



# Performance of GynTect® – a DNA methylation marker panel-based diagnostic test, on a widely used diagnostic platform

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## Conflict of interest

K. Eichelkraut is application specialist at oncgnostics GmbH,  
a company that aims to commercialize DNA methylation markers.

# Carcinogenesis of cervical carcinoma

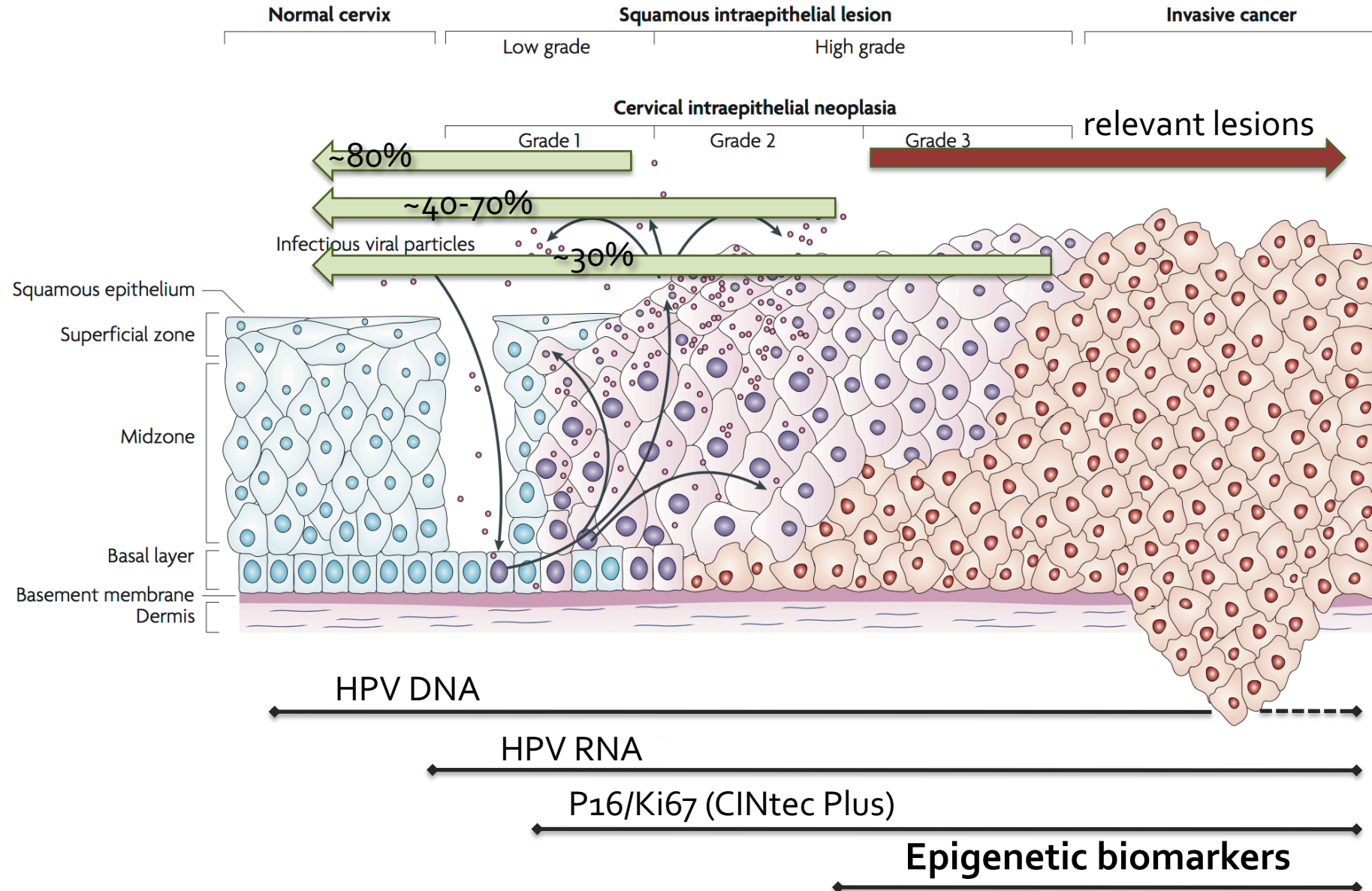
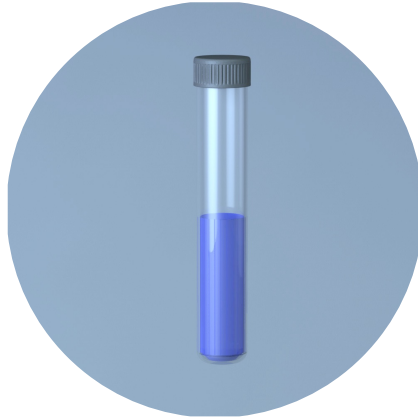
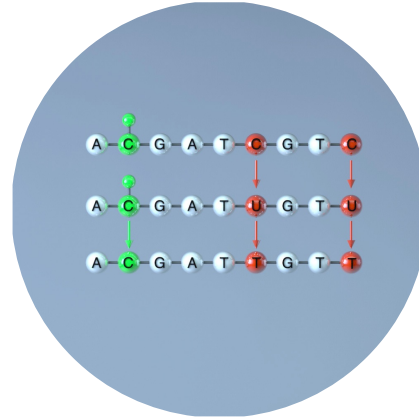


