

Comparison between the Roche Cobas 4800, Abbott RealTime, Seegene Anyplex HPV28, and novel Seegene Allplex HPV28 assays for high-risk HPV detection and genotyping

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RATIONALE

150

Different HPV genotypes¹

250

Commercially available HPV assays²

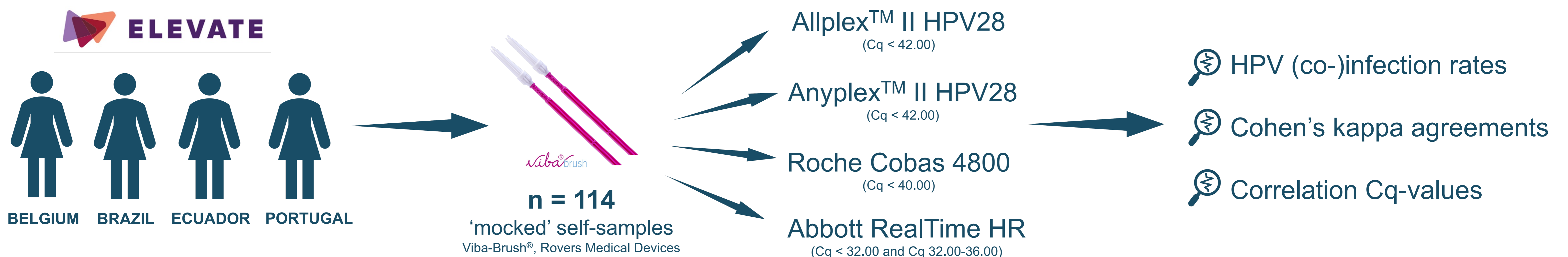
Comparison of novel with available HPV genotyping assays is essential

OBJECTIVE

The recently developed **Seegene Allplex™ II HPV28** assay is a novel qPCR HPV assay, designed to separately detect and quantify 28 distinct HPV genotypes with individual Ct-values.

Considering the importance of self-sampling within future screening programs, our study evaluated and compared the diagnostic performance of this novel **Seegene Allplex™ II HPV28** assay and those of the **Roche Cobas**, **Abbott RealTime** and **Seegene Anyplex™ II HPV28** assay for the use of mocked self-samples.

METHODS



RESULTS

Table 1. Positive, negative, and overall Kappa agreements between results of the four HPV assays

A. Using the Abbott RealTime manufacturer's Cq cutoff for positivity (< 32.00).

		Abbott RealTime	Anyplex™ 28	Allplex™ 28
Roche Cobas	Overall agreement (%)	85.9	95.6	95.6
	Negative agreement (%)	100.0	100.0	100.0
	Positive agreement (%)	84.9	95.3	95.3
	Kappa coefficient (95% CI)	0.42 (0.21-0.63)	0.74 (0.52-0.95)	0.74 (0.52-0.95)
Abbott RealTime	Overall agreement (%)		90.4	90.4
	Negative agreement (%)		100.0	100.0
	Positive agreement (%)		89.1	89.1
	Kappa coefficient (95% CI)		0.65 (0.47-0.84)	0.65 (0.47-0.84)
Anyplex™ 28	Overall agreement (%)			100.0
	Negative agreement (%)			100.0
	Positive agreement (%)			100.0
	Kappa coefficient (95% CI)			1.00 (1.00-1.00)

B. Using a less stringent Abbott RealTime Cq cutoff range for positivity (32.00 – 36.00).

		Abbott RealTime	Anyplex™ 28	Allplex™ 28
Roche Cobas	Overall agreement (%)	92.9	95.6	95.6
	Negative agreement (%)	100.0	100.0	100.0
	Positive agreement (%)	92.4	95.3	95.3
	Kappa coefficient (95% CI)	0.60 (0.37-0.83)	0.74 (0.52-0.95)	0.74 (0.52-0.95)
Abbott RealTime	Overall agreement (%)		96.5	96.5
	Negative agreement (%)		100.0	100.0
	Positive agreement (%)		96.0	96.0
	Kappa coefficient (95% CI)		0.85 (0.70-0.99)	0.85 (0.70-0.99)
Anyplex™ 28	Overall agreement (%)			100.0
	Negative agreement (%)			100.0
	Positive agreement (%)			100.0
	Kappa coefficient (95% CI)			1.00 (1.00-1.00)

High concordance between the four included qPCR HPV assays

Positivity rate
78.9% (Abbott) – 92.9% (Cobas)

Coinfection rate
4.7% (Cobas) – 6.9% (Anyplex)

Overall agreement
85.9% (Cq cutoff <32.00)
91.2% (Cq range 32.00-36.00)

