Oova: A two-in-one at-home test for measuring Luteinizing Hormone and Progesterone.

Several studies were conducted to assess the performance of the Oova urine device for the quantitative measurement of Luteinizing Hormone (LH) and Pregnanediol-3 (PdG) in urine. Urine is collected in both midstream and dip test format and results are conveyed via lateral flow immunoassay, like a pregnancy test. The results are subsequently interpreted in real-time using a machine learning empowered smartphone application. The disposable tests do not require special storage and are tested in layperson use.

Our research found that urine collected and tested using the Oova device provides accurate LH and PdG results when compared with commercial lab analysis. Device precision studies showed that Oova performs consistently when used by multiple professionals and using multiple manufacturing lots of devices. Study technicians found that Oova was easy to use and interpret. Practitioners strongly preferred the Oova device over other hormone measuring products including over the counter (OTC) tests and in some instances, it was clear that Oova had the potential to replace conventional lab work for hormone trend monitoring.

Oova is registered with the FDA. Future studies will assess the performance of testing other analytes.

Introduction

Monitoring hormone levels in individuals affected by infertility remain the standard of care for ensuring proper management of the condition. Typically, Luteinizing Hormone (LH) is tested, and a positive or negative result is conveyed using a threshold-based test. Upon a positive result, the patient believes they are ovulating. Similarly, pregnanediol-3 (PdG) is tested to confirm the release of an egg.

Unfortunately, due to the poor sensitivity and dynamic range of traditional, lateral flow-based immunoassays, these tests provide very little insight. These tests are designed to work at predetermined thresholds and therefore often mislead a woman who does not fit this average profile.

We have designed, developed, and validated the Oova test to improve the urine analysis experience and make it much more valuable for an aging population of women trying to conceive. The system consists of three components: 1) low-cost, disposable cartridges, 2) a re-usable handle, and 3) a machine learning-powered smartphone application.

The Oova test uses advanced nanotechnology to filter non-specific binding, adjust for pH, and normalize hydration levels before measuring the hormones.

We have significantly demonstrated that the Oova test is able to quantitatively measure both LH and PdG, in an at-home setting, as compared to ELISA quantified antigen standards and an AXXIN AX-2X-S reader device.

High-Quality Urine Analysis, At-Home

- Works as midstream and dip
- No batteries, Bluetooth, or hardware
- A process that delivers consistent and reliable results in 10 minutes
- >18 month stability at room temperature

Lab Precision

Oova follows an unprecedented quality assurance and manufacturing process to ensure that unrivaled precision and accuracy is consistently provided.

Two Hormones

The only test on the market that quantitatively measures both LH and PdG in a single test. One scan, real-time data.

HIPAA Compliant

Clinicians and providers have access to hormone measurements through Oova's HIPAA compliant dashboard. Free to use for monitoring, always.

Results

Per CLSI guidelines, results from spiked urine samples with known hormone concentrations were compared on the Oova platform and an industry-standard benchtop reader for urinalysis (AXXIN AX-2X-S reader device).

The Oova reader's most difficult challenge is compensating for various lighting conditions, that cannot be controlled due to inherent variations in the end user's environment. Oova's solution has integrated an algorithm that leverages a combination of matching learning and rule-based image processing techniques to account for the aberrations to obtain consistent, repeatable results.

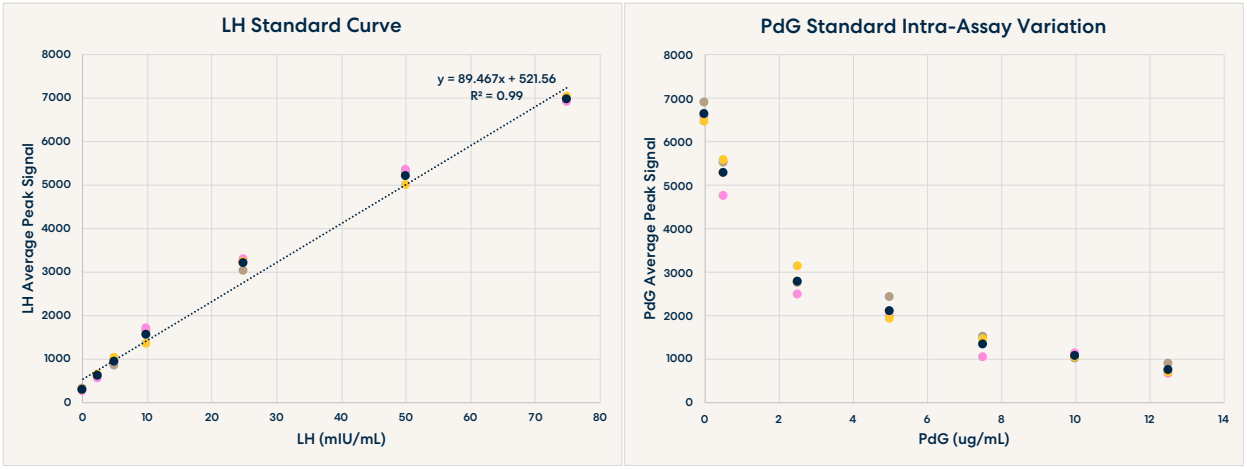

Figure 1. Performance curves for both LH and PdG. Each verification lot is represented by a colored marker (three in total).

The linear regression results show a slope close to 1.00 and a minimal intercept, with a high correlation coefficient (**Figure 1**). The 95% confidence interval for the slope estimate contains the value 1.00, supporting the conclusion that there is no difference between the methods. The results of the analysis confirm that the Oova reader is as accurate as the countertop device (**Table 1**).

Analysis	Methods	Results
Precision	Two levels, each run-in duplicate, two runs per day for 20 days	R2 = 0.9944 showing almost perfect correlation between Oova's smartphone diagnostic and industry standard.
Lot-to-Lot Variation	Four levels of samples (negative, low, medium, and high) were assayed across three lots	No significant variation between lots at low/medium/high LH and PdG concentration levels was observed.
Limit of Blank	Highest value returned when no analyte is present	No significant difference was observed across all lots.
Limit of Detection	Lowest analyte concentration at which detection is feasible	No significant difference was observed across all lots (LH = 2.4 mIU/mL, PdG = 0.76 ug/mL).
Limit of Quantification	Upper limit of quantification at which detection is reliable or accurate	No signal saturation was detected, indicating accuracy at high concentrations (LH = 100 mIU/L, PdG = 10 ug/mL).

Table 1. Results from standard CLSI guideline tests across three independent lots of Oova's test strips

Discussion

Verification studies were conducted to demonstrate and document that the performance of the Oova test meets product and design specifications for the detection of LH and PdG in urine samples. All results from the Oova reader were compared to the gold standard AXXIN reader and further calibrated as required. Three independent lots were manufactured and compared to confirm reproducibility and consistency. The Oova system detected the respective analytes and blanks like the AXXIN reader. The results from the verification studies provide sufficient information to utilize the Oova test in a clinical setting to accurately measure and monitor both LH and PdG.