One Blood Drop to New Hope: A Novel Test Method To Improve Fertility Assessment

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At-home blood collection, such as the dried blood spots for fertility workups has been challenging due to low circulating Anti-Mullerian Hormone (AMH) concentrations and dependence on trained personnel for reliable blood sample collection. AMH is a hormone produced by small-growing antral follicles (AFC) in the ovary and has been suggested to provide a snapshot of a woman's reproductive potential. This study aimed to develop and validate an AMH blood test using dried matrix micro samples (DMMS), a novel technique that allows continuous absorption of a single blood drop. This DMMS AMH test is convenient, cost-effective, accessible, and can help assess women's fertility at an early stage. Diagnosing poor responders (=5AFC,POI) will help avoid repeated IVF cycles and diagnosing hyper responders (>40AFC,PCOS) will help avoid ovarian hyper-stimulation. In addition, this test can help breast cancer subjects in assessing their fertility potential before and after estrogen treatment. AMH measurements from DMMS are reproducible (<8%CV), accurate (no cross-reactivity to FSH, LH, Inhibin B and Estradiol) with non-significant interference to hematocrit (dilutes linearly, y=0.98x). DMMS AMH measurements strongly correlate to plasma AMH levels (rs=0.996) and have a slope of 0.66. DMMS AMH concentrations with 0.66 factor can be reported to plasma equivalents. DMMS AMH measurements were highly correlated to AFC collected using trans-vaginal ultrasound (rs=0.813). The fertility assessment at >5AFC and AMH cutoff of 0.66ng/mL has a sensitivity of 91.8% and accuracy of 90.9%. The addition of Inhibin B measurements to the AMH test improved the sensitivity to 95.9% with an accuracy of 94.6%.

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