirmed
- All samples tested with cobas HPV
- All samples tested with GynTect
- All CINs, CxCa and 59 of NILM samples tested with CINtec Plus (p16/Ki67)

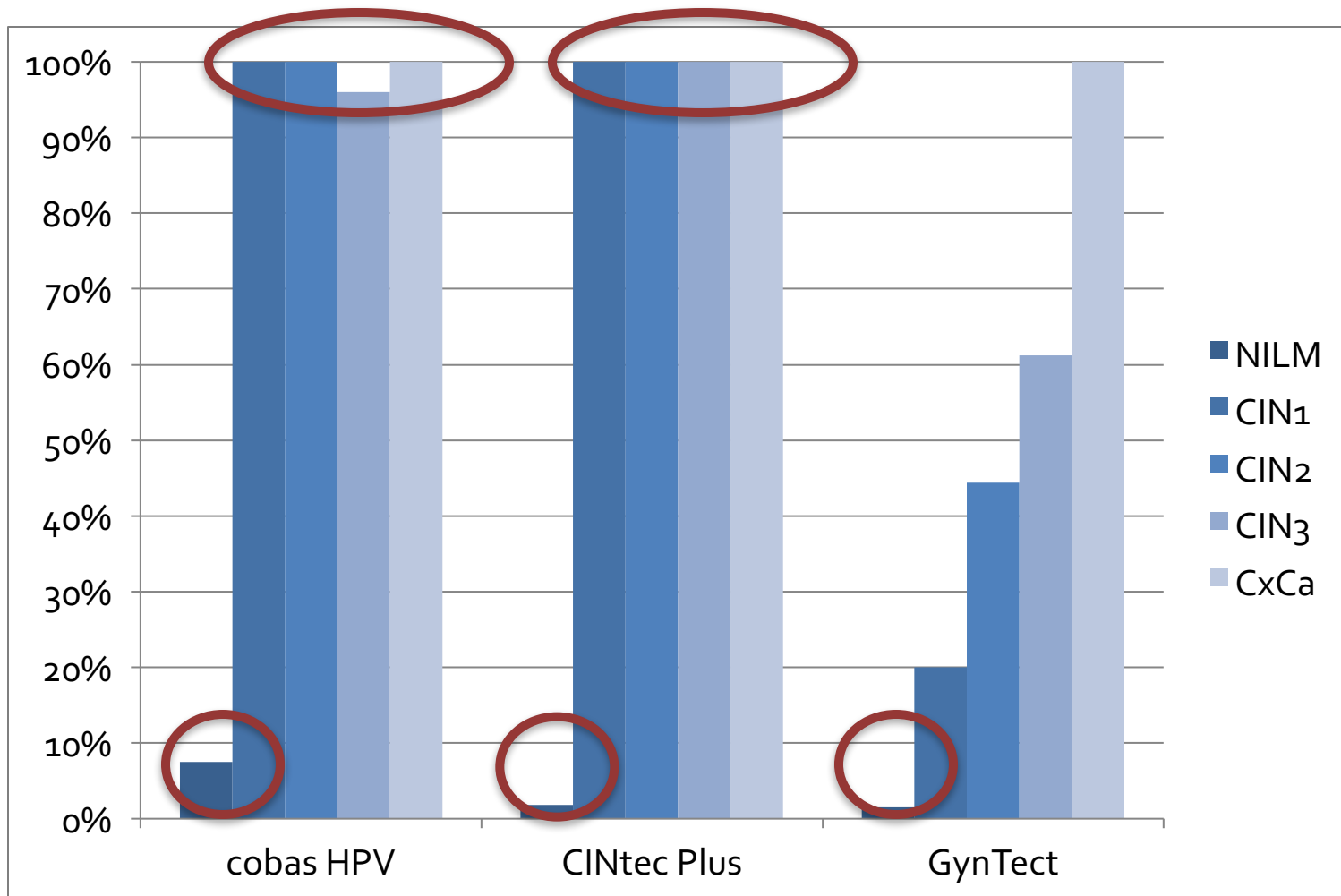
GynTect[®] detection rates



	CIN 2+
sensitivity	59.7 %
specificity	98.0 %

	CIN 3+
sensitivity	64.8 %
specificity	94.6 %

Comparison of all three test systems



Comparison of all three test systems

