

Eurogin 2016 - Salzburg

CLINICAL PERFORMANCE OF GYNTECT - METHYLATION MARKERS FOR TRIAGING HPV-POSITIVE WOMEN

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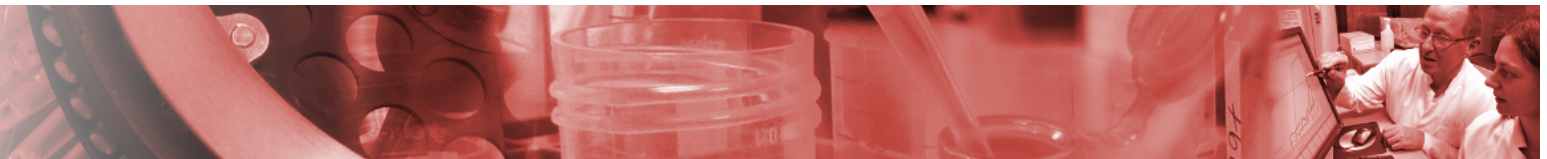
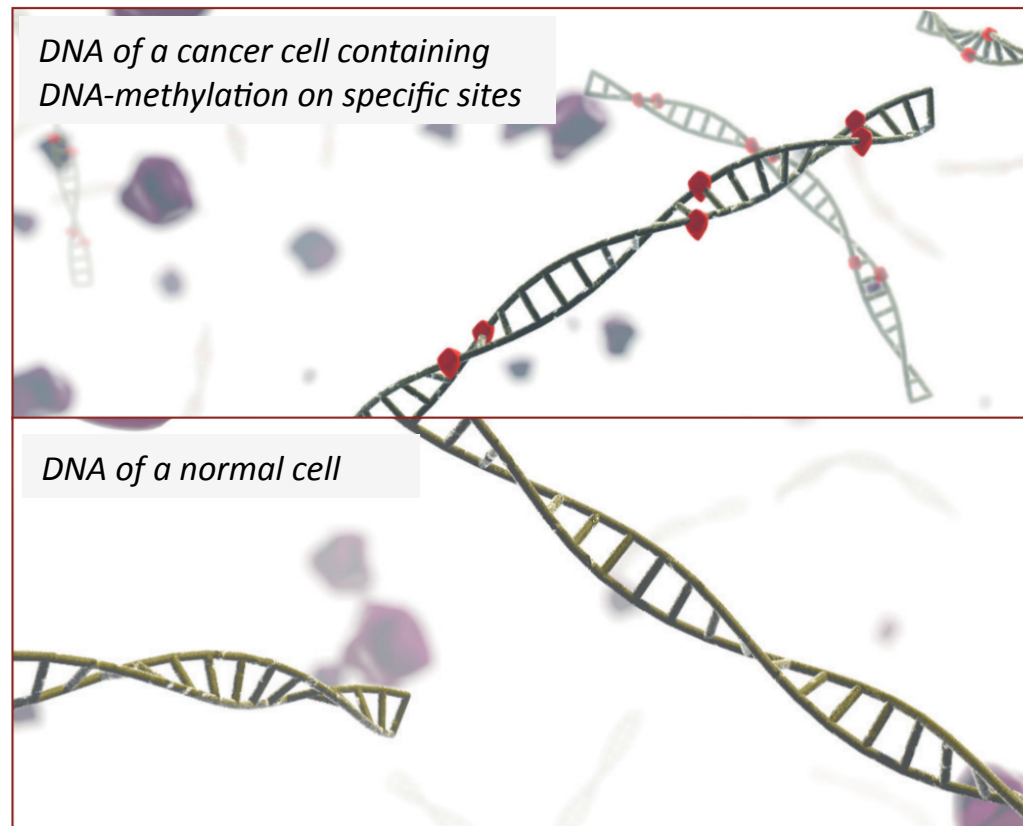
Conflict of interest

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

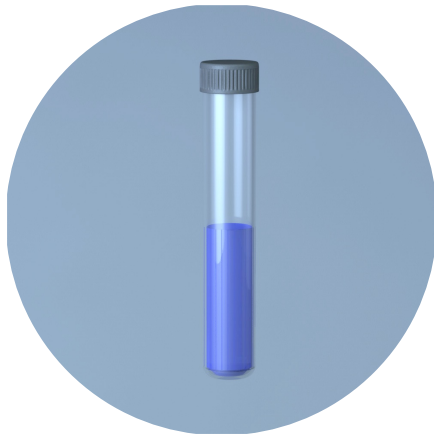


Host cell methylation markers ...