Figure: The natural history of cervical HPV infection: unresolved issues. Nat Rev Cancer. 2007 Jan;7(1):11-22.

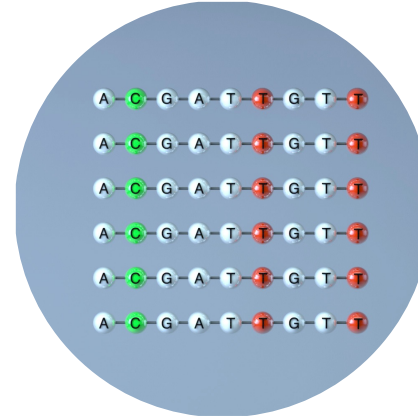
# Technology – GynTest® Procedure



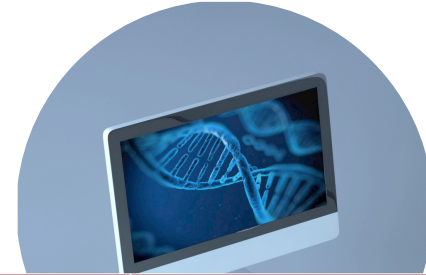
**Patient sample:**  
taken in PreservCyt®  
(Hologic)



**Bisulfite treatment:**  
„Fixation of DNA  
methylation“



**Analytical PCR:**  
detection of 6 markers  