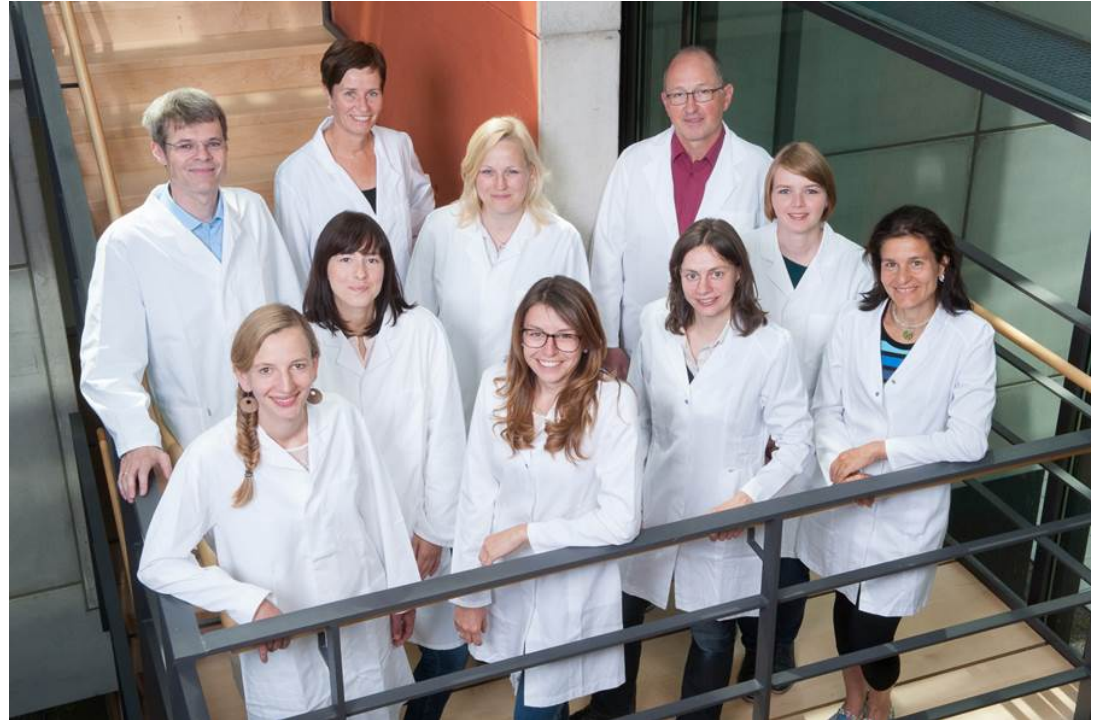
	cobas HPV	CINtec Plus	GynTect
Sensitivity			
CIN2+	97.3%	100.0%	59.7%
CIN3+	96.4%	100.0%	64.8%
Specificity			
CIN2+	90.2%	90.2%	98.0%
CIN3+	82.6%	69.6%	94,6%
invalid test results	0.36%	3.62%	1.43%

CIN3+	cobas HPV	CINtec Plus	GynTect
sensitivity	96,4%	100%	64,8 %
specificity	82,6%	69,6%	94,6 %
PPV	57,6%	69,2%	74,5 %
NPV	98,9%	100%	91,7 %

Thank you for your attention!



