



Evaluation of two new anti-Müllerian hormone (AMH) assays for the investigation of disorders of sexual development in neonates

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Background

- Anti-Müllerian hormone (AMH) inhibits the *in utero* growth of the Müllerian structures in female fetuses.
- In neonates with suspected disorders of sexual development (DSDs), the presence of testicular tissues and functioning Sertoli cells can be investigated by measuring serum AMH concentration.

Objective

- To evaluate the performance of two new, automated AMH assays within a hospital laboratory setting.

Method

- The technical performance of two new assays for AMH (Beckman Coulter and Roche) was evaluated and compared with each other using standard laboratory protocols.
- Serum AMH concentrations were measured in 44 neonates (24 females & 20 males) with no suspected DSDs.

Results

- AMH results generated by the two assays were highly comparable (Pearson correlation coefficient = 0.966; Figure 1).
- Both assays were linear within their reportable ranges.
- Precision studies showed that coefficients of variation (CVs) at the limits of quantitation (LOQ) were <7%.
- All AMH concentrations measured in the male and female neonates were within their respective reference intervals provided by one of the manufacturers (Table 1).

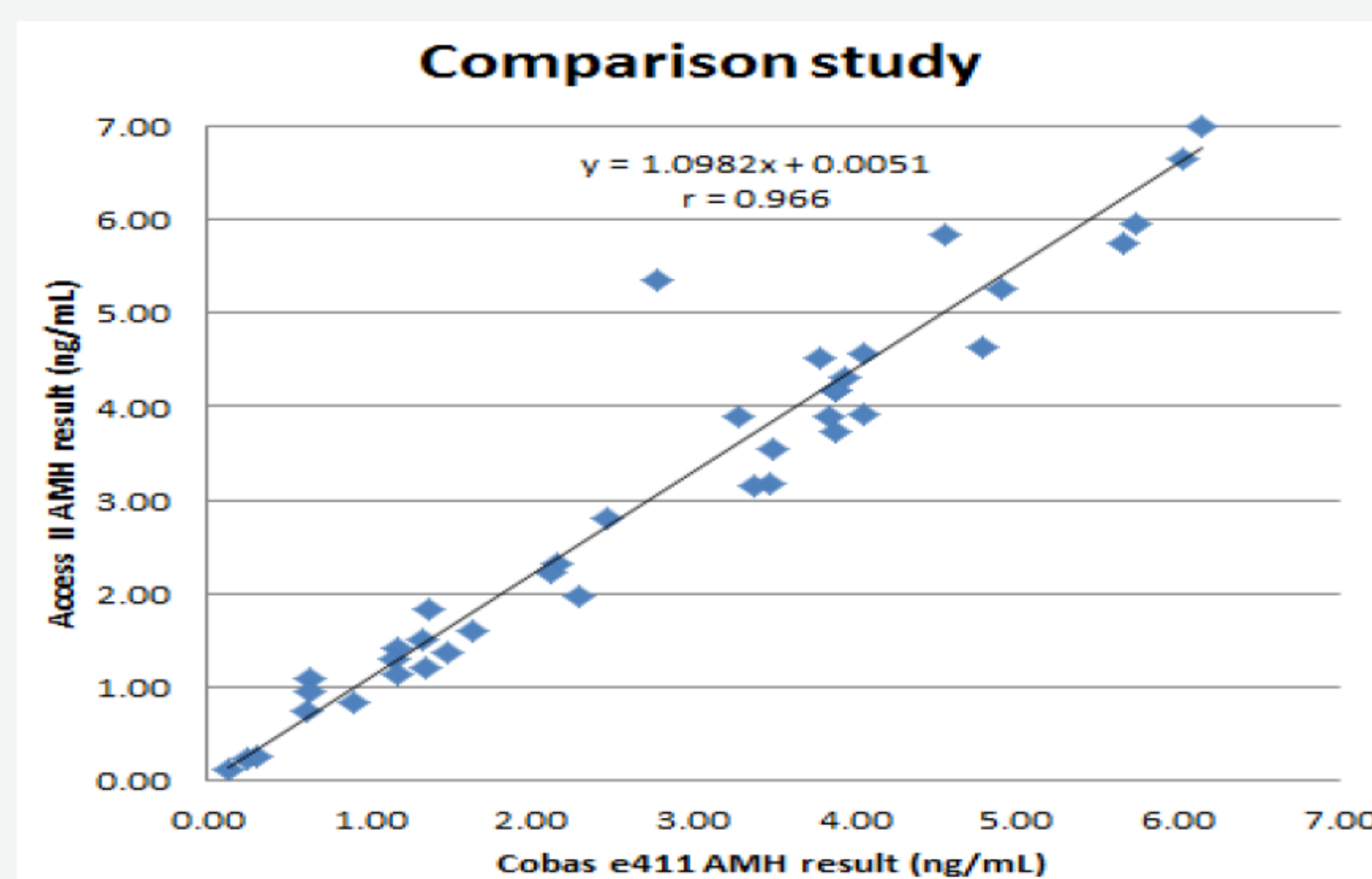


Figure 1: Comparison of two AMH assays

| | Mean age (days) | Age range (days) | N | Mean±SD [AMH] (ng/ml) | Range of [AMH] (ng/ml) | [AMH] reference interval from manufacturer (ng/ml) |
|----------------|-----------------|------------------|----|-----------------------|------------------------|--|
| Females | 5.9 | 0 to 29 | 24 | 0.22 ±0.47 | 0.02 to 2.28 | 0.01 to 3.39 |
| Males | 11.7 | 0 to 30 | 20 | 70.5 ±48.7 | 15.5 to 157.6 | 15.11 to 266.59 |

Table 1: Serum AMH concentrations (using the Beckman Access II platform) in neonates

Conclusion

- Serum AMH concentrations in the two gender groups of neonates (without DSDs) do not overlap with each other.
- Both AMH assays are analytically sensitive enough to be used in neonates for the investigation of DSDs.
- Differential AMH concentrations in male and female neonates render this test a useful tool for the investigation of DSDs.

