ABSTRACT: CORRELATION OF FACTORS AFFECTING THE AMH NORMAL RANGE FOR WOMEN IN THE REPRODUCTIVE YEARS

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BACKGROUND: AMH has important functions for both male and female reproductive organ development. After puberty, when menstrual cycling begins, AMH slowly decreases throughout life until it becomes undetectable at menopause. AMH is produced in the primary, secondary, tertiary follicles. In conjunction with FSH and Age, it is the most used marker for estimating ovarian reserve. Unilab of Dade is a private laboratory dedicated to reproductive medicine. Procedures used for patient diagnosis are first validated and then verified periodically for linearity, normal range, specimen requirement and additional parameters that may be deemed necessary by our Director or clinicians. This study evaluated 900 orders received for AMH levels during 2008. The following conditions were analyzed:

1. Specimen Stability
2. Validity of the calculated normal range
3. AMH levels vs. Age
4. AMH levels vs. FSH
5. AMH level and incidence of pregnancy

METHOD: Subjects were screened for AMH levels using the Diagnostics Systems Laboratories (DSL) ACTIVE® MIS/AMH ELISA procedure. This is an enzymatically amplified two-site immunoassay. Patient samples received were tested and used for the calculated ranges. Patients that were followed in treatment towards pregnancy were used in the physiological range. Three age groups were evaluated: 18-30 years, 31-36 years, and 37-50 years. These samples were evaluated for Normal Range, Age, FSH, and Pregnancy correlation.

RESULTS:
1. Sample Stability according to the insert range is 24 hours at 2-8°C. Stability was expanded to seventy-two hours at ambient temperature with less than 1% decay.
2. The normal estimated range was first calculated for each age group by determining a Mean and 2 Standard Deviations for results obtained between <0.05 - 5.0 ng/mL.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Mean Low Limit</th>
<th>High Limit</th>
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<tbody>
<tr>
<td>18-30</td>
<td>2.53 ± 1.27</td>
<td>0.021 - 5.0</td>
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<tr>
<td>31-36</td>
<td>1.85 ± 1.25</td>
<td>0.015 - 4.35</td>
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<tr>
<td>37-50</td>
<td>1.17 ± 1.15</td>
<td>0.006 - 3.47</td>
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3. Physiological range was obtained by determining the AMH level detected for each group with patients resulting in an elevated HCG.

4. Additional relationships:
   A. AMH vs. AGE
   B. AMH vs. FSH
   C. None detectable levels of AMH

CONCLUSIONS:
1. Normal levels of AMH correlate with age and FSH.
2. Age Group 18-30 years: AMH levels of 0.5-5.0 ng/mL correlate well with FSH values of 0.1-8.0 mIU/mL.
3. Age Group 31-36 years: Incidence of higher FSH values begins to increase with lower AMH counterparts.
4. Age group 37-50 years: Shift of FSH to higher ranges with large percent in abnormal range. AMH values continue to decrease with a high percent of Non-Detectable levels noted.
5. AMH Non-Detectable may be inducible towards pregnancy as occurred in two cases of this study.

THERAL OUTLINE:
1. To verify sample stability for increased transportation time.
2. To validate AMH as a measurement of ovarian reserve.
3. Compare in vivo vs. in vitro results after stimulation.
4. Validation of the AMH normal range.

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