... questions



Dr. rer. nat. Martina Schmitz
oncgnostics GmbH • Jena

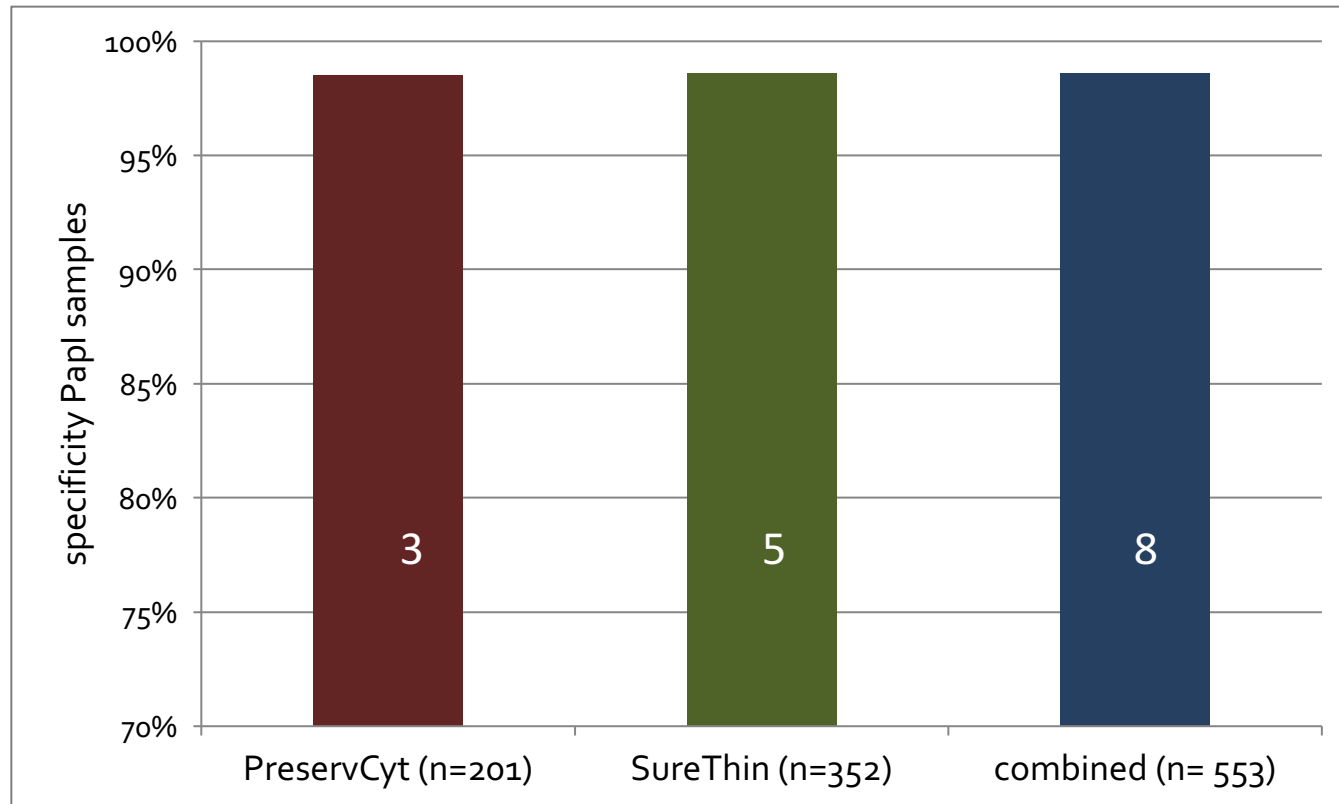
Tel.: +49-(0)3641-8741972
martina.schmitz@oncgnostics.com