via realtime PCR



biomarker	quality control marker
ASTN1	IDS-M
DLX1	ACHE
ITGA4	
RXFP3	
ZNF671	



# Sample setting

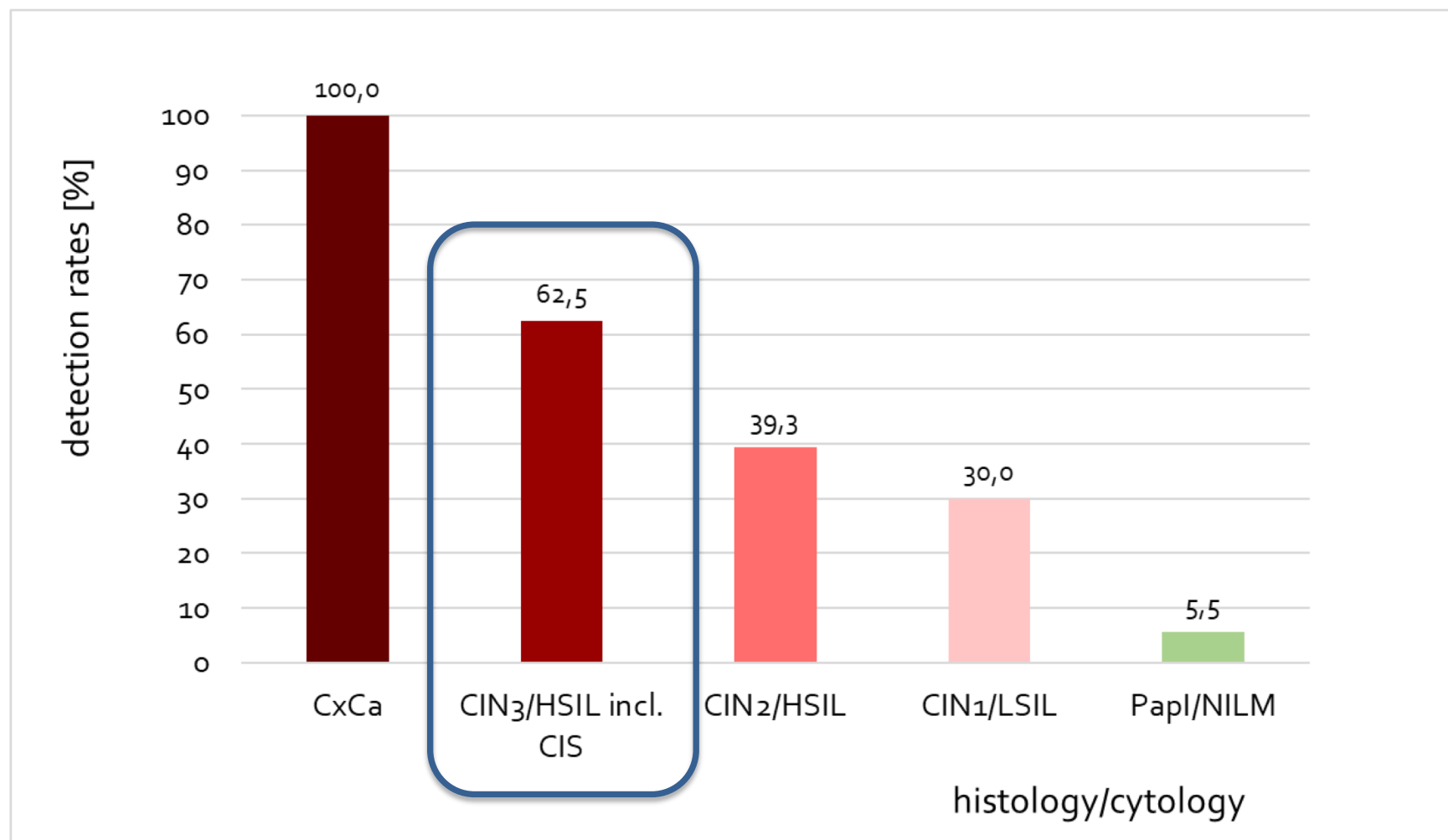
## *Samples from CytoMol lab, Frankfurt, Germany*

status	number of patients
NILM	200
CIN <sub>1</sub> /LSIL	21
CIN <sub>2</sub> /HSIL	28
CIN <sub>3</sub> /HSIL incl. CIS	66
CxCa	13
<b>total</b>	<b>328</b>

