

## RESEARCH OUTPUTS / RÉSULTATS DE RECHERCHE

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# Inter-laboratory variability of the standardized ETP-based APC resistance assay



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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.

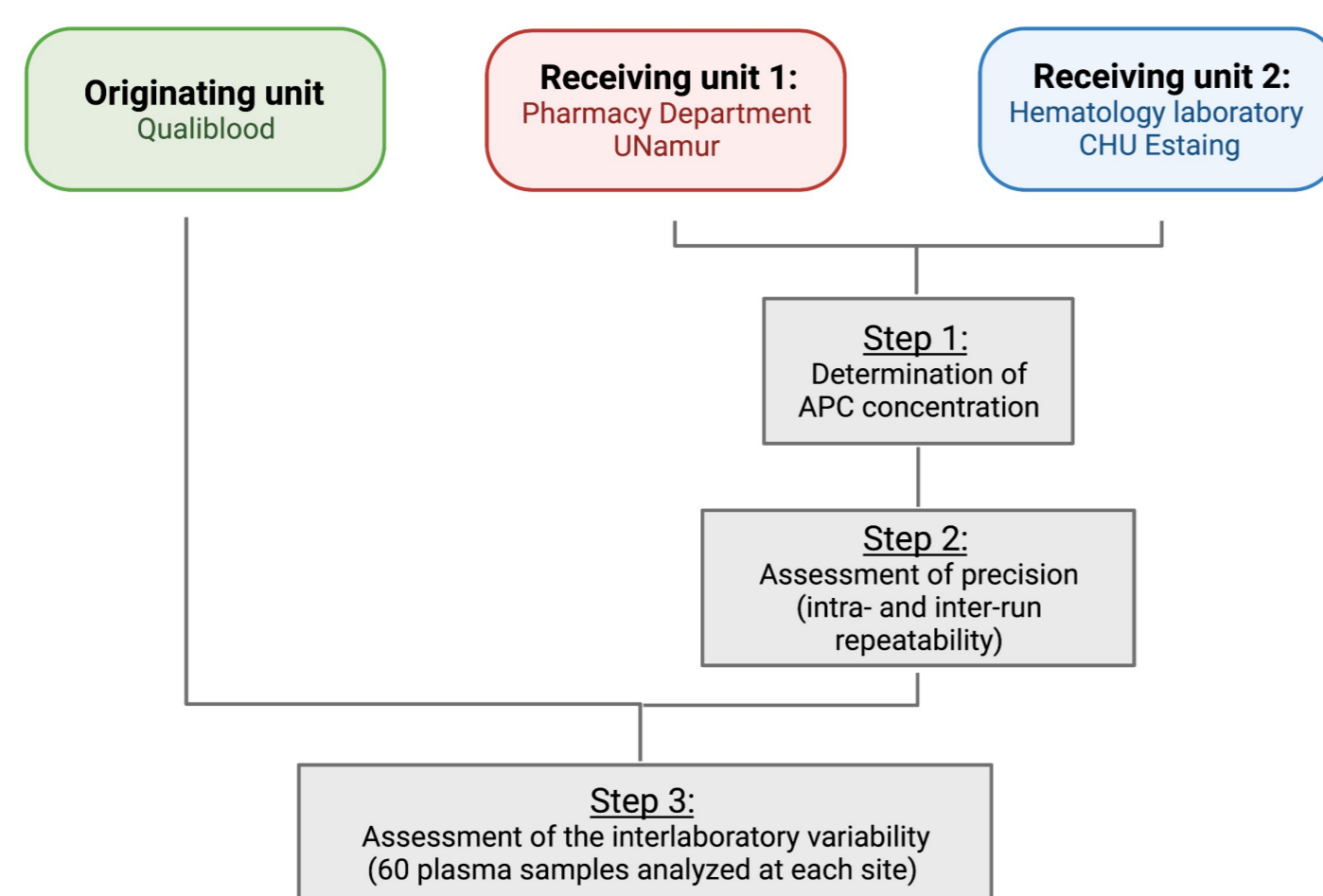
## AIMS

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

