

Analytical variation in factor VIII one-stage and chromogenic assays

Experiences from the ECAT external quality assessment programme

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(Mis)classification haemophilia A

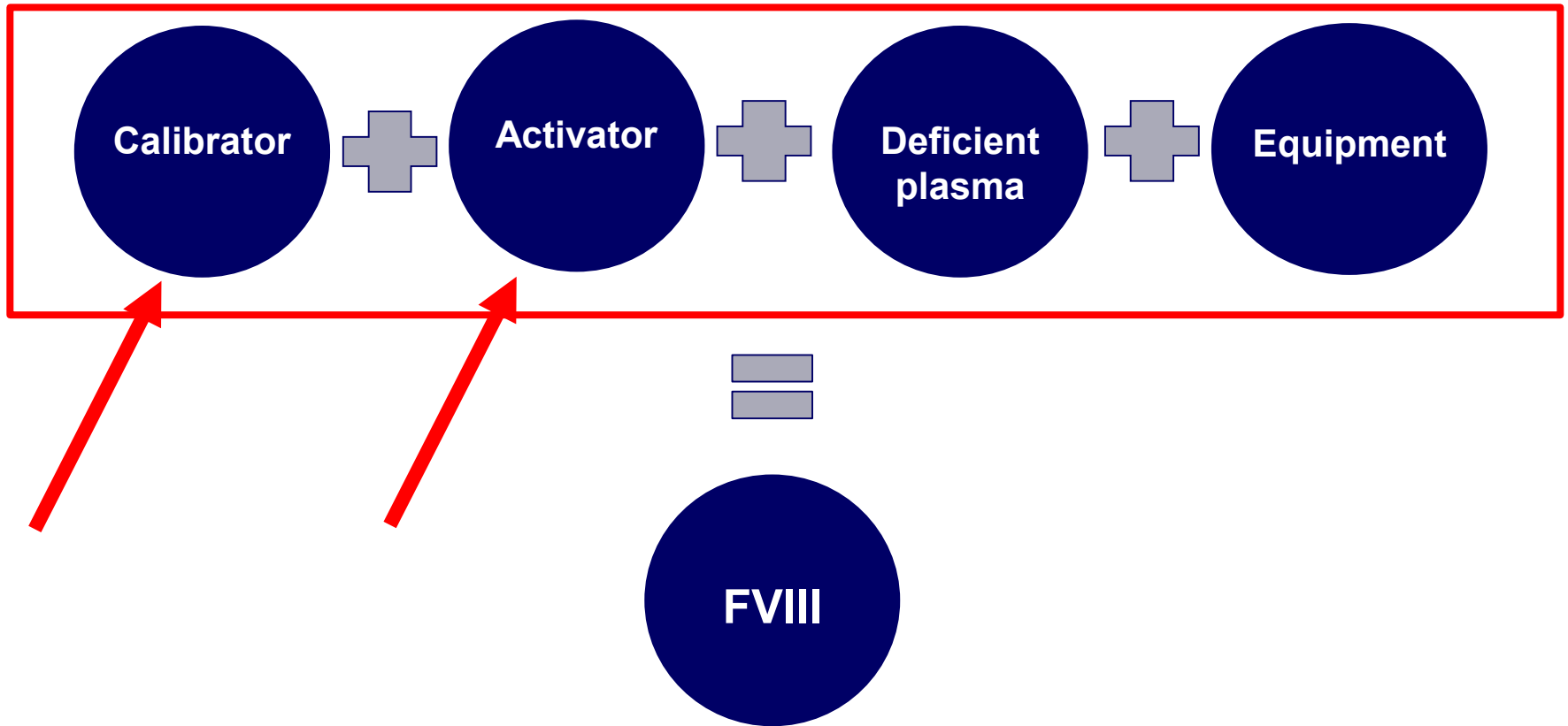


Aim

To investigate and quantify variation in FVIII activity

- 1) One-stage assay (OSA) and chromogenic substrate assay (CSA)
- 2) ECAT surveys

