

# Effect of format on ability to conduct and interpret home pregnancy tests by untrained users

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## Abstract

**Objective:** Clinical analytical tests are now often being marketed to untrained people, in formats normally only used in the laboratory environment. For example, although many home pregnancy tests are designed to be used by women with no training, direct copies of laboratory tests in strip and cassette formats are also available. The objective of this randomised study was to determine whether these types of tests could be used accurately by a lay person, in comparison to tests specifically designed for home use.

**Relevance:** It is important to challenge the assumption that tests formatted to be simple to use by trained individuals in a clinical environment, such as simple strips or cassette styles which require pipetting of sample, can also be used by lay people in the home environment. Therefore it is of relevance to investigate how the effect of environment and training can influence test accuracy.

**Methodology:** Pregnancy tests of different formats (branded midstream digital, branded midstream easy-use visual, branded midstream visual, store-brand midstream visual, strip and cassette) that are available to purchase from pharmacies, were tested by lay women (n=112) in their own homes. The women completed questionnaires regarding their ability to conduct the test. The same women then attended a study centre where they read the results of the same tests conducted on standards

(0, 25, 50 mIU/ml hCG) by a trained technician. Accuracy of volunteer interpretation of test results was determined for each format. Additional questionnaires were completed regarding study conduct. All testing was randomised.

**Results:** Despite strip and cassette tests only being suitable for use with collected urine samples, women still tried to use these tests in-stream when testing at home (n=9 for strips and n=1 for cassette). With midstream tests, where there is an option for in-stream testing, most women chose to test in-stream (80-86% for the different midstream formats). Accuracy of women reading the correct result was 99% for branded midstream digital, 97% for branded midstream easy-use visual, 75% for branded midstream visual, 61% for store-brand midstream visual, 69% for cassette and 59% for strip test. Women reported the midstream tests as being easier to use and read.

**Conclusions:** Laboratory-format pregnancy tests are not suitable for home use because many women can not use the tests correctly, nor interpret the results. This is likely to be due to lower ease of use of these formats and also problems with interpretation of instructions for use. These types of tests should only be used by laboratory professionals. Only tests formatted to facilitate use by untrained people, with simple to understand instructions, should be available for home use.

## Introduction

- It is important for women who suspect that they may be pregnant to obtain an accurate pregnancy test result that they can rely on
- A misread or inaccurate result may have clinical consequences. For example: it can lead to a delay in women seeking healthcare advice, it can cause unnecessary anxiety, a false-negative result may lead to a continuation of behaviours that a pregnant woman would normally change, and an uncertain result can lead to a need for the woman to repeat the test<sup>1</sup>
- Many home pregnancy tests are reported to be 99% accurate if performed on the day that menses is due<sup>2,3</sup>
- However, home test accuracy is also dependent on user interpretation of results and their ability to perform the test correctly<sup>3,4</sup> e.g. up to a quarter of women can misread the traditional parallel line-based visual test results of home pregnancy and ovulation tests<sup>5,6</sup>
- Home pregnancy tests are available in three main format types: strip, cassette or midstream test sticks (Figure 1)
- Strip and cassette format tests are primarily designed to be used by healthcare professionals in a laboratory or clinic environment, but are now available to be used by untrained women without adaptation of the format or instructions for use
- The aim of this study was to evaluate the ease of use and accuracy of pregnancy tests based on a strip, cassette or midstream test stick format, when used by women in both the home and in a controlled environment

## Methods and procedures

### Study population

- Inclusion criteria: females aged 18–45 years who had not used a home pregnancy test within the previous 12 months. The study was conducted in the UK.

### Part 1

- Eligible volunteers were supplied with a study pack, which included a written informed consent form, pregnancy tests, with their instructions for use and questionnaires for completion after using each test
- Six pregnancy tests were evaluated in the study:
  - Boots Pharmaceuticals Pregnancy Test (store-brand midstream visual test, manufactured by Boots Pharmaceuticals<sup>TM</sup>, UK)
  - OneStep Pregnancy Test (strip test manufactured by AI DE Diagnostica Co, Ltd, China)
  - One Step hCG Test (cassette test manufactured by AI DE Diagnostica Co, Ltd, China)
  - Clearblue<sup>TM</sup> COMPACT pregnancy test (branded midstream visual test manufactured by SPD Swiss Precision Diagnostics GmbH, Switzerland)
  - Clearblue<sup>TM</sup> PLUS pregnancy test (branded midstream easy-use visual test manufactured by SPD Swiss Precision Diagnostics GmbH, Switzerland)
  - Clearblue<sup>TM</sup> DIGITAL pregnancy test (branded midstream digital test manufactured by SPD Swiss Precision Diagnostics GmbH, Switzerland).
- Volunteers were randomised to one of six possible sequence orders for performing product testing (testing was conducted over 3 days, with approximately 12h between each testing occurrence). A questionnaire (a series of 7-point Likert scales measuring various attributes of the device tested) was completed after each test
- A final comparative questionnaire was completed after all home testing