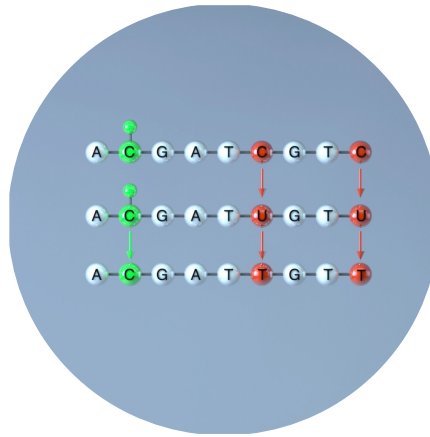
... SEEM TO BE A LATE EVENT DURING CARCINOGENESIS – MORE SPECIFIC.



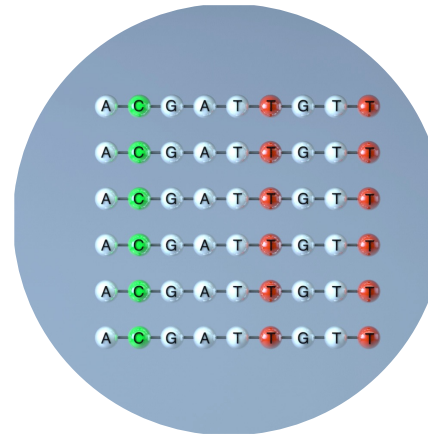
Workflow of GynTect



Patient sample:
Lysis in STM™
media from HC2



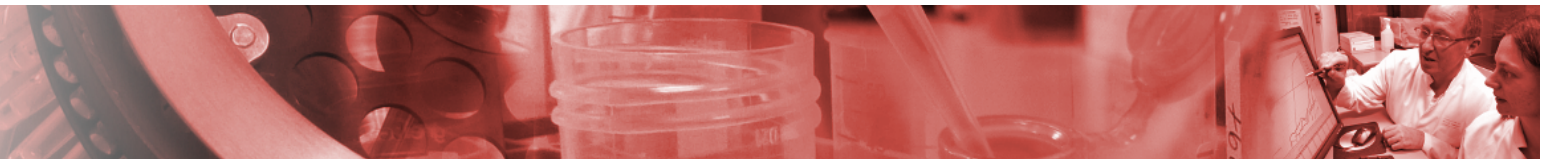
Chemical treatment:
Bisulfite treatment for
fixation of DNA
methylation