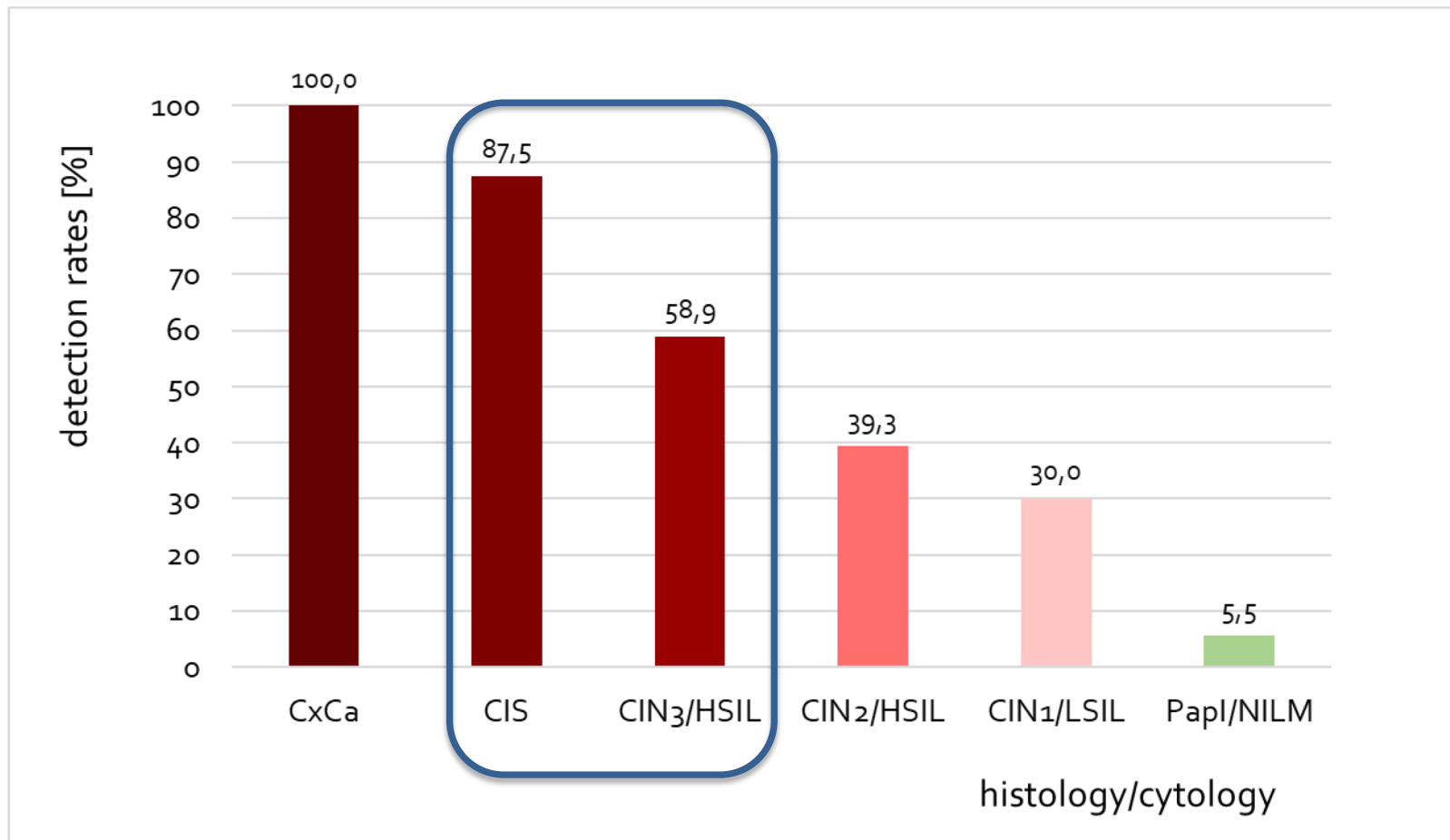
- cytology-based screening, retrospective study
- all CINs histopathologically confirmed
- all CINs and CxCa are HPV positive
- all samples tested with GynTect® on
  - cobas z 480 Analyzer (Roche Diagnostics)
  - ABi7500 real time PCR System (Life Technologies)



