

Comparison of two methylation based diagnostic assays on a cohort of 140 HPV positive cervical scrapes: GynTect® and QIASure Methylation Test

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Conflict of interest

C. Dippmann is PhD student in the Department of Gynecology.
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Carcinogenesis of cervical carcinoma

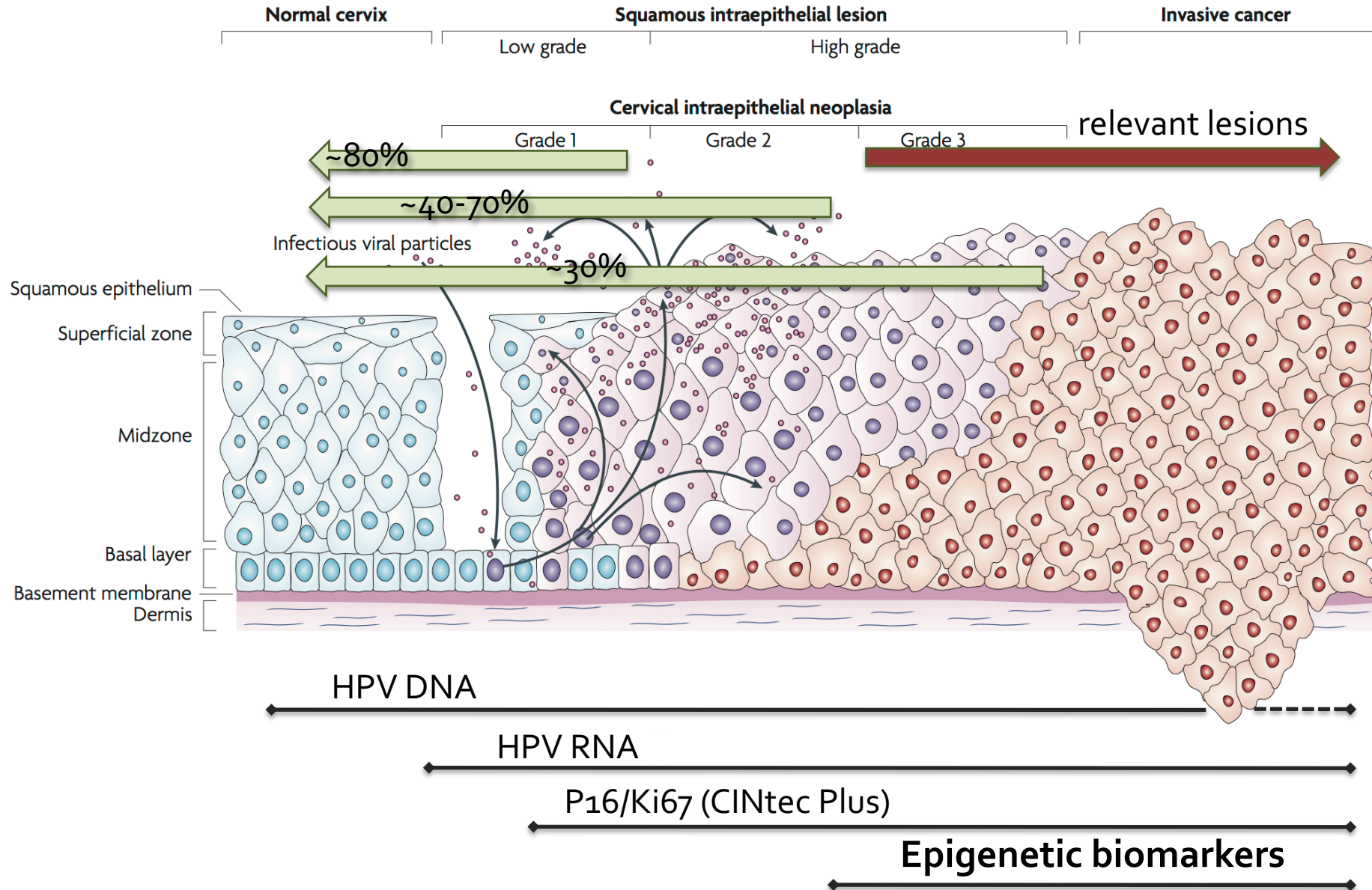
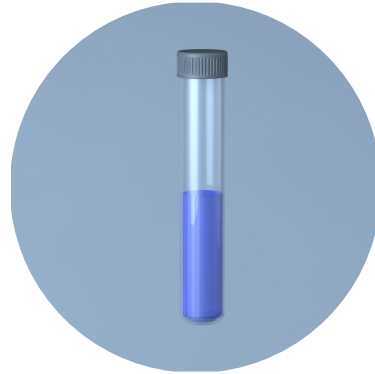