CytoMol



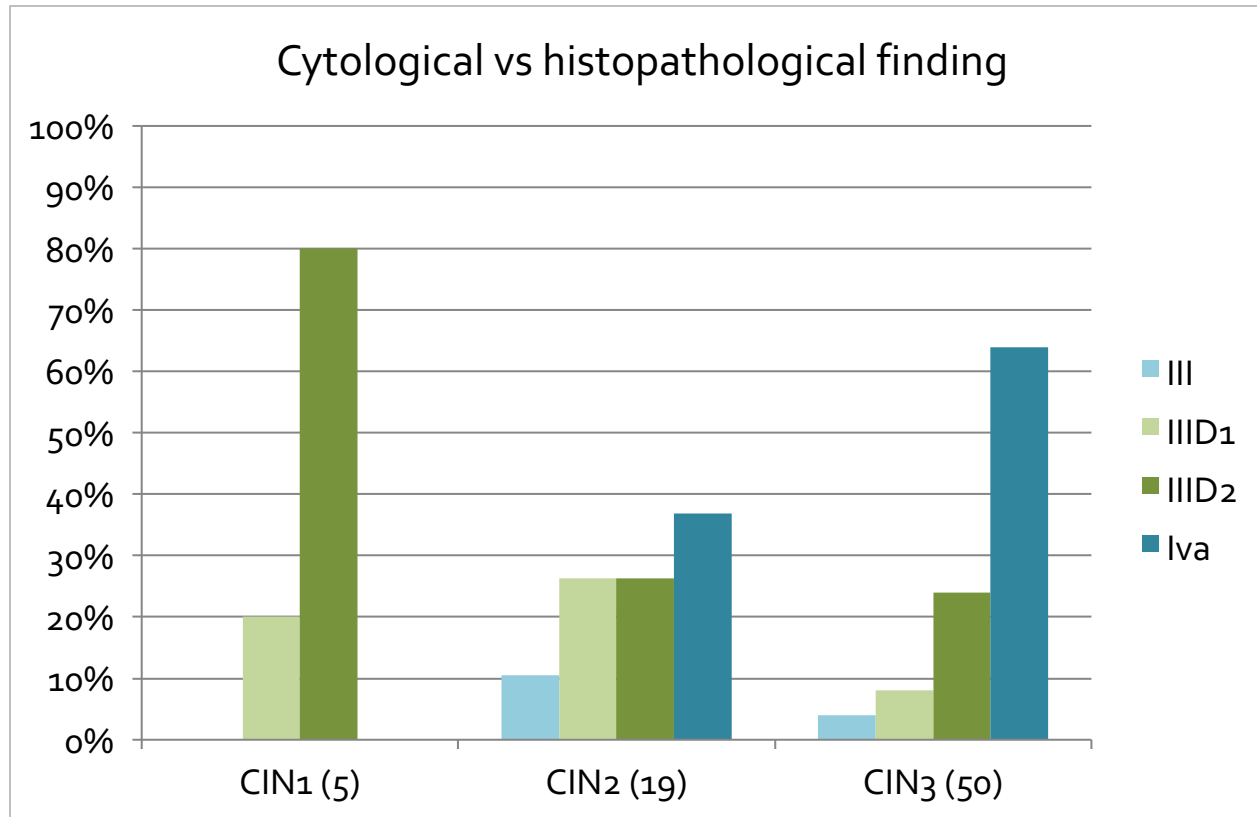
GynTect[®] assay specificity



false-positives

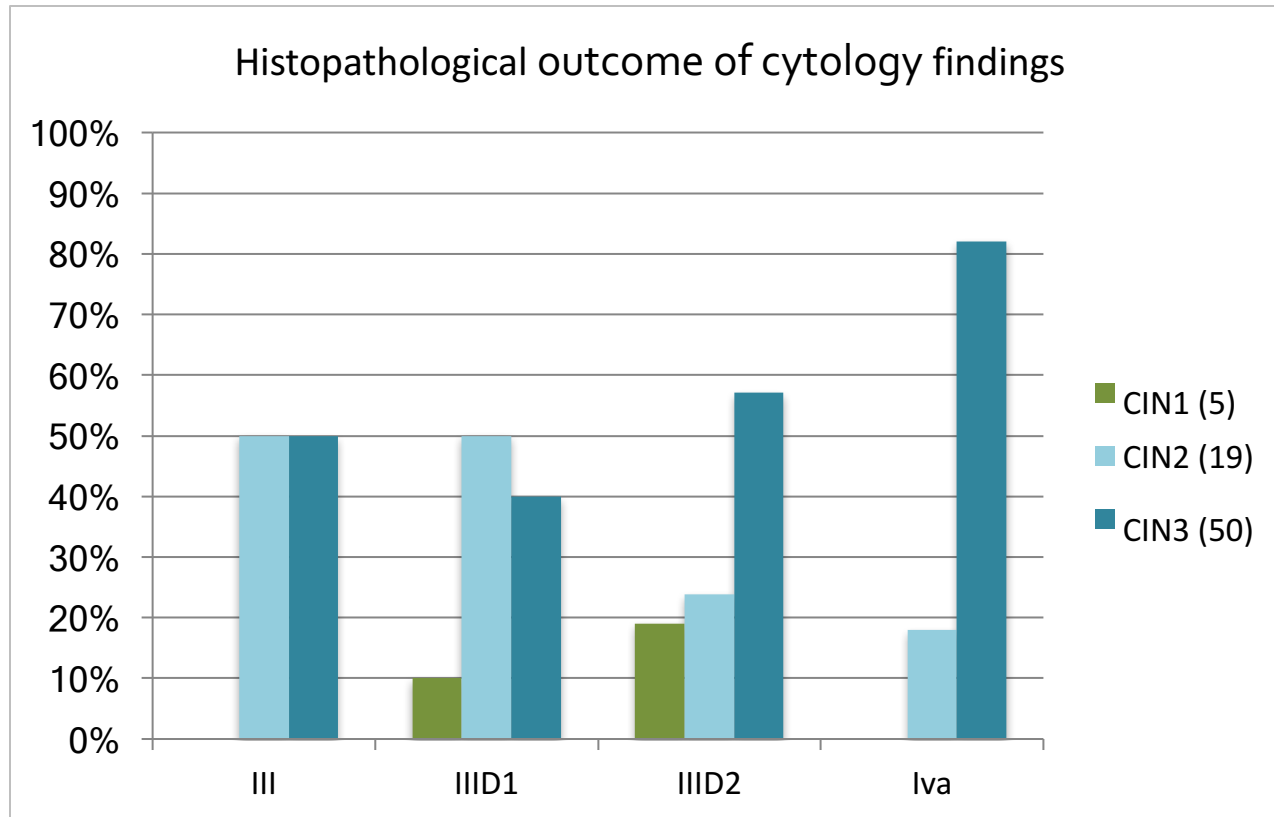


Cytology (Münchener Nomenclatur III)