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

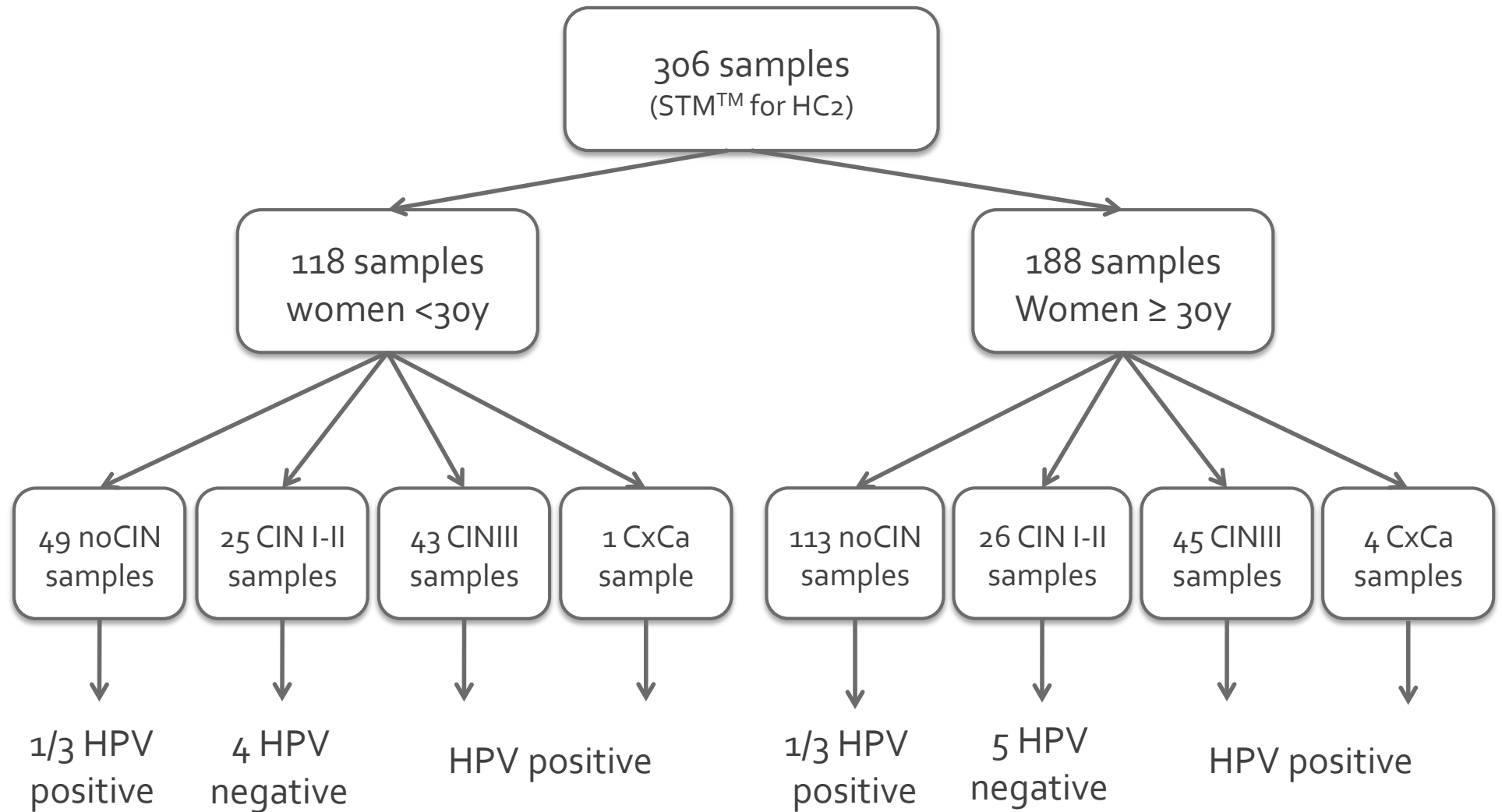


Data analysis:
Positive if at least a
proportion of
markers is positive