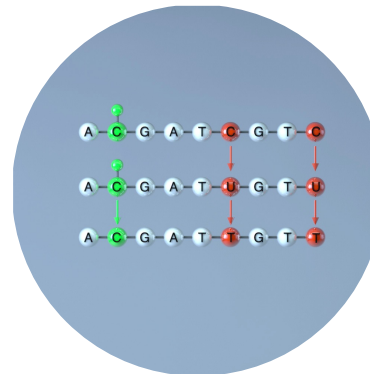
Figure: The natural history of cervical HPV infection: unresolved issues. Nat Rev Cancer. 2007 Jan;7(1):11-22.

Workflow of GynTect®

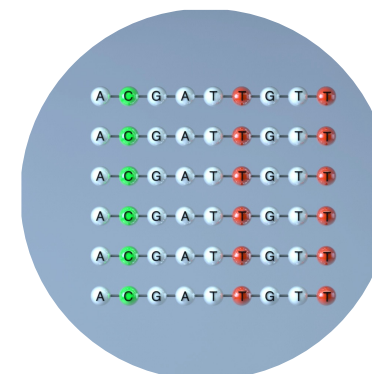
Epigenetic biomarker	Quality control marker
ASTN1 DLX1 ITGA4 RXFP3 SOX17 ZNF671	IDS-M ACHE



Patient sample:
PreservCyt
ThinPrep Media



Chemical treatment:
Bisulfite treatment for
fixation of DNA
methylation



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

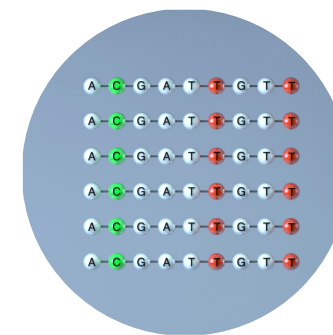
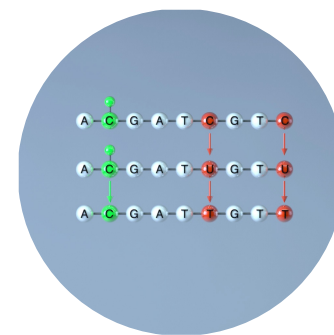
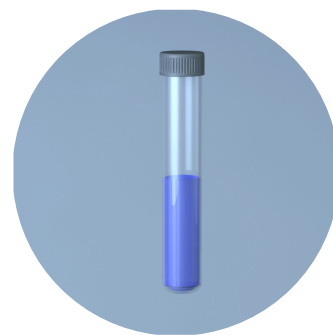