Test system



Test systems

SIEMENS



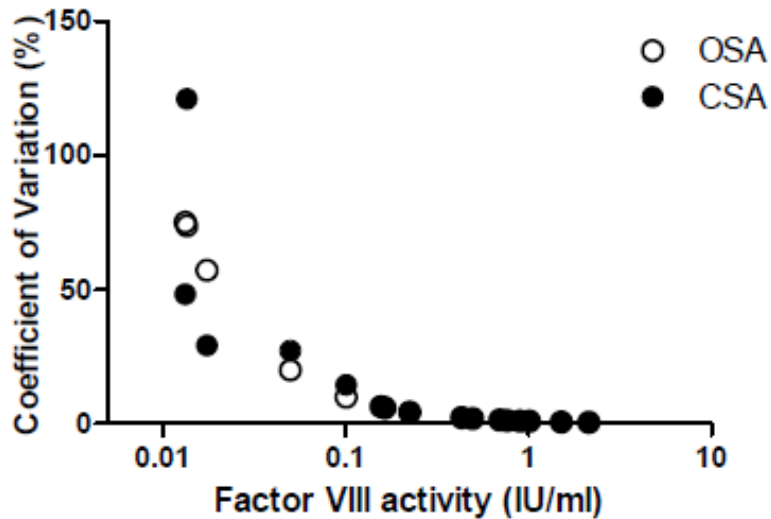
**Stago**

2010 - 2016

>10 laboratories

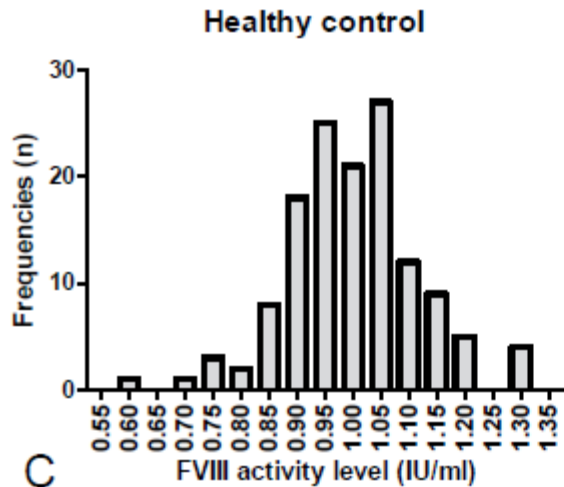
CV increases when FVIII decreases

A

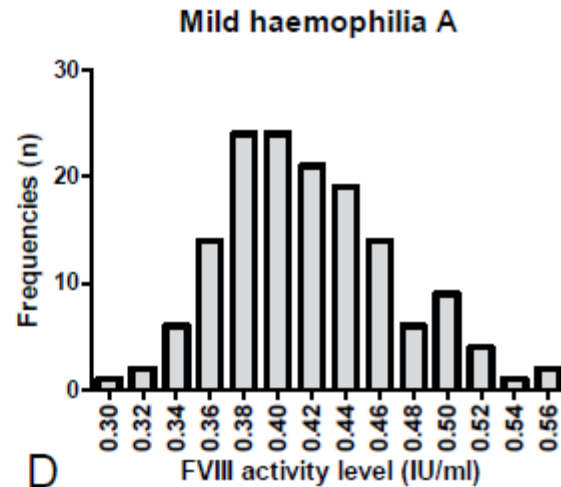


Variation in OSA results in misclassification (ECAT)