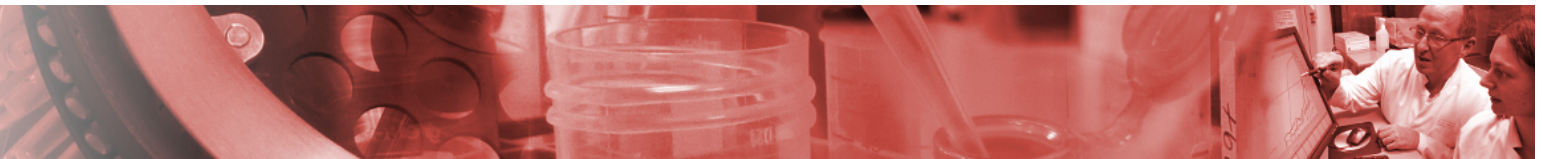
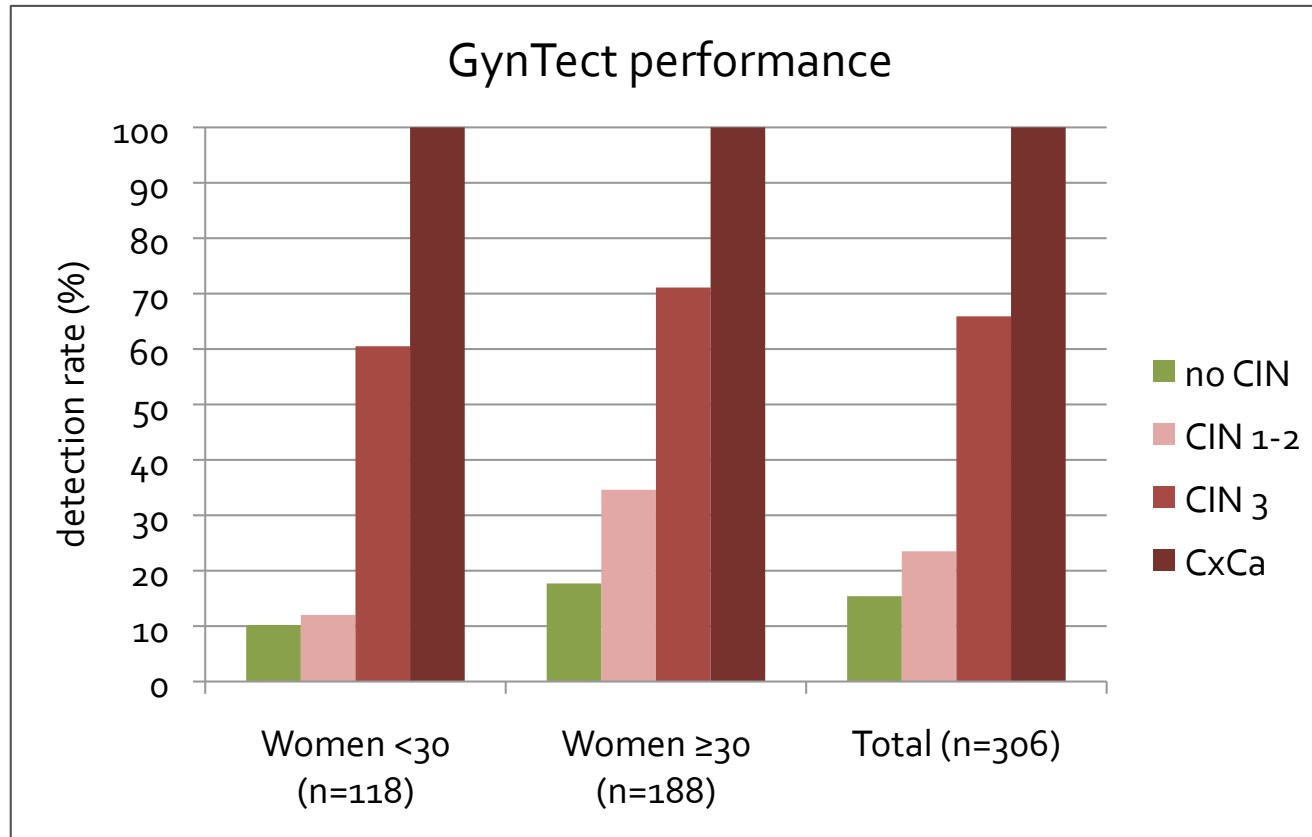
Retrospective trial – sample cohort

(University Hospital Jena, Germany)



Retrospective trial – results

