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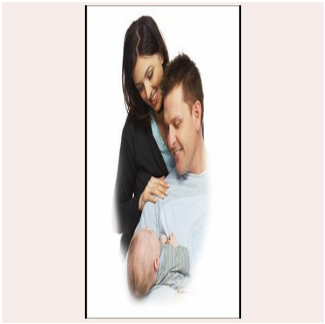
Automated AMH Given CE Mark Approval



Beckman Coulter Diagnostics' automated Anti-Müllerian Hormone test available to improve fertility assessment and treatment. Company brings innovation to women's health with new assay to measure and predict ovarian response and reserve.

Beckman Coulter Diagnostics has obtained CE Mark on its new automated Access anti-Müllerian hormone (AMH) assay. The new test is the company's latest innovation in women's health testing and further advances Beckman Coulter's rich 15-year history and experience in supporting global fertility assessment and treatment.

The Access AMH assay brings automation and convenience to Beckman Coulter's established AMH tests, which include the AMH Gen II ELISA assay and the Immunotech EIA AMH/MIS assay. The company's AMH assays have become the industry standard since the first commercial AMH assay was introduced in 1999, as evidenced by more than 2,000 scientific articles and publications. Importantly, Access AMH is the only automated assay having excellent correlation to AMH Gen II, providing laboratories and physicians with convenient results that are consistent with current test values and published literature.

"The automated Access AMH will deliver increased sensitivity and precision, providing more reliable results for our patients, with absolute values with which we are familiar," said Prof. Richard Fleming, director at the Glasgow Centre for Reproductive Medicine Ltd.

Access AMH improves test accuracy by combining the proven AMH Gen II antibodies with calibrators using recombinant human AMH to provide a direct comparison to human patient samples.

"Beckman Coulter's automated AMH test is an important addition to our reproductive endocrinology testing menu, which includes a complete line of assays for evaluating women's health," said John Blackwood, senior vice president of Beckman Coulter's Chemistry/Immunoassay business unit. "AMH has proven to be one of the most significant new markers in reproductive endocrinology in the last 10 years. The innovation Beckman Coulter brings to AMH testing demonstrates our commitment to partnering with physicians and laboratories to continuously develop and improve our assays to transform patient care."

The Access AMH assay features:

- Convenient transition to automated testing through consistent and standardised results with Beckman Coulter's AMH Gen II assay
- Improved support of fertility assessment through increased sensitivity and precision at the low end of the analytical measuring range
- Improved accuracy of patient results from calibrators prepared with recombinant human AMH
- Efficient and cost-effective results with less technician handling time and increased ease of use compared to manual assays
- Speed and flexibility through fully automated instrumentation
- Increased stability from lyophilised calibrators

The Access AMH assay is now available on Beckman Coulter's Access 2 immunoassay system in Europe and other select markets. The assay will be available on all Beckman Coulter immunoassay systems in Q4 of 2014. Beckman Coulter will continue to offer the AMH Gen II and IOT AMH assays along with its new automated AMH assay.
Source: Beckman Coulter Diagnostics

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