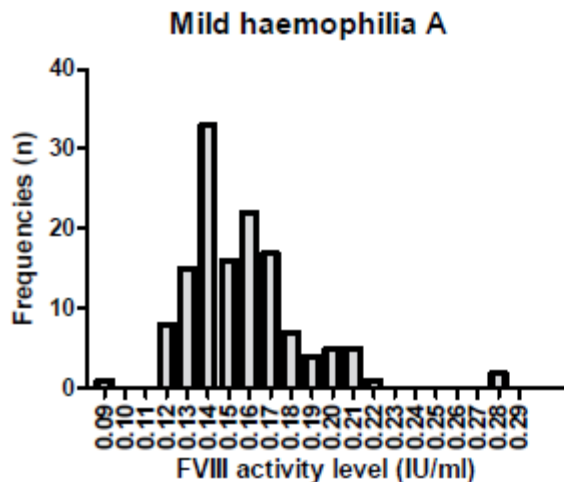
A



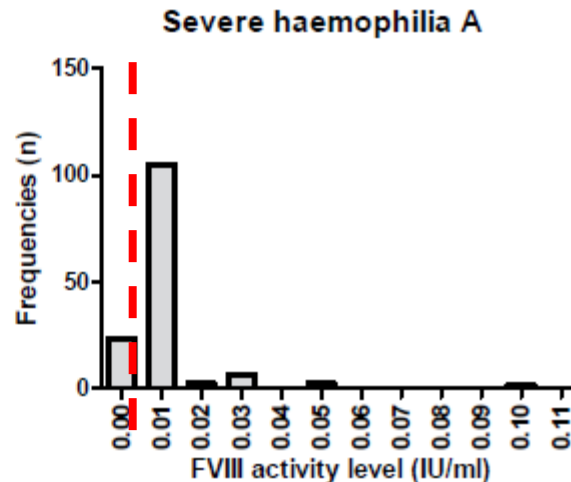
B



C



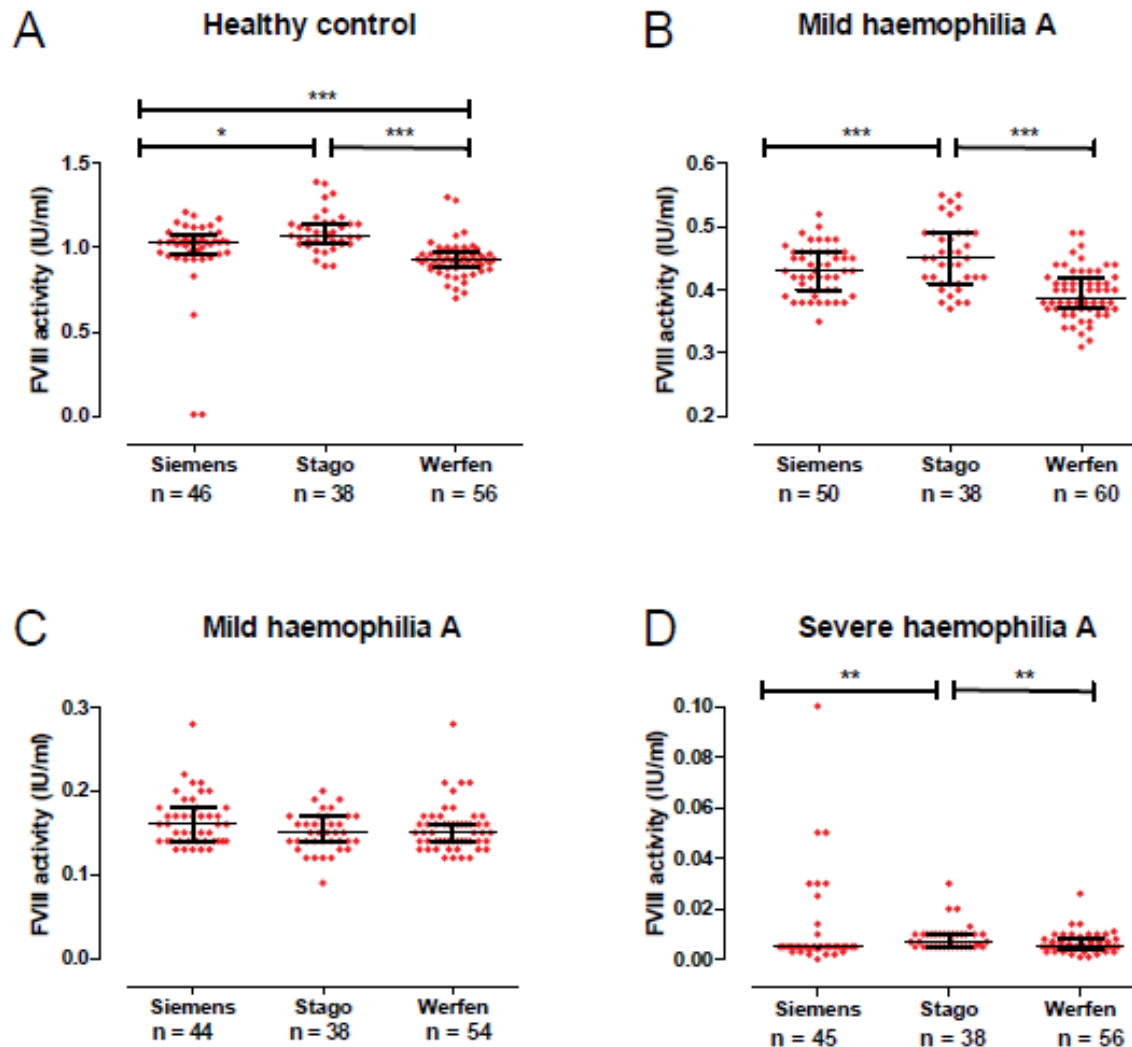