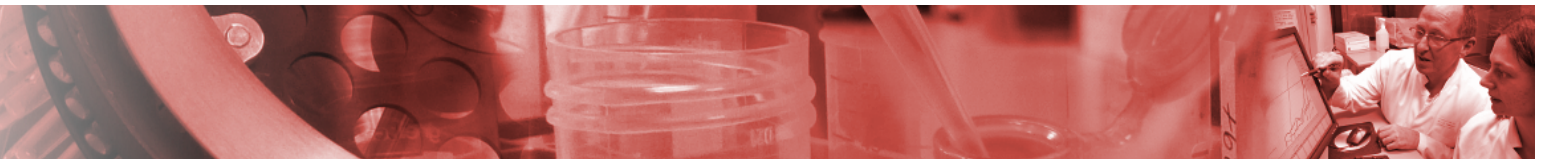
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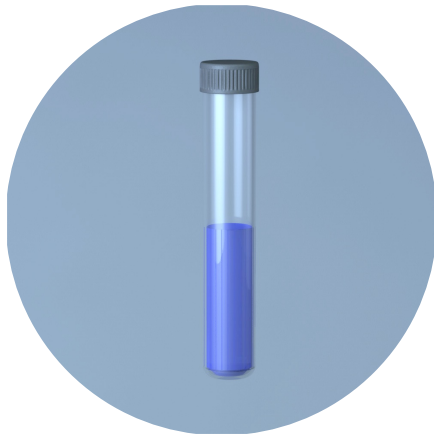
Retrospective trial – results

