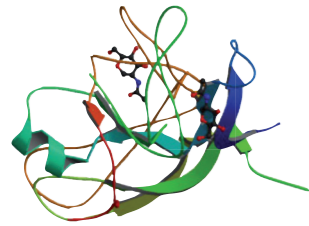# P-118

Accuracy of New Clearblue Digital Pregnancy Test with Conception Indicator

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Introduction

The Clearblue Digital Pregnancy Test with Conception Indicator is the first pregnancy test that is capable of telling a woman if she is pregnant, and if so, indicating when she conceived. This is achieved with dual hormone sensors and a digital display that further categorises 'Pregnant' results into one of 3 groups; 1-2, 2-3 or 3+ weeks since conception (Figure 1). The product achieves this by assessing the hCG levels in urine and defining if they are at a low threshold, typical of early pregnancy (1-2 weeks post conception) or at or above a high threshold level which is typical of 3 weeks + post conception. Levels of hCG between these thresholds indicate 2-3 weeks since conception (Figure 2).

Results

The performance of the pregnancy test in providing a 'Pregnant' result and correctly categorising the time

Inside a Clearblue Digital Pregnancy Test with Conception Indicator

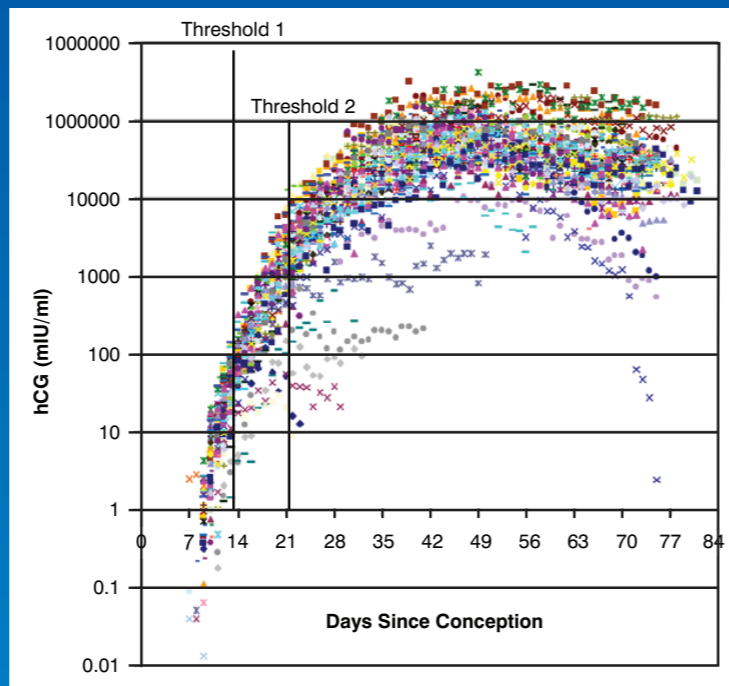Figure 1. The Clearblue Digital Pregnancy Test with Conception Indicator

Figure 2. hCG levels in urine samples during early pregnancy, indicating the thresholds detected by the Clearblue Pregnancy test with Conception Indicator

since conception was assessed using urine samples from pregnant women.

For the pregnancy result evaluation, samples were collected from 400 women attending a clinic and seeking a pregnancy test. Results from the Clearblue Digital Pregnancy test with Conception Indicator were compared with results quantified by a sensitive automated hCG analysis method (AutoDelfia, Perkin Elmer). The overall accuracy was 99.7% for detecting pregnancy compared to a laboratory method. (Table 1)

The ability of Clearblue Digital Pregnancy Test with Conception Indicator to return a "pregnant" result when testing early for pregnancy (testing before the period is due) was determined using over 2500 urine samples collected from women aged 18-45 from the start of the cycle to 90 days post conception. LH surge was identified

in the laboratory using home ovulation tests, and samples from day -4 to day +7 relative to the day the period was due* were tested with the Clearblue Digital Pregnancy Test with Conception Indicator. The success of the test in providing a 'Pregnant' result for each day of pregnancy before the day the period was due was calculated. The detection rates for early testing are shown in Figure 3.

The accuracy of the Conception Indicator result was also determined using over 2500 samples from women aged 18-45 collected from LH surge until 42 days post conception. This was achieved by comparing the result provided by the conception indicator feature (1-2, 2-3 and 3+ weeks since conception) against the time since conception as established by LH surge detection and taking LH surge +1 as the day of conception. Over 7500 devices were tested and the Conception Indicator feature of the test was found to be 92% accurate.

Conclusion:

The new Clearblue Digital Pregnancy Test with Conception Indicator shows excellent performance characteristics, and is the first pregnancy test to provide the answers to the two most important questions a woman has when using a pregnancy test; 'Am I pregnant?' and 'If so, when did I conceive?'.
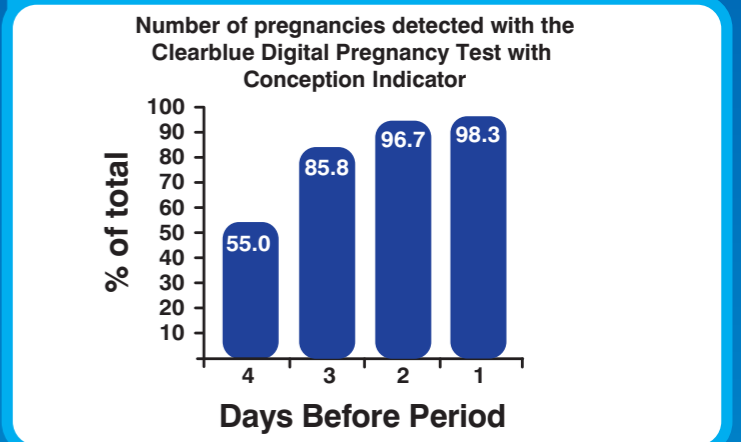
Support

Results

Figure 3. Accuracy of the Clearblue Digital Pregnancy Test with Conception Indicator in determining pregnancy in urine samples collected before the day the period is due.

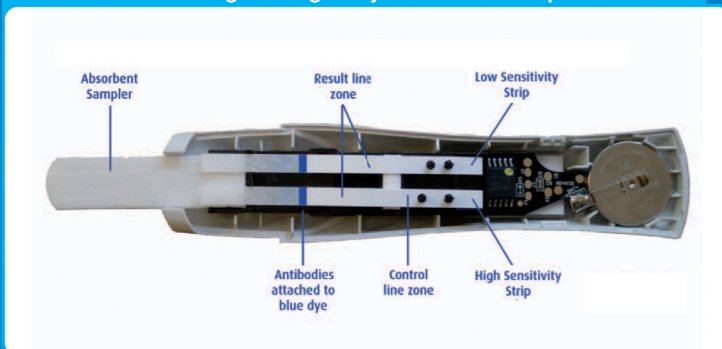|	Results from Clearblue Digital Pregnancy Test with Conception Indicator		
Result expected from quantitative method	Not pregnant	Pregnant	Correlation
Not pregnant	820	4	820/824
Pregnant	0	360	360/360
All	820	364	1180/1184

Table 1. Comparison of results from the Clearblue Digital Pregnancy Test with Conception Indicator with results from a quantitative method.