

Agreement between urinary luteinising hormone, results from Clearblue Advanced Digital Ovulation Test and ultrasound-observed ovulation

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Introduction

- Home ovulation tests are a convenient method for women to time intercourse in order to maximise their chances of conception
- The Clearblue Advanced Digital Ovulation Test, detects the surge in luteinising hormone (LH), and the pre-ovulatory rise in urinary estrone-3-glucuronide (E3G) that marks the onset of a woman's fertile period^{1†}
- This identifies the additional pre-ovulatory days not detected by LH-only ovulation tests, where intercourse can lead to pregnancy, which many women find useful
- Results are digitally displayed to the user as:



Low (basal LH/E3G):
clear circle



High (E3G rise detected):
flashing smiley face



Peak (LH surge detected):
smiley face

[†]E3G is recognised by the World Health Organization as an ideal urinary metabolite for the identification of the onset of the fertile phase.²

Objectives

- To examine the performance of the Clearblue Advanced Digital Ovulation Test compared with ultrasound-observed ovulation.

Methods

- Daily urine samples were collected from complete menstrual cycles of volunteers in the **Menstrual Cycle Monitoring Study** (MeMo; NCT01802060)^{3,4}
 - N=40; all regularly menstruating with documented ovulation; aged 18–37 years, mean age 28.9 years
- Urine samples were tested, blinded and randomised, using three batches of Clearblue Advanced Digital Ovulation Test
- During one complete menstrual cycle, volunteers visited the study centre for blood sampling and transvaginal ultrasound every 2 days, or daily from follicle size >16mm until post-ovulation
- The concentration of urinary LH was measured by the AutoDELFI analysis platform (Perkin Elmer, Waltham, MA, USA), and serum LH by AVIDA-Centaur XP Immunoassay System (Siemens, Erlangen, Germany).

Conclusions

- The surge in urinary LH predicts ovulation, supporting the premise of home ovulation tests to provide women a means of appropriately timing intercourse
- The Clearblue Advanced Digital Ovulation Test accurately predicted ovulation and identified days of high fertility prior to ovulation
- Identifying more days for timing of intercourse is of benefit because multiple acts of intercourse across the fertile phase have been predicted to increase the chances of pregnancy.⁵

References

1. Burger HG. Int J Gynaecol Obstet (1989) Suppl 1: 5–9. 2. World Health Organization. Fertil Steril (1983) 39: 647–654. 3. Johnson S, et al. Clin Chem Lab Med (2015) 53:1099–1108. 4. Roos J, et al. Eur J Contracept Reprod Health Care (2015). doi:10.3109/13625187.2015.1048331. 5. Wilcox AJ, et al. BMJ (2000) 321: 1259–1262.

Results

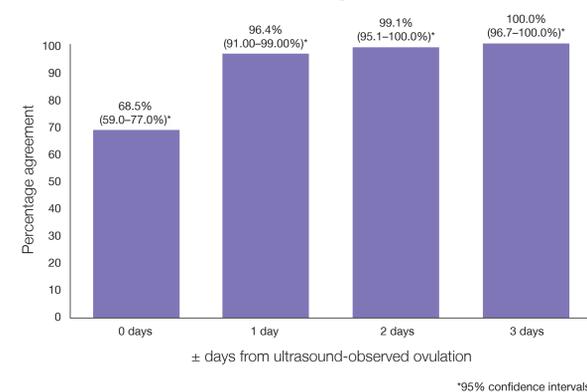
Timing of ovulation and LH levels

- Median day of ultrasound-observed ovulation was 14.5 (range day 8.5–26.5)
- Urinary LH surge preceded ultrasound observed ovulation by a mean of 0.81 days
- Median LH levels on the day prior to ovulation were:
 - Urine: 44.6 mIU/ml (10th–90th percentiles 6.5–101.0)
 - Serum: 38.3 mIU/ml (10th–90th percentiles 26.9–75.0).

Accuracy of Clearblue Advanced Digital Ovulation Test-estimated day of ovulation compared with ultrasound-observed ovulation

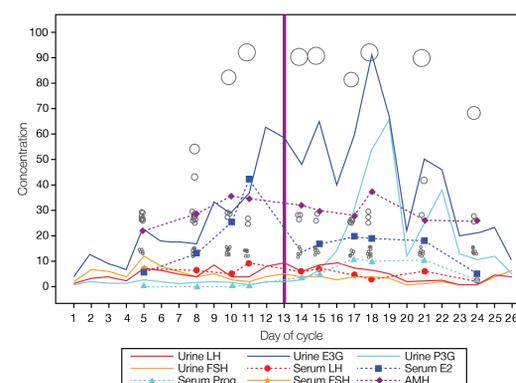
- Clearblue Advanced Digital Ovulation Test detected the LH surge in 92.5% of cycles tested (1 cycle with peak urinary LH of 15.7 mIU/ml accounted for 3% of no surge observations) (figure 1).
- For one volunteer, no peak was detected by Clearblue Advanced Digital Ovulation Test. This was a correct result as no serum or urine LH surge was present in that cycle (figure 2).

Figure 1. Percentage agreement between true ovulation day (determined by ultrasound) and Clearblue Advanced Digital Ovulation Test-estimated day of ovulation.[‡]



[‡]Second peak day of Clearblue Advanced Digital Ovulation Test; first peak day corresponds to the day of the LH surge, and the LH surge precedes ovulation by ~24 hours.

Figure 2. Cycle from a volunteer where no peak fertility was detected by Clearblue Advanced Digital Ovulation Test.



The circles are a map of the individual follicles for this volunteer, with size of circle directly related to the size of follicle, and the number of circles per day indicating the number of follicles for each day.

AMH, anti-Müllerian hormone; E2, estradiol; E3G, estrone-3-glucuronide; FSH, follicle-stimulating hormone; LH, luteinising hormone; Prog., progesterone; P3G, progesterone-3-glucuronide.

Disclosures

Johnson S, Panchal-Soora S and Marriott L are employees of SPD Development Company Ltd. The MeMo study was funded by SPD Development Company Ltd.