# GynTest® Performance



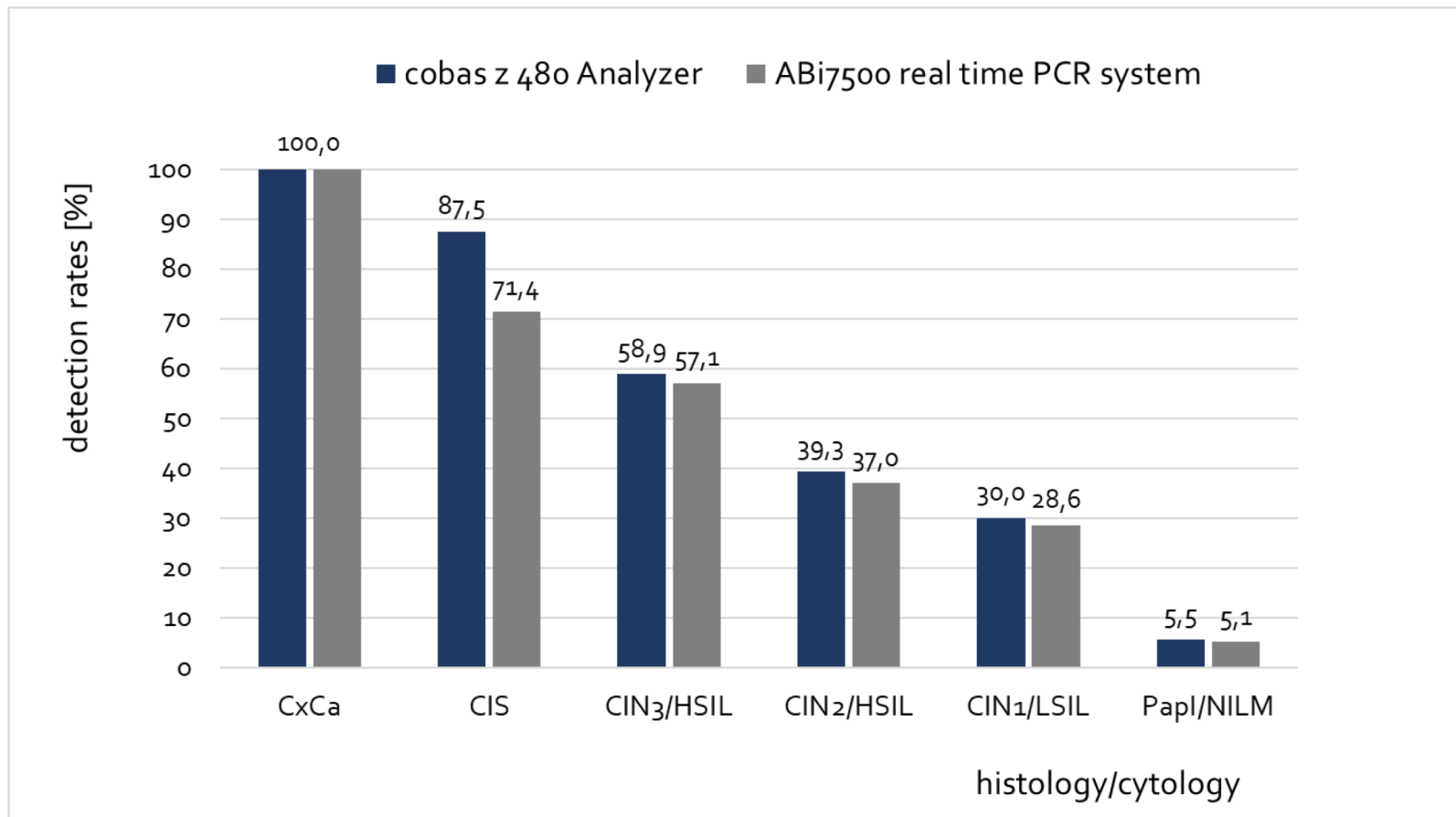
# GynTest® Performance – separate consideration of CIS



	CIN3+
sensitivity	66.7%
specificity	88.7%

	CIN2+
sensitivity	59.0%
specificity	92.2%

# GynTest® Performance – comparison of two PCR devices



● 95% consistent result



# GynTest® Performance – comparison of two PCR devices

	<i>cobas z 480 Analyzer</i>	<i>ABi7500 real time PCR system</i>
<b>CIN<sub>3</sub>+</b>		
sensitivity	66.7%	63.4%
specificity	88.7%	89.3%
prevalence	22.6%	22.6%
PPV	63.2%	63.4%
NPV	90.1%	89.3%
<b>CIN<sub>2</sub>+</b>		
sensitivity	59.0%	56.1%
specificity	92.2%	92.6%
prevalence	31.4%	31.2%
PPV	77.6%	77.5%
NPV	83.1%	82.3%





# Thank you for your attention!



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