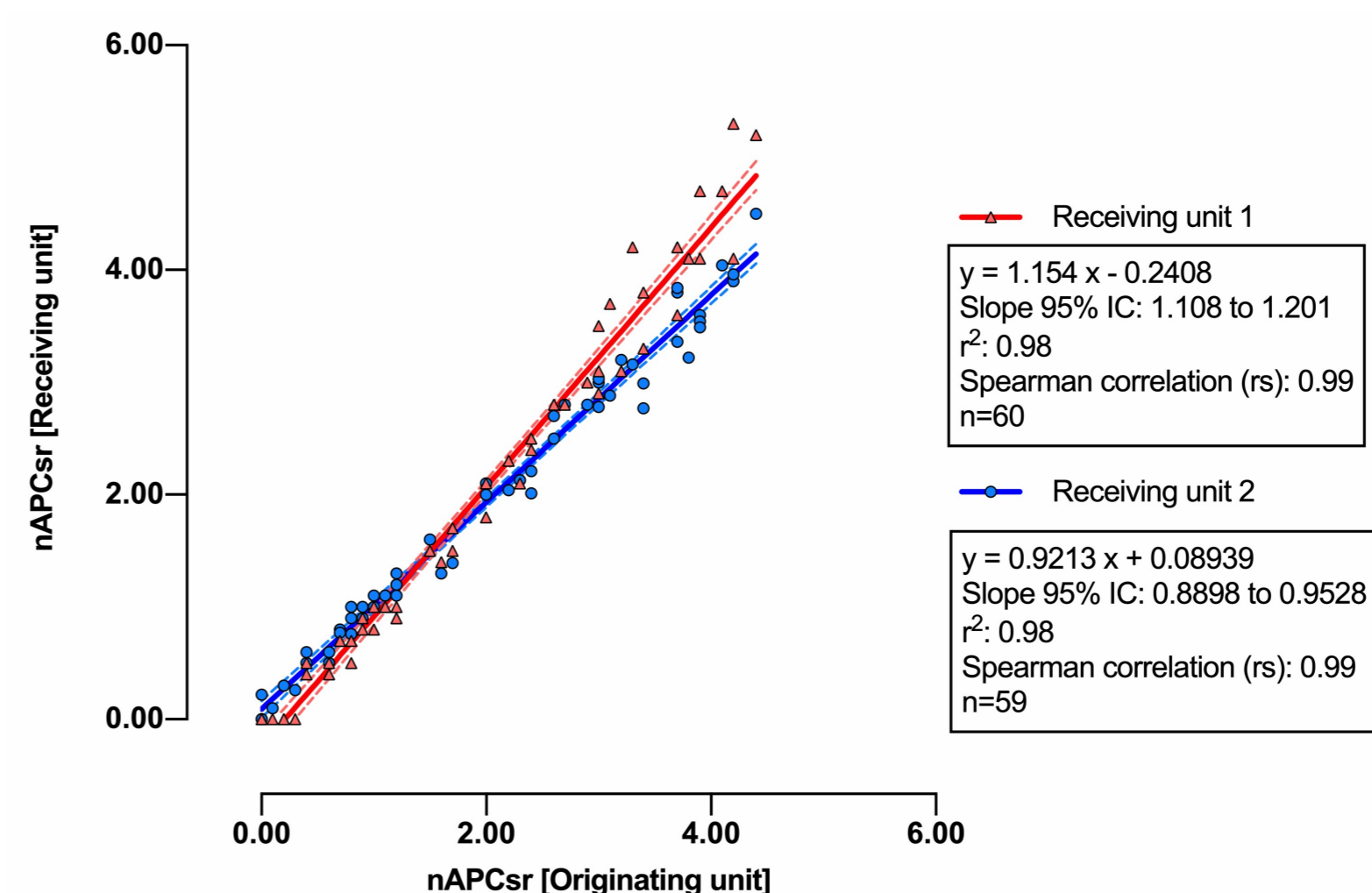
- APC concentration was defined at 1.21 µg/mL and 1.14 µg/mL in receiving unit 1 and receiving unit 2 respectively.
- Intra- and inter-run (**Table 1**) repeatability showed SD below 3% in both receiving units.
- Spearman correlation showed effective pairing between the originating and the receiving 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