D



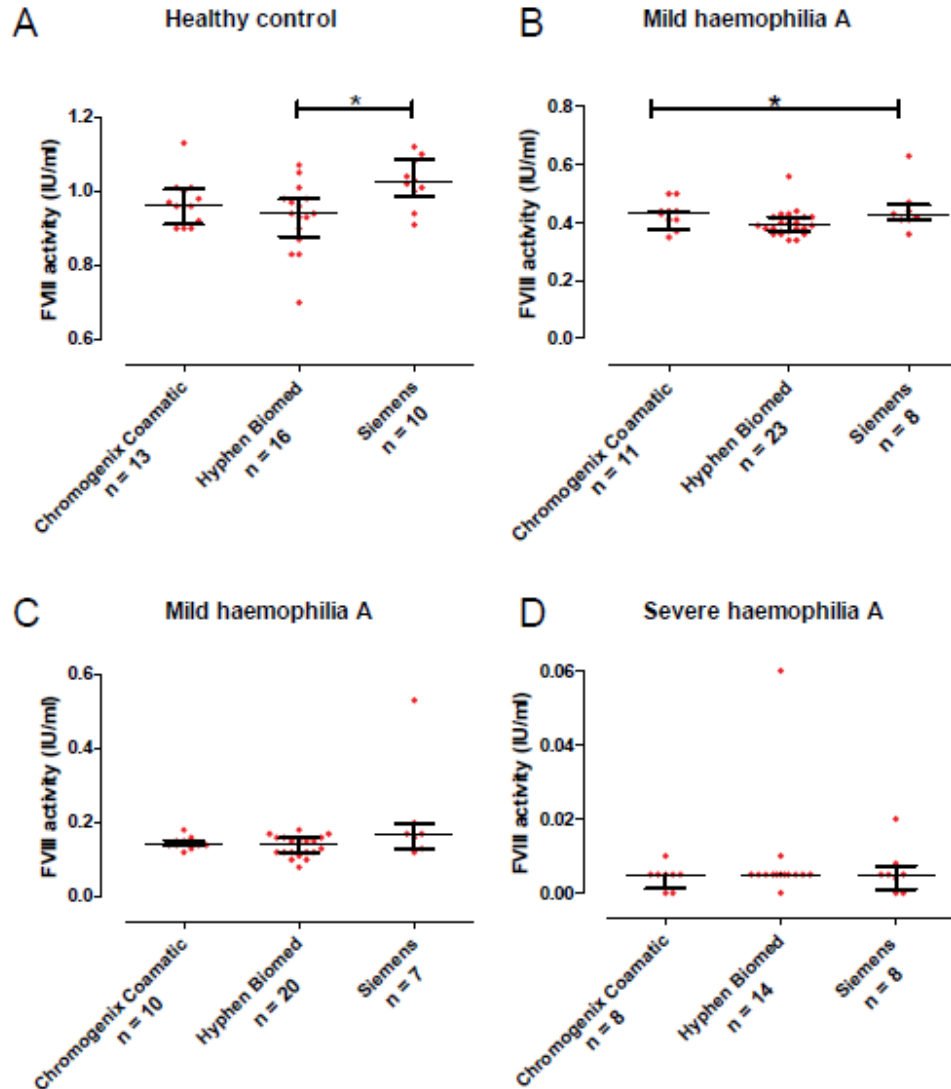
Misclassification

OSA 37/139 (26.6%)
CSA 4/30 (13.3%)