Data analysis:
Positive if at least a
proportion of
markers is positive



Workflow of QIASure Methylation Test

Epigenetic biomarker	Quality control marker
FAM19A4 hsa-mir124-2	ACTB



Patient sample:
PreservCyt
ThinPrep Media

Chemical pre-treatment:
Isolation of genomic DNA

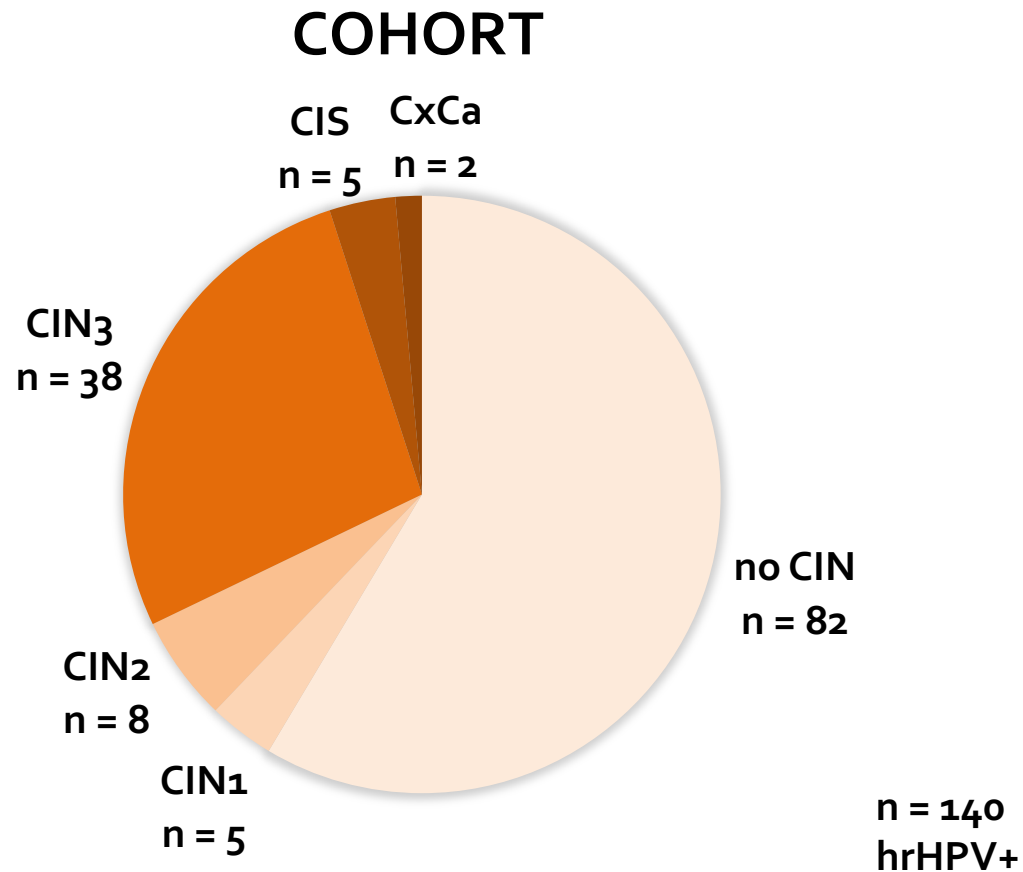
Chemical treatment:
Bisulfite treatment for fixation of DNA methylation