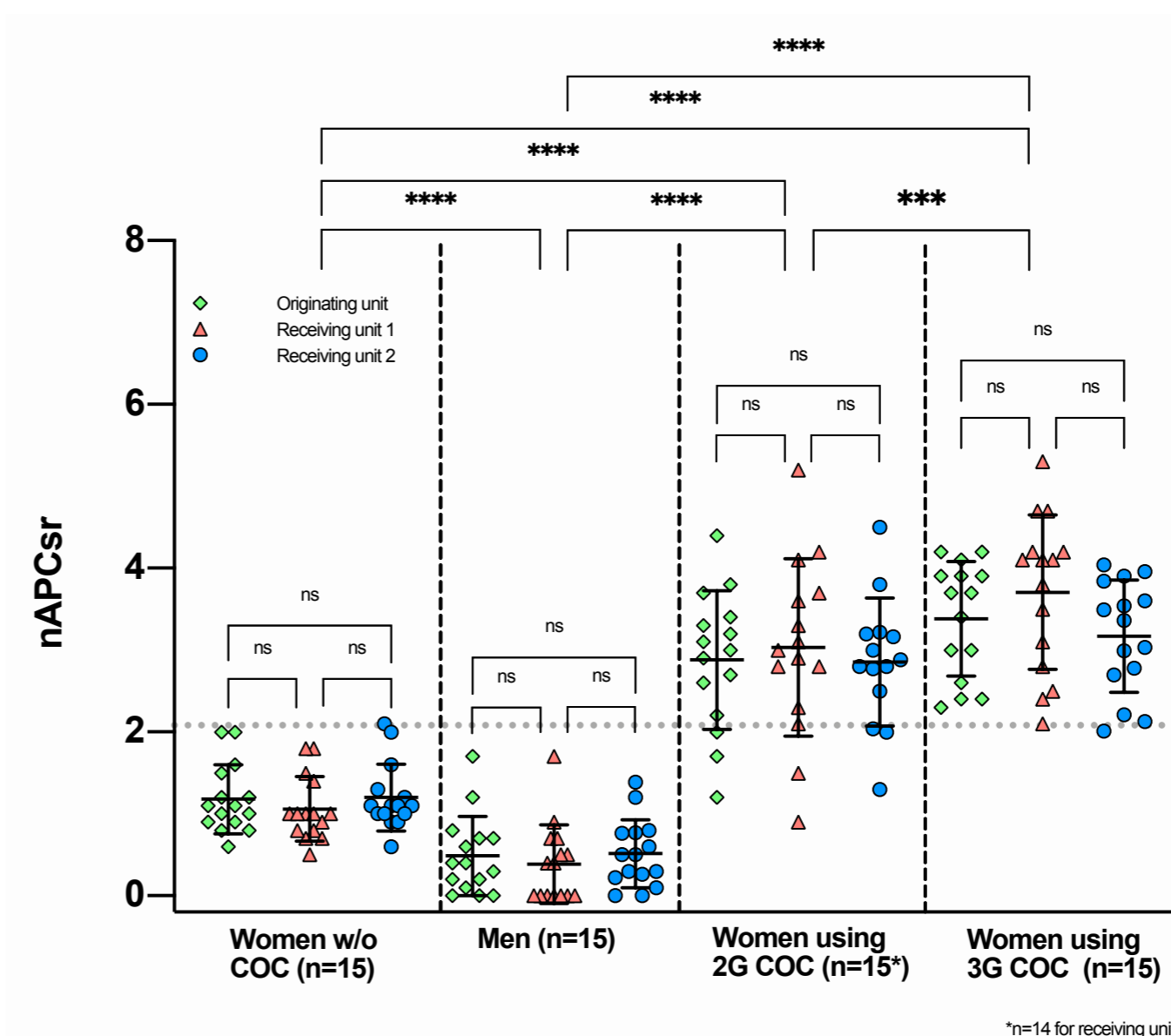
- Excellent intra-laboratory precision and inter-laboratory reproducibility.
- The normalized APC sensitivity ratio obtained with this validated methodology, provides an appropriate sensitivity irrespective of the laboratory in which the analysis is performed.

**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 2<sup>nd</sup> generation (2G) COC and women using 3<sup>rd</sup> generation (3G) COC obtained at the different units.