(University Hospital Jena, Germany)

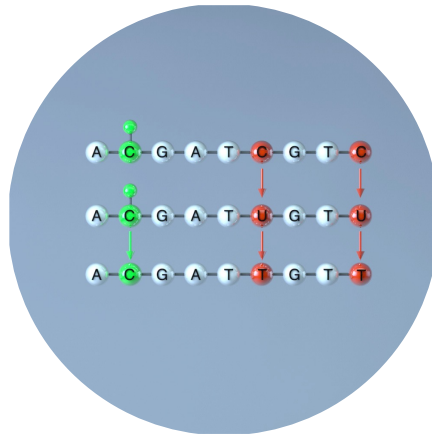
	< 30y	≥30y	total
Sensitivity CIN 3+	61.4 %	73.5 %	67.7 %
Specificity CIN 3+	89.2 %	79.1 %	87.3 %



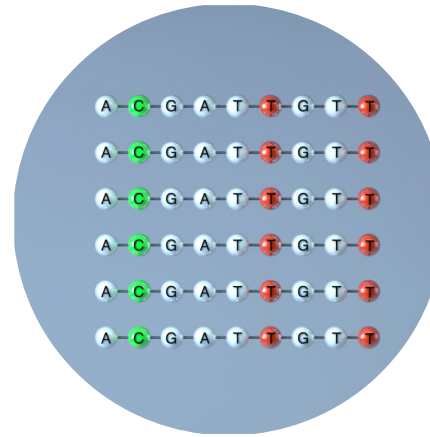
Workflow of GynTect 2.0



Patient sample:
Lysis in STM™
media from HC2



Chemical treatment:
Bisulfite treatment for
fixation of DNA
methylation



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



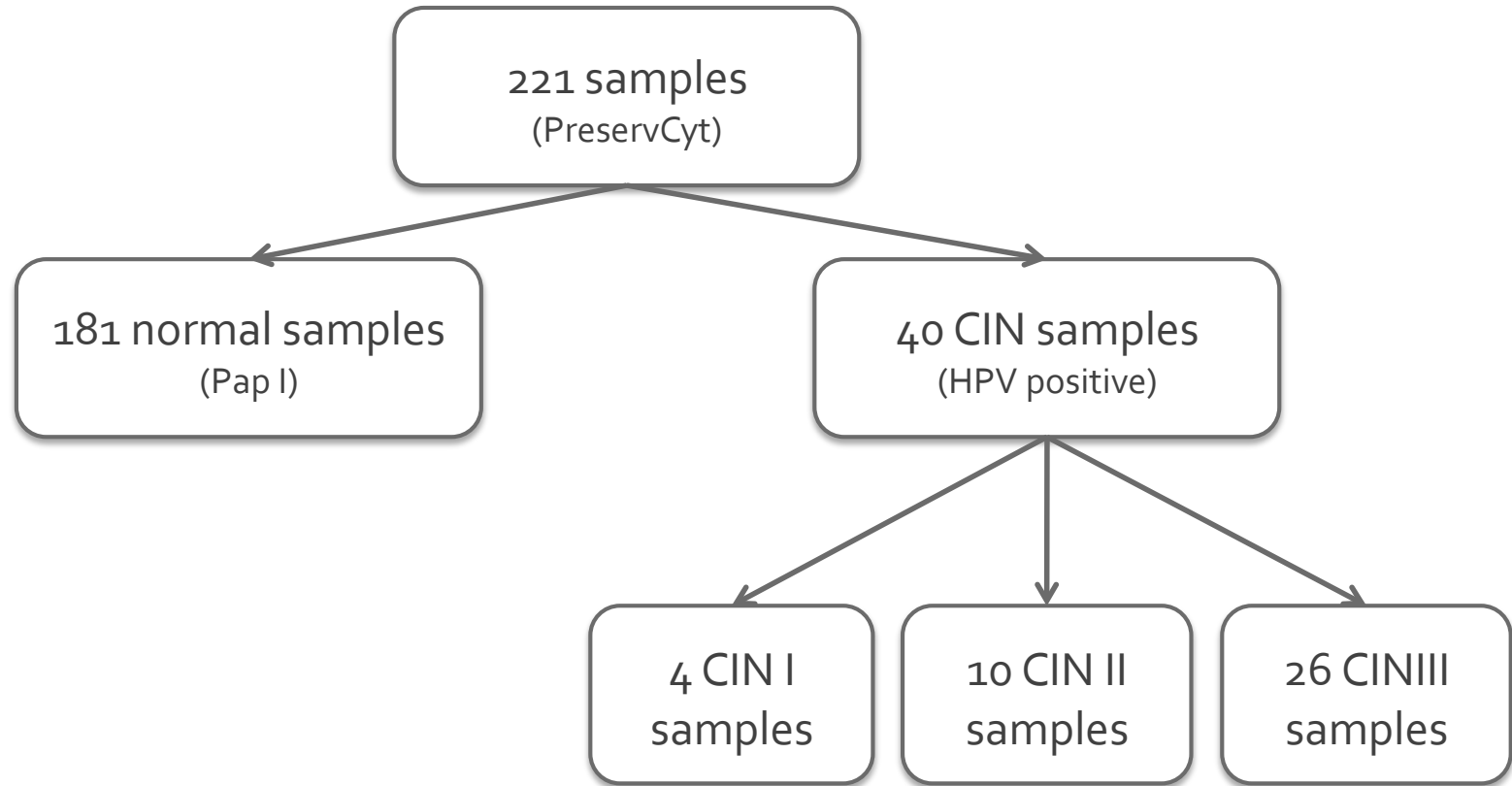
Data analysis

- NEW: using LBC media without the additional step of extracting genomic DNA



Evaluation trial – sample cohort

(CytoMol, Frankfurt, Germany)

