

# Ability of women to read and interpret home ovulation tests

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## Introduction

Becoming pregnant is often not as straightforward as many couples expect. Indeed, when using natural fertility awareness methods alone, two-in-three couples fail to conceive in their first cycle, one-in-five fail to conceive within their first six cycles, and one-in-ten fail to conceive within their first 12 cycles.<sup>1</sup> For successful natural conception, intercourse must occur within a window that spans five days prior to ovulation and ends on the estimated ovulation day,<sup>2</sup> with peak fertility being the day before, and the day of ovulation.

Menstrual cycle length varies considerably both between and within women, with the majority of this variation being attributable to the follicular phase. Therefore, reliance on the text-book assumption that ovulation occurs on day 14 will result in many couples trying to conceive at the wrong stage of the menstrual cycle (see ACOG 2011 poster by Johnson *et al* entitled: *Accuracy of perception of ovulation day in women trying to conceive*). It has been shown that women with more awareness of their most fertile time have an increased chance of conception.<sup>3</sup>

Ovulation occurs 24-36 hours after the onset of the Luteinizing Hormone (LH) surge,<sup>4</sup> so detection of the LH surge provides a means to prospectively identify the time of peak fertility. Home ovulation tests provide a simple way for women to appropriately time intercourse in order to maximize their chance of conception. However, as most products differ in terms of their exact LH assay and the way their results are displayed to the consumer, the ability of the user to obtain the correct result may vary between products. For example, current line ovulation tests rely on the user interpreting the intensity of a colored line in a results window against a similarly colored line in the reference window. This interpretation can cause problems as it is clearly subjective, and as a result, the Clearblue Digital Ovulation Test was developed. This device automatically compares the intensity of the two lines and presents the result via a simple digital reading. The objective of this study was to compare the results of the Clearblue Digital Ovulation Test with three commonly used line ovulation tests.

## Methods

Complete menstrual cycles comprising daily urine samples obtained in advance from 25 volunteers (aged 18-45) were tested using four different home ovulation tests (Clearblue Digital Ovulation Test (CB-DOT), Clearblue Ovulation Test (CB-OT), First Response (FR), and Answer (AN)). Testing was performed according to manufacturers' instructions, including the determination of the day that testing should start (based on the volunteers reported menstrual cycle length). A total of 40 cycles were measured.

The test results were read and interpreted by both female volunteers (72 volunteers, aged 18-45, external to the study site) and trained study technicians. The order that each ovulation test was presented to the volunteers was randomized across the different menstrual cycles, and both volunteers and technicians were blinded to the menstrual cycle they were testing. Volunteer and technician testing was performed and recorded independently, with neither party being able to observe the other's results. 'Agreement' was achieved when the recorded results from the technician and volunteer were identical for all samples tested throughout a single cycle.

A secondary endpoint of the study was to examine volunteers' experiences when using the tests. Therefore, volunteers were also asked to rate each product using a seven-point Likert scale (1 - 7; with 1 being the highest ranking and 7 being the lowest ranking), according to the following questions:

- How **CERTAIN** were you of the test results?
- How **CLEAR** did you think the test results were?
- How **EASY** did you think the test results were to read?
- How much do you **TRUST** the results of this test?
- How **ADVANCED** do you believe this test to be?
- How **ACCURATE** do you believe this test to be?
- How **LIKELY** do you think you would be to recommend this test to a friend who wanted to use an Ovulation Test?

Volunteers were then asked to rate each of the tests using the following criteria:

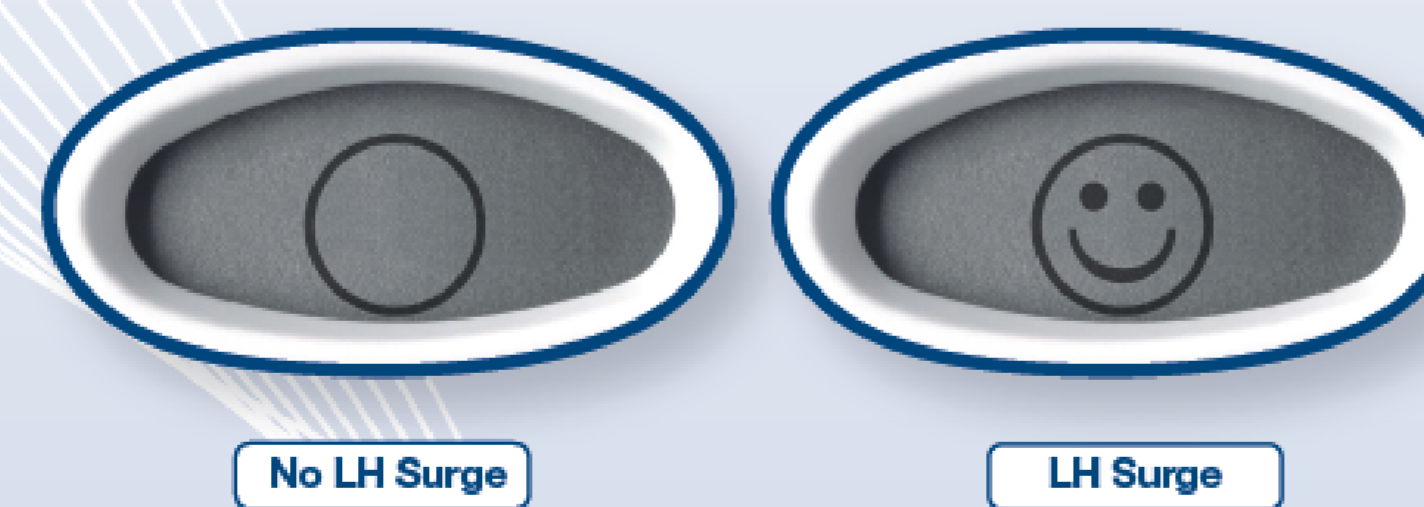
- Overall, this is the Ovulation Test I most prefer
- This has the test result display I most prefer
- This test gives me the most accurate results
- This is the test I trust the most
- This test is the most advanced
- This test is the 'smartest' or 'most intelligent' test
- This test gives me absolute confidence in the result
- I would choose this test over all others.

## Interpretation of Ovulation Tests

### Visual Tests



### Digital Tests



## Results

Agreement analysis (i.e. the technician and volunteer agreeing on the results of all samples within a particular cycle) showed that CB-DOT was associated with a significantly higher percentage agreement (97.3%) than either CB-OT (83.5%; p=0.0153), AN (73.0%; p=0.0011), or FR (64.3%; p=0.0001: see Figure One).