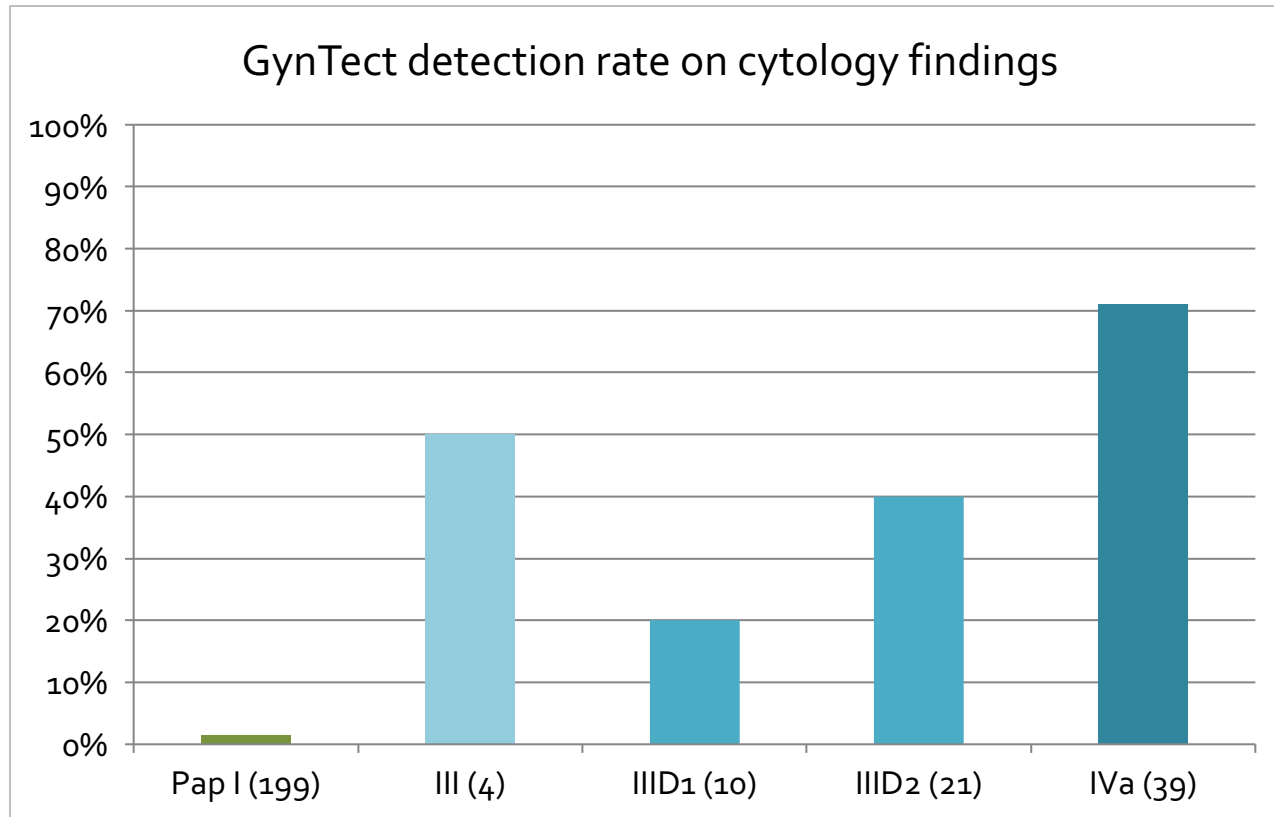
Pap III = ASC-H
Pap IIID1 = LSIL
Pap IIID2 = HSIL
Pap IVa = HSIL

Cytology (Münchener Nomenclatur III)



Pap III = ASC-H
Pap IIID₁ = LSIL
Pap IIID₂ = HSIL
Pap IVa = HSIL

Cytology (Münchener Nomenclatur III)



Pap I = NILM
Pap III = ASC-H
Pap IIID1 = LSIL
Pap IIID2 = HSIL
Pap IVa = HSIL