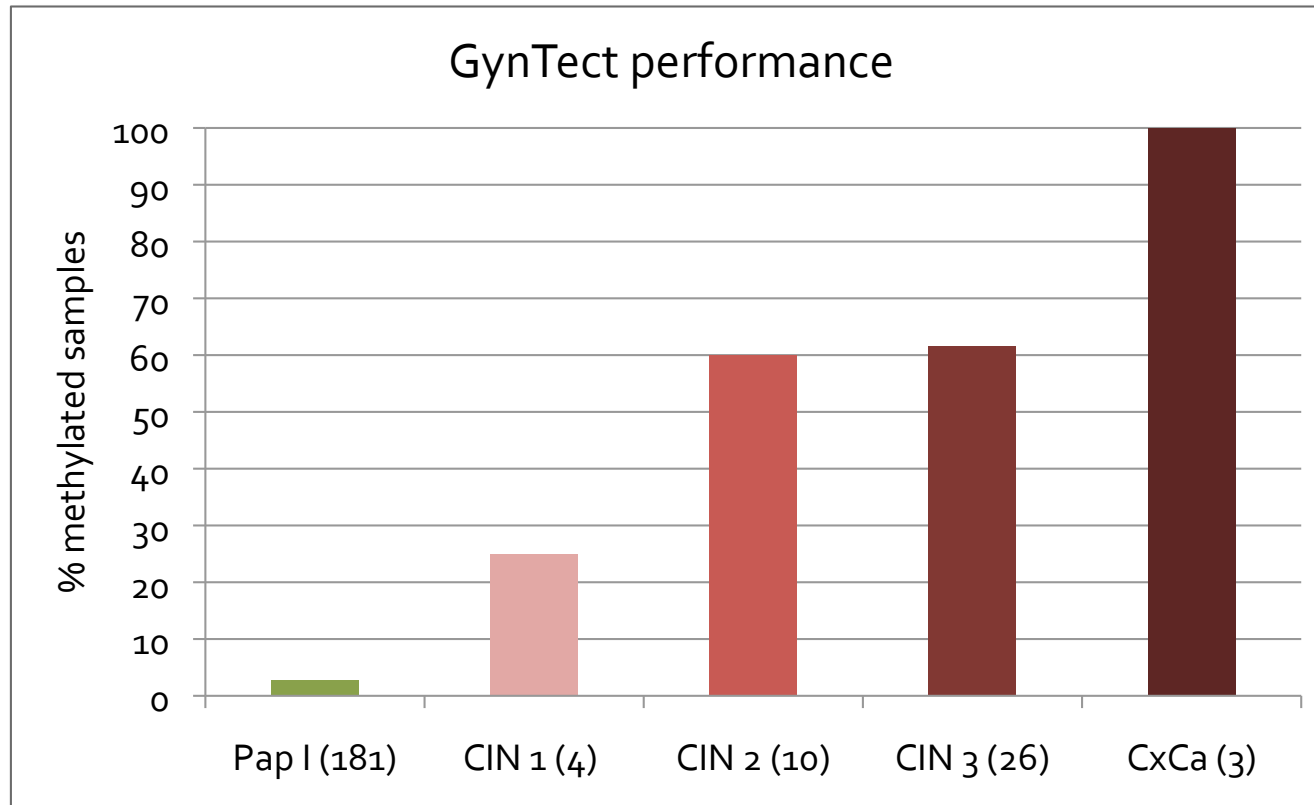


- no cancer cases!
- 3 cancer cases from University Hospital Jena (PreservCyt samples) -> blinded testing!



Evaluation trial – results

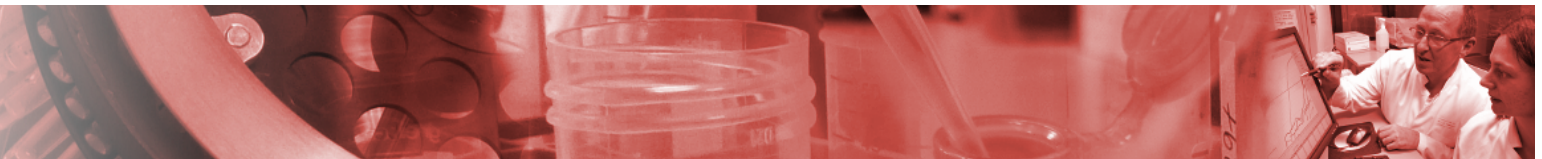
(CytoMol, Frankfurt, Germany & CxCa samples from University Hospital Jena)



Evaluation trial – results

(CytoMol, Frankfurt, Germany & CxCa samples from University Hospital Jena)

	CIN 2+	CIN 3+
Sensitivity	64.1 %	65.5 %
Specificity	96.8 %	93.8 %
PPV	80.6 %	61.3 %
NPV	92.7 %	94.8 %



