First fully automated immunoassay for Anti-Mullerian Hormone (AMH) on the cobas e analyzers

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1. Abstract

The Anti-Mullerian Hormone (AMH) gained importance in the assessment of ovarian reserve in women. So far, only manual AMH assays are available to determine the AMH level in serum. However, conflicting results were observed in some cases, raising the question to the assay’s reliability.

Methods: Development of a high-sensitive, fast and fully automated AMH assay on the cobas e analyzers.

Results: cobas e AMH is an immunoassay using two AMH specific antibodies in a sandwich format to measure the hormone in serum or lithium heparin plasma. Primarily the 146 kD total AMH (pAMH and AMHLC) is detected. 50 μL of sample volume is mixed with the AMH reagent on the fully automated analysis platform, and the quantitative result is available after approximately 18 min. The assay is standardized against Beckman AMH Gen II and covers a measuring range from 0.01 to 23 ng/mL. The overall recovery against the Immunotech calibration reagents ranged from 1.0 to 2.2 % and 1.5 to 2.8 % respectively. LoD (LoQ) was about 90 %.

2. - Elecsys® AMH – Test principle

Assay principle
Sandwich immunoassay, using Beckman Coulter Gen II anti-AMH antibodies.

Sample volume
50 μL.

Linearity
Elecsys® AMH Gen II (modified version) (ng/mL)

6 - Method comparison

Sample Repeatability Intermediate precision

SD CV % (UCL95 %) SD CV % (UCL95 %)

Conc (ng/mL) 7 days @ 20 – 25 °C 7 days @ 2 – 4 °C 9 months @ – 20 °C

HS 02 0.448 0.008 1.7 (2.2) 0.009 1.9 (2.3)
HS 04 1.05 0.014 1.3 (1.7) 0.019 1.8 (2.2)
HS 05 1.98 0.026 1.3 (1.6) 0.032 1.6 (2.0)
HS 07 4.07 0.047 1.2 (1.6) 0.067 1.6 (2.0)
HS 08 6.86 0.096 1.4 (1.8) 0.116 1.7 (2.0)
HS 11 11.7 0.183 1.1 (1.4) 0.254 1.5 (1.9)
HS 12 15.0 0.265 1.4 (1.8) 0.281 1.5 (1.8)
HS 13 19.0 0.265 1.4 (1.8) 0.281 1.5 (1.8)
HS 14 34.1 0.497 1.2 (1.6) 0.716 1.6 (2.0)
HS 15 55.9 0.811 1.1 (1.4) 1.384 1.5 (1.9)
HS 16 72.0 1.00 1.0 (1.3) 1.748 1.4 (1.7)

7 – Linearity

AMH target values (ng/mL)

AMH measured values (ng/mL)

8 – Precision data cobas e A11

Conclusions: The fully automated Elecsys® AMH immunoassay run on routine cobas e instruments demonstrated an excellent precision with a high sensitivity. Even though the Elecsys® assay uses the same antibodies as the Beckman Coulter Gen II, complement interference was not observed. The unique assay format uses free IgG, which is not prone to complement binding.

As a consequence, the availability of the fully automated Elecsys® AMH assay will represent a fast and precise alternative to manual AMH assay testing.

Reference: Gassner et al., Clin Chem Lab Med 2014; (ahead of print)