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Clotting

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BACKGROUND

- Regulatory bodies recommend assessing the impact of steroid contraceptives on ETP-based APC resistance assay during their development.
- This assay was recently validated and standardized.

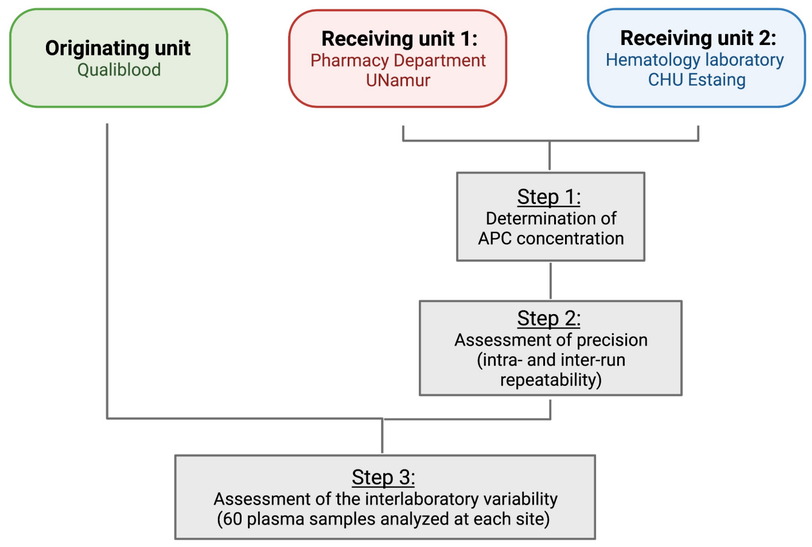
AIMS

To assess the inter-laboratory transferability of the ETP-based APC resistance assay.

METHODS

The study scheme is described in **figure 1**

Figure 1:
Study scheme for the transferability of the ETP-based APC resistance assay



RESULTS

- APC concentration was defined at 1.21 µg/mL and 1.14 µg/mL in receiving unit 1 and receiving unit 2 respectively.
- Intra- and inter-run (**Table 1**) repeatability showed SD below 3% in both receiving units.
- Spearman correlation showed effective pairing between the originating and the receiving units (**Figure 2**).
- The sensitivity of the test was maintained and subgroups analysis still reported significant differences between healthy individuals and women using combined oral contraceptives (**Figure 3**).

SUMMARY/CONCLUSION

- Excellent intra-laboratory precision and inter-laboratory reproducibility.
- The normalized APC sensitivity ratio obtained with this validated methodology, provides an appropriate sensitivity irrespective of the laboratory in which the analysis is performed.

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Table 1: Intra-run (N=5) and inter-run (N=3) repeatability (N=5) of the commercial reference plasma and the 3 quality controls. Results are expressed as mean inhibition % ± SD

Tested plasma	Intra-run repeatability		Inter-run repeatability	
	Unit 1	Unit 2	Unit 1	Unit 2
Reference plasma	78.8% ±0.4%	75.3% ±1.2%	80.9% ±01.9%	78.5% ±1.2%
QC low	100.0% ± 0.0%	100.0% ±0.0%	100.0% ± 0.0%	97.9% ±1.9%
QC intermediate	40.2% ± 0.7%	37.7% ±0.9%	42.8% ± 2.6%	39.6% ±2.3%
QC high	2.8% ± 0.7%	4.0% ±1.5%	5.0% ± 2.3%	6.0% ±2.1%

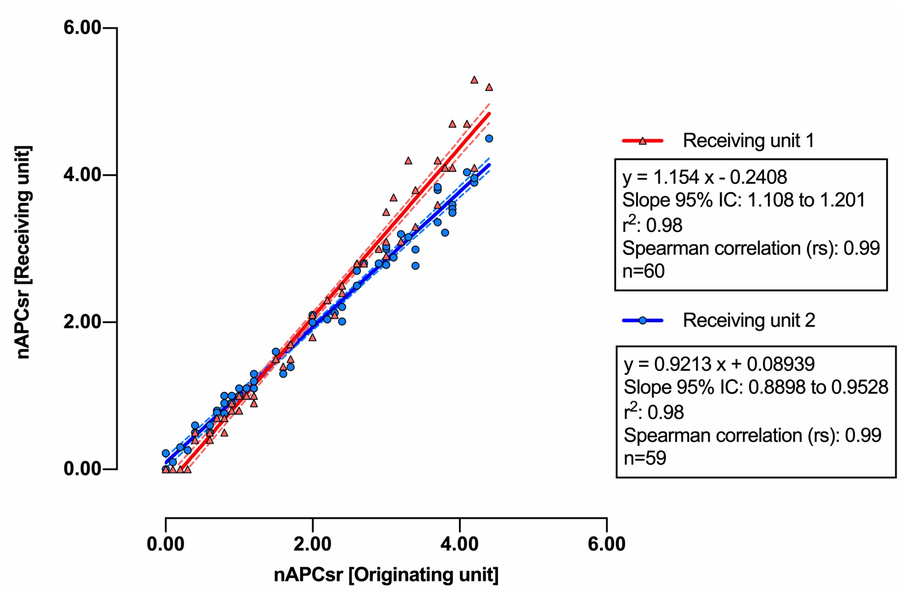

Figure 2:
Correlation between normalized APC sensitivity ratio (nAPCsr) obtained at the receiving units and nAPCsr obtained at the originating unit.

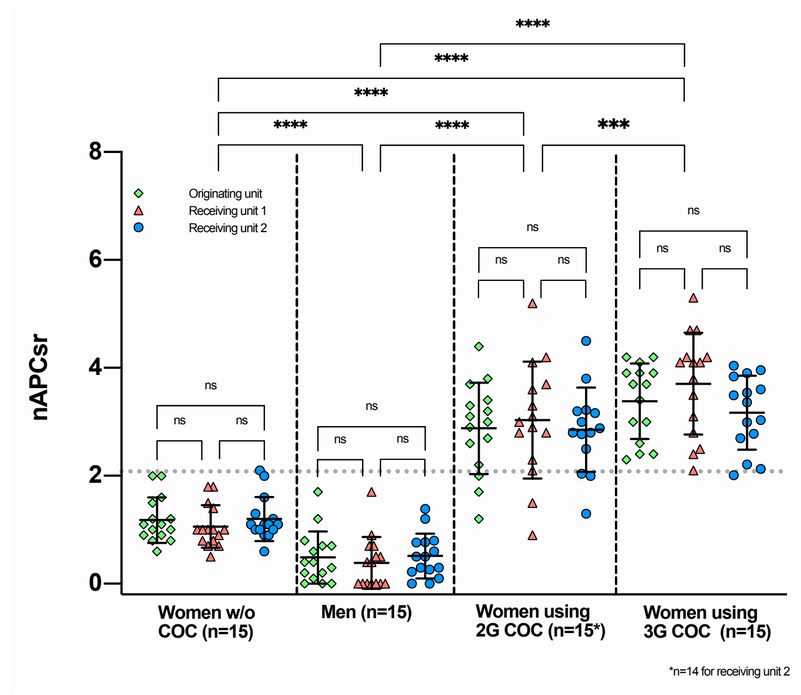

Figure 3: Normalized APC sensitivity ratio (nAPCsr) values of individuals from each subgroup (i.e., women without combined oral contraceptive (COC), men, women using 2nd generation (2G) COC and women using 3rd generation (3G) COC obtained at the different units.