Key question – specificity

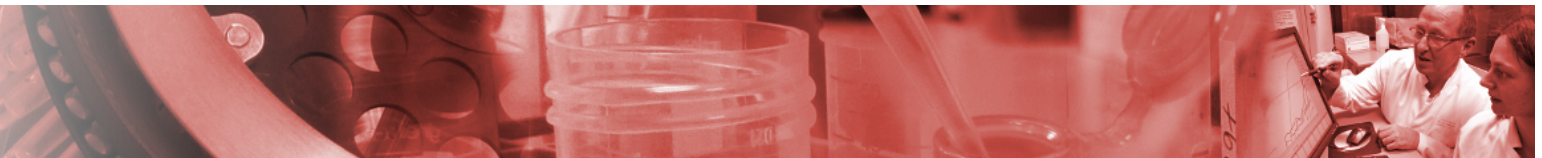
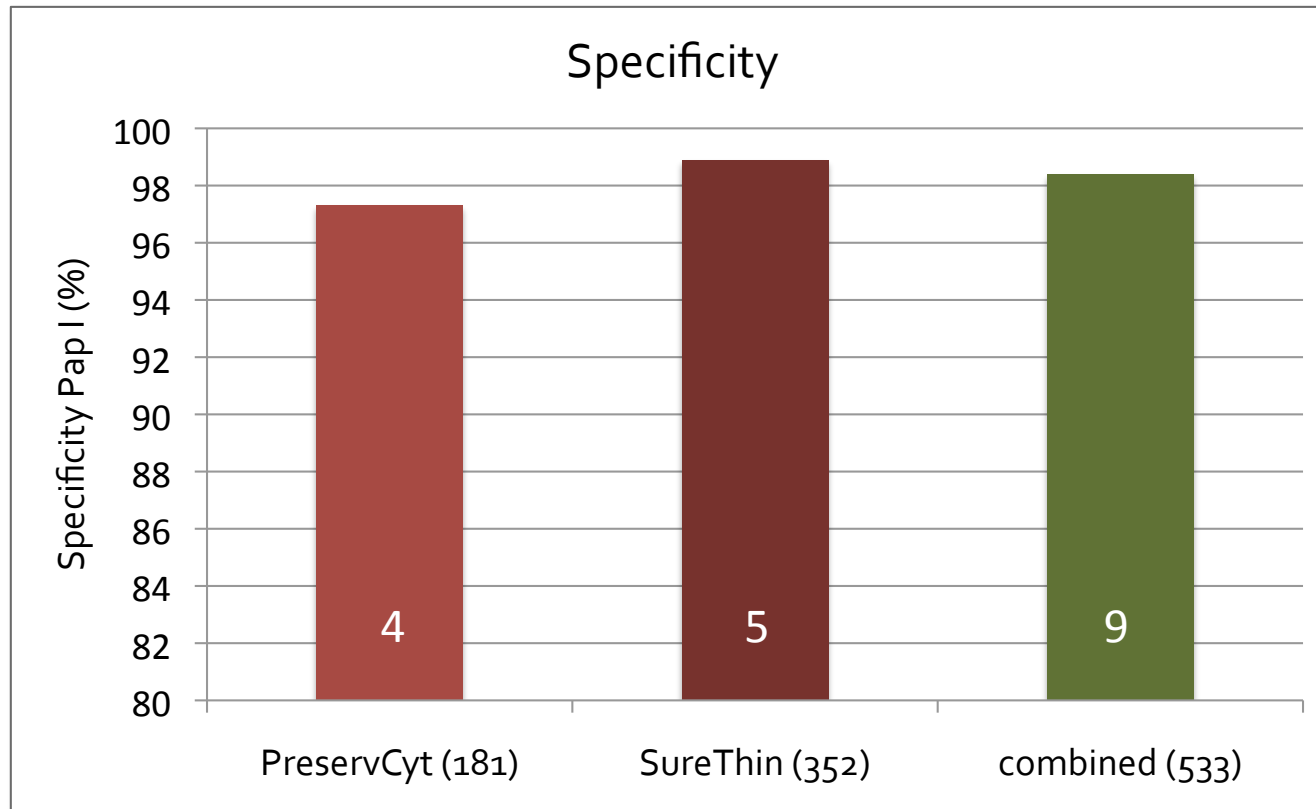
(CytoMol Frankfurt & ZyDoLab, Dortmund, Germany)

- 356 samples collected in SureThin Solution (Cyto Globe, Burgdorf, Germany)
- 181 samples collected in PreservCyt Solution (Hologic, US)



Key question – specificity

(CytoMol Frankfurt & ZyDoLab, Dortmund, Germany)



Conclusion

- Good performance using samples collected in STM media from HC2 (Qiagen)
- Better performance using samples collected in LBC media
- High specificity in samples from routine screening tested Pap I
- Detection rate CIN2 & CIN3: not all lesions develop to higher lesions or cancer!
- Especially for false positive tested women from colposcopy clinic Jena: follow up!
- Methylation markers are a suitable tool to triage women having a positive HPV due to high specificity



Thank you for your attention!



CytoMol



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