Analytical PCR:
Detection of 2 markers via real-time PCR

Data analysis:
Positive if one of the two markers is positive

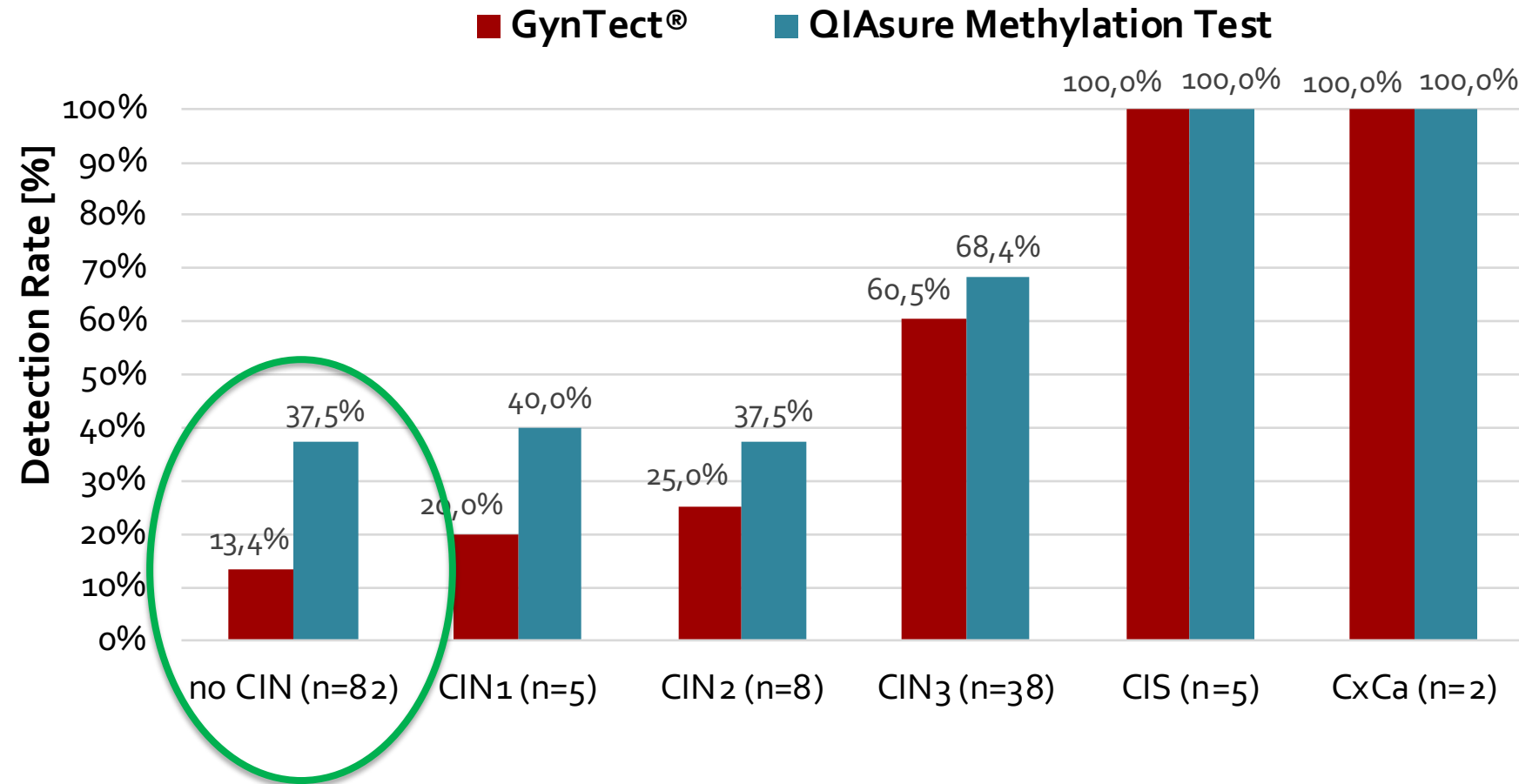


Comparative study: GynTect® | QIAzure Methylation Test

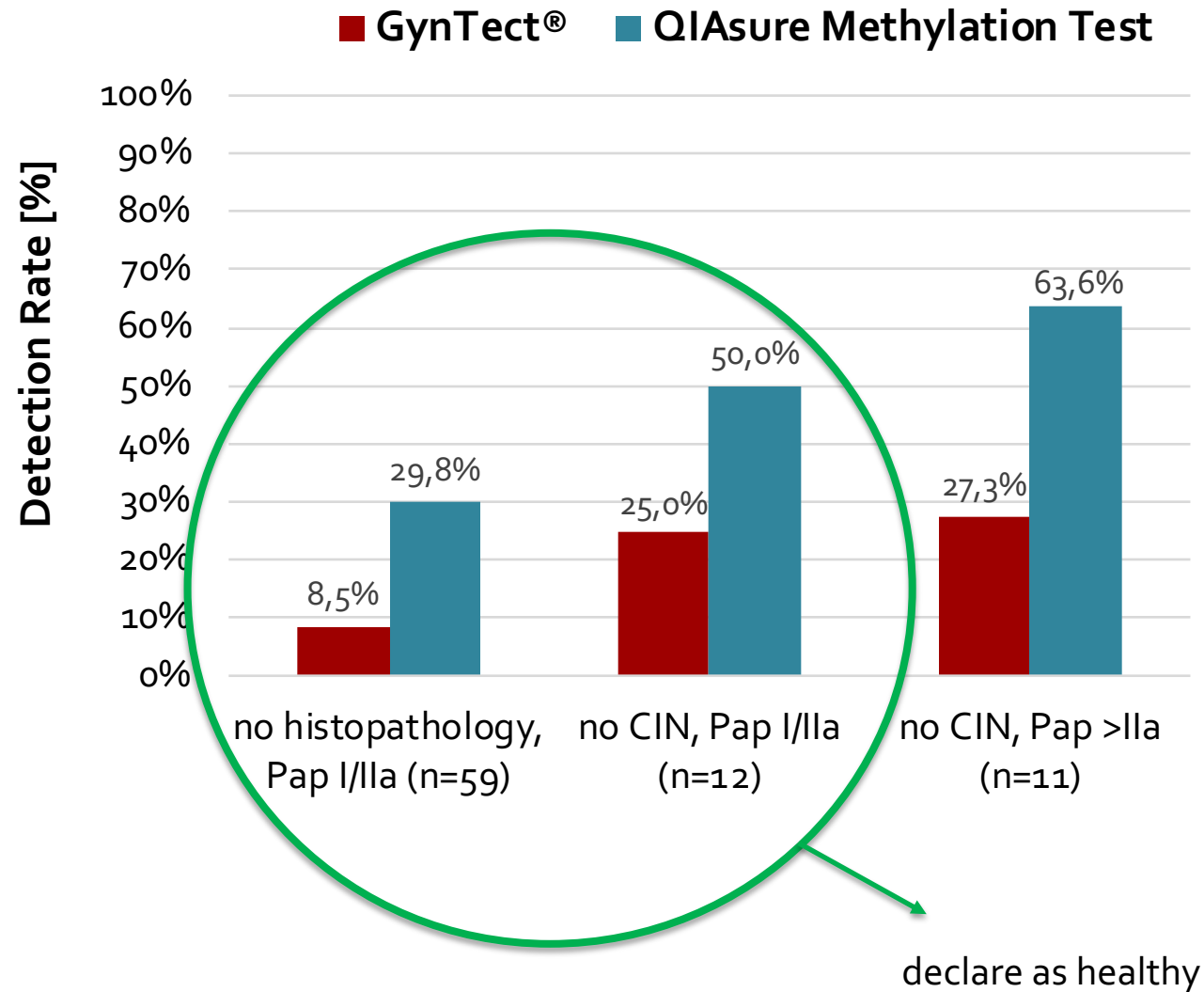


- Samples from the colposcopy clinic of the university hospital in Jena
- Cytology-based screening, retrospective study
- All CINs histopathologically confirmed
- All samples tested with GynTect® - IFU compliant
- All samples tested with QIAzure Methylation Test - IFU compliant

GynTest® | QIAzure Methylation Test detection rates