Significant correlations
Cobas – Abbott: r = 0.71
Cobas – Allplex: r = 0.78
Abbott – Allplex: r = 0.73

References

¹Sousa H., Tavares A., Campos C., et al., *Papillomavirus Res.* 8, 100179, doi: 10.1016/j.pvr.2019.100179
²Poljak M. et al., *Clin Microbiol Infect.* 9, 1144-1150, doi: 10.1016/j.cmi.2020.03.033

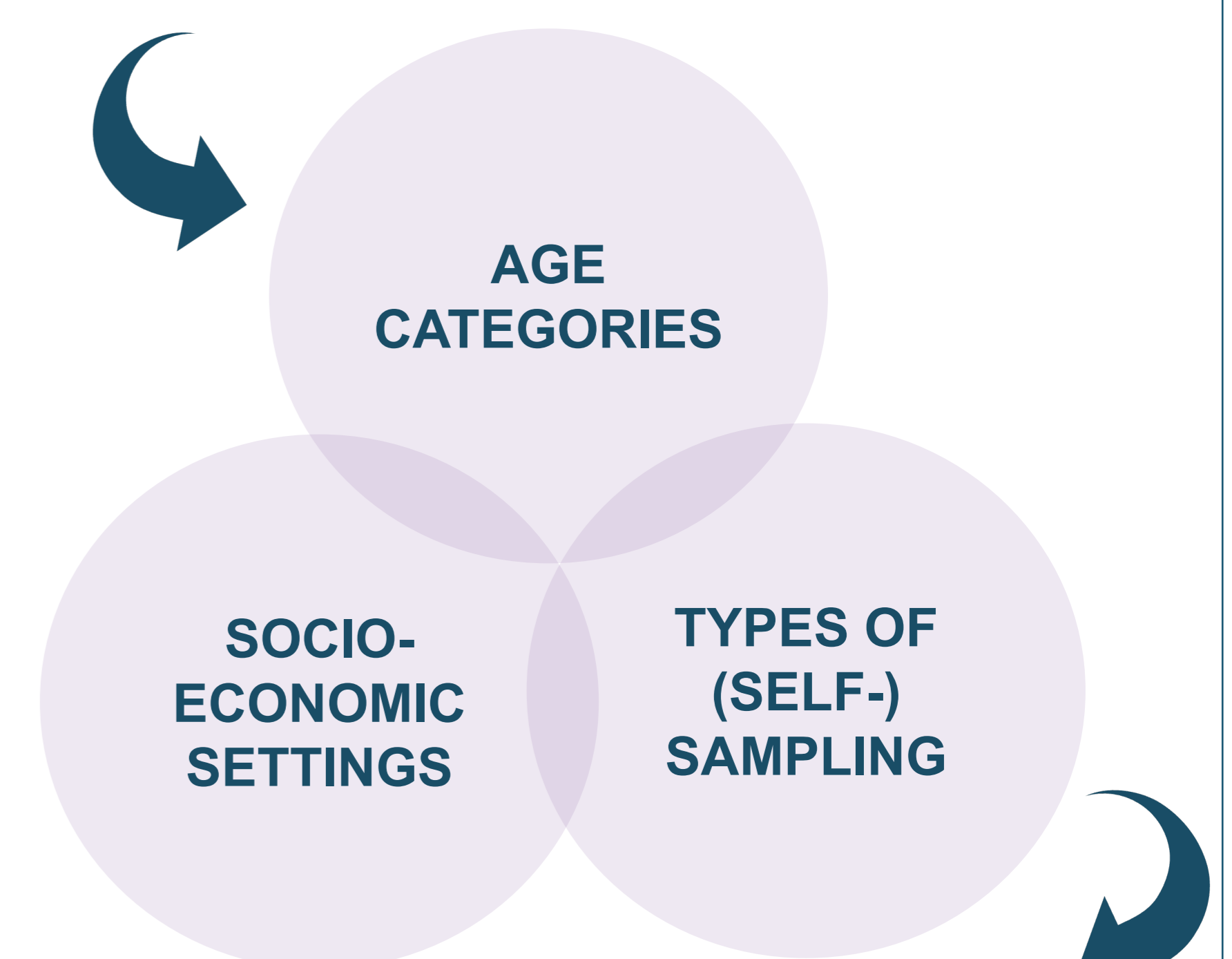
Acknowledgements & conflict of interest

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IMPACT

Considerable changes in agreements after adjustment Cq-cutoff Abbott RealTime assay

For research within specific:



Manufacturer's Cq-cutoffs of HPV assays, which are often validated and optimized for specific circumstances, should be handled with caution