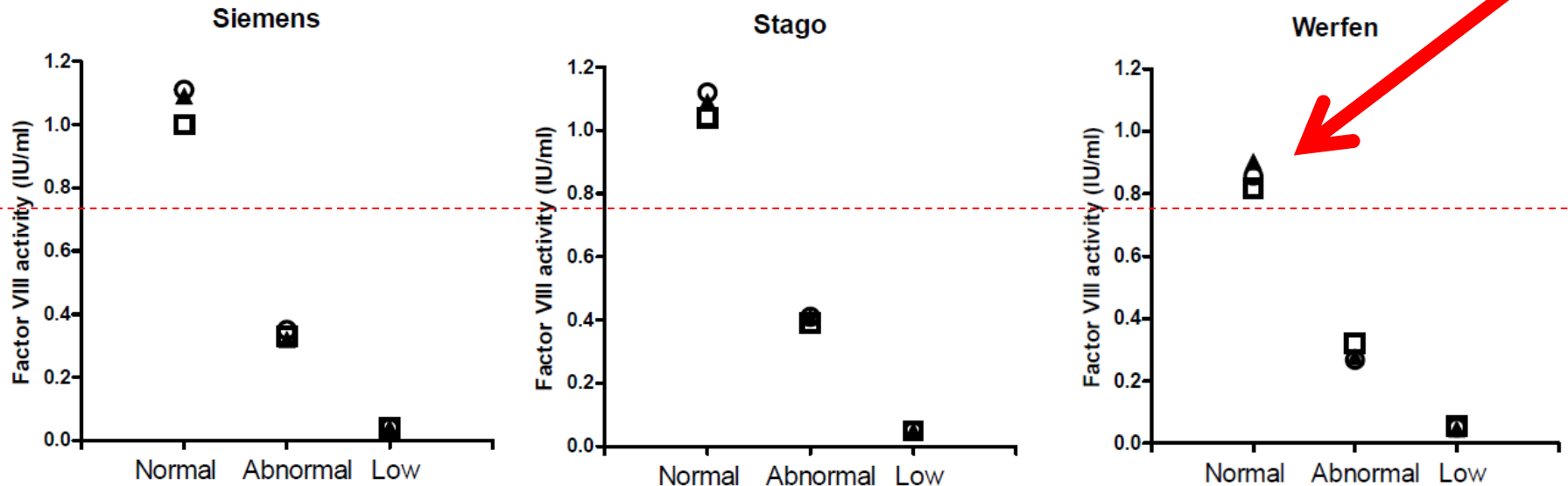
OSA – test systems companies



CSA – no consistent differences



Exchange deficient plasma in OSA



Deficient plasma

- Siemens
- Stago
- ▲ Werfen

Calibrator

	Assigned calibration value (IU/ml)	Measured FVIII value (IU/ml)
STA-Unicalibrator	1.10	1.21
HemosIL calibrator	0.98	1.12

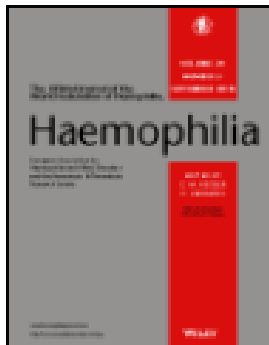
Underestimation in FVIII levels?

Conclusion

- FVIII activity levels are negatively associated with CV
- Variation results in misclassification in both CSA and OSA
- Variation in OSA

Company test systems

Calibrator



Haemophilia

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