GynTect® | QIAzure Methylation Test detection rates



Comparison of both test systems

	GynTest®	QIAzure Methylation Test
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Sensitivity

CIN2+	60.4 %	67.9 %
CIN3+	66.7 %	73.3 %
Cancer	100 %	100 %

Specificity

CIN2+	88.2 %	66.2 %
CIN3+	86.9 %	65.9 %

CIN3+	GynTest®	QIAzure Methylation Test
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PPV	73.2 %	54.1 %
NPV	83.0 %	81.8 %

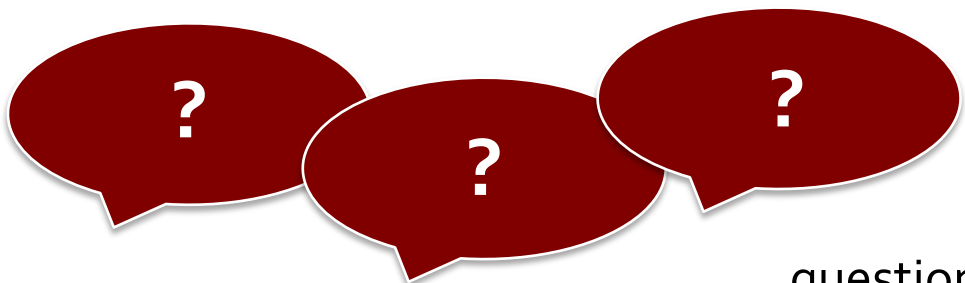


Thank you for your attention!



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... questions ?