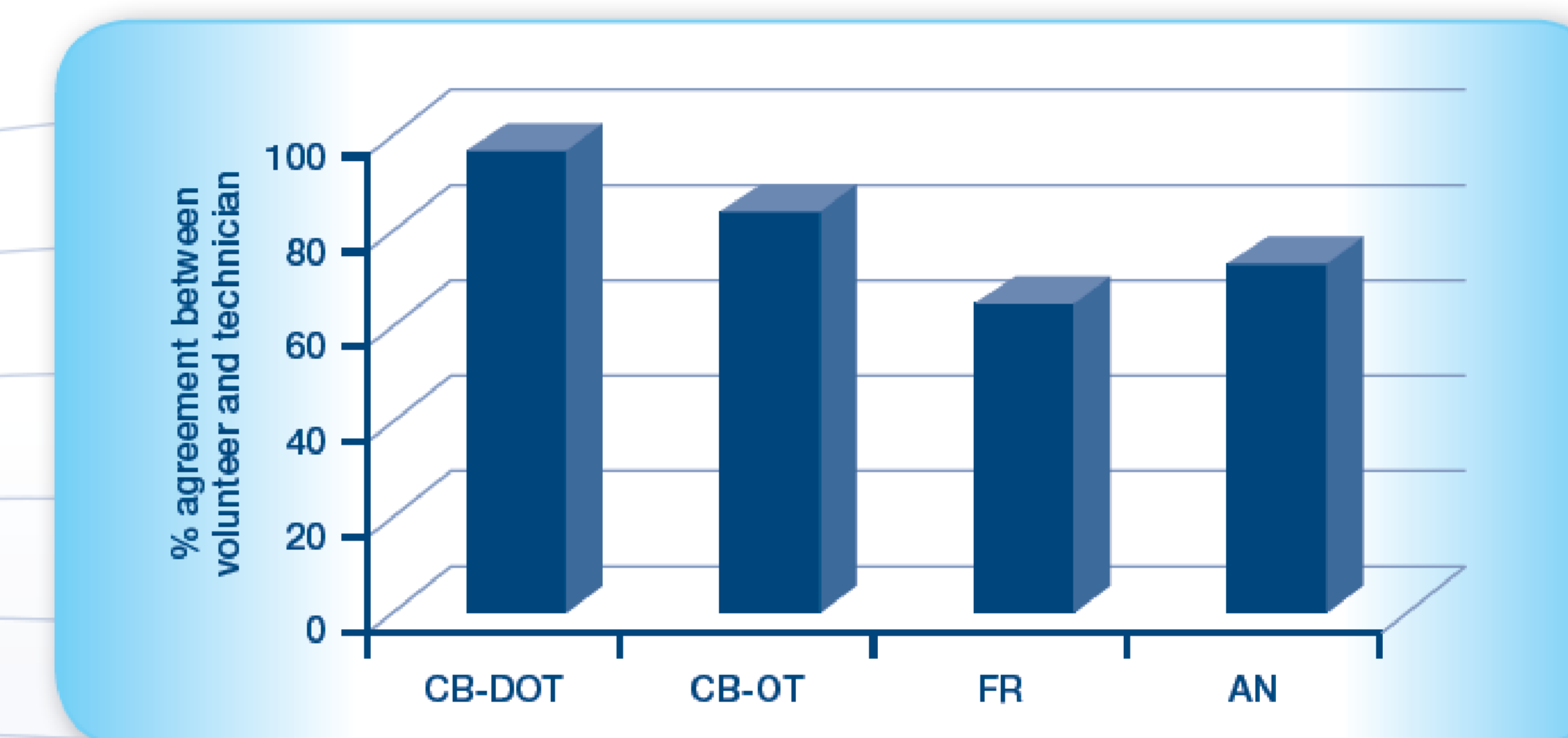


Figure One: When cycle results were read and interpreted, CB-DOT was associated with a significantly higher percentage of volunteer-technician agreement than any of the three line ovulation tests.

For the secondary endpoint of assessing the certainty with which volunteers read CB-DOT results when compared to the three line ovulation tests, CB-DOT was found to have significantly superior (lower) Likert scores than CB-OT, FR, and AN for all seven attributes. Table One shows the percentage of women awarding a Likert score of 1 to each of the seven attributes and indicates that CB-DOT is much more likely to be ranked highest for all attributes tested.

Attribute	CB-DOT	CB-OT	FR	AN
How certain of results	93.1	30.1	20.8	16.7
How clear are results	95.8	26.4	23.6	13.9
How easy are results to read	95.8	33.3	16.7	12.5
How much do you trust the results	43.1	11.1	5.8	4.2
How advanced is the test	54.2	9.7	5.8	4.2
Would you recommend to a friend	70.8	22.2	5.8	11.1

Table One: When compared with the three line ovulation tests, a significantly higher percentage of volunteers awarded CB-DOT the highest Likert score of 1 for each of the seven attributes.

With regards to ovulation test preference, 97.2% of volunteers said that CB-DOT was their most preferred test. This compared to 1.4% for CB-OT and 1.4% for AN. No volunteers preferred FR.

CB-DOT was also most commonly rated the test that was most trusted (by 93.1% of volunteers), most advanced (98.6%), and most intelligent (97.2%), and the test that contained the most preferred display (98.6%) and gave the most accurate result (91.7%).

In addition, 88.9% of volunteers said that they had most confidence in CB-DOT and 97.2% said that they would choose this test over the three line ovulation tests.

## Discussion

Trying to conceive can be a difficult time for couples, especially when conception does not occur as quickly as expected. Therefore, it is important that products designed to increase the chance of conception are accurate, easy to interpret, and trusted by users. The subjective comparison of the intensity of a result and reference line can make it very difficult to interpret the result, especially if LH concentration at the time of the surge is low, or there are high baseline levels of LH. Our study hypothesised that the removal of this subjective interpretation, via the use of a device with an automated optical reader and associated digital display, would both eliminate this uncertainty and produce more accurate results.

As expected, agreement between the volunteer/technician results was considerably higher for CB-DOT than for any of the line tests, thus demonstrating the ease with which an untrained volunteer could expertly interpret the CB-DOT results. In contrast, approximately one-in-three users incorrectly interpreted the First Response test, and approximately one-in-four users incorrectly interpreted the Answer test. Volunteers also reported that the digital test was easier to read and understand, and that they preferred it to visual tests.

For a couple wishing to conceive, the use (and correct interpretation) of a reliable ovulation test can increase their chance of timing intercourse to coincide with the woman's peak fertile period. This, in turn, can help the woman become pregnant sooner.<sup>5</sup> This is particularly important in today's society, where women are becoming pregnant later in life, and maternity is often planned to fit around existing work or lifestyle commitments. In addition, for apparently healthy fertile couples, a continued failure to conceive can adversely affect their social and emotional well-being.

## Conclusion

This study shows that one in four women misread a line test. When compared to line tests, users read digital tests significantly more accurately, and with significantly more certainty.

### References

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