### Part 2

- Volunteers attended a study centre and were asked to interpret results presented to them using three different urine standards (0, 25 or 50 mIU/ml of hCG) for each study device
- Testing was conducted by the study co-ordinator according to each product's respective instructions for use. The study co-ordinator also independently recorded the test result and was blinded as to which sample was being evaluated
- Following each test interpretation, volunteers completed a further questionnaire (a series of 7-point Likert scales, which evaluated their overall experience of reading the results of the test on urine standards at the study centre); a separate questionnaire was completed after interpreting each test
- Finally volunteers completed Questionnaire 3, where they ranked their experience of using all the different tests within the study

### Statistical analysis

- SAS version 9.2 was used for all statistical analyses. For Questionnaire 2, the number of volunteers scoring 1 or 2 was analysed using an analysis of covariance model appropriate for the cross-over study; the model included terms for subject, within the subject factors of period and product. A correction for multiple comparisons between products was performed.

## Results

- A total of 111 volunteers were recruited into the study and had data available for analysis (1 volunteer was excluded due to being age 17 at time of study)
- The mean age was 32 years (range 18–44 years) and 93.7% were white (0.9% Asian, 2.7% Black, 2.7% mixed race), 46.8% of volunteers were educated to degree level or above, 36.9% A levels or equivalent, 16.2% GCSE level or below

### Part 1 Results

- The results of Questionnaire 1, showing the percentage scoring 1 or 2 for each product by question when evaluating tests at home are summarised in Table 1

### Summary of key findings from home evaluation of tests:

- Women prefer the midstream method of urine sampling**
  - >80% of women chose to test midstream for all four midstream test stick devices evaluated, when they also had the option of dipping the test stick into a sample
  - Contrary to the instructions for use, women still tried to use strip and cassette tests in-stream when testing at home (n=9 for strips and n=1 for cassette)
- Cassette tests often failed to display a result**
  - 22.5% of users reported that the cassette test did not display a result, compared with 3.6% for the strip test and store-brand midstream visual test, 1.8% for the branded midstream digital and visual tests, 0.0% for the branded midstream easy-use visual test
- Women were more certain of their results when using a midstream test**
  - Only 31% and 56% of women were certain of their result using cassette and strip tests, respectively, whereas certainty was >70% for the midstream tests

Table 1. Percentage of volunteers scoring 1 or 2 for each product when evaluating the tests at home in a randomised order (7-point Likert questions, where 1 is the most positive response and 7 the most negative; a score 1 or 2 represents an active preference for the attribute being examined)

Questionnaire evaluation	Strip, %	Cassette, %	Store-brand midstream visual, %	Branded midstream visual, %	Branded midstream easy-use visual, %	Branded midstream digital, %
Certainty of testing correctly	56.8	31.5	74.8	85.6	91.0	81.8
Easy to use	27.0	11.7	73.0	74.8	90.1	90.0
Hygienic to use	10.8	12.6	60.4	45.5	73.9	74.5
Liked the test	8.1	3.6	34.2	31.5	77.5	72.7

### Part 2 Results

- The results on the accuracy of volunteers' reading of test results, which were run by the study co-ordinator, are summarised in Table 2
- Volunteers completed Questionnaire 2 after reading each test, and these results are summarised in Table 3

### Summary of key findings from study centre comparison of accuracy of women's interpretation of test results

- Women frequently misread the results of cassette and strip tests**
  - 30% and 40% of women misread the results for the cassette and strip tests, respectively, compared with <3% incorrectly reading the branded midstream digital or easy-use visual test results
- Most women preferred the midstream tests**
  - Cumulatively 52.3% and 74.5%, respectively, rated the importance that the test could be used midstream as 1 or 2 on the 7-point Likert scale
  - When ranking the products tested (in Questionnaire 3 after completing all test usage and reading), >95% of women preferred the midstream test stick format over cassette or strip tests
- Most women preferred the branded midstream digital test overall**
  - >97% of women preferred this test over the branded midstream visual test, the store-brand midstream visual test, the cassette test and the strip test, while 87% of volunteers preferred the midstream digital test over the midstream easy-use visual test.

Table 2. Comparison of volunteer result interpretation and co-ordinator interpretation

Product	Co-ordinator result	Volunteer results, n			Percentage agreement
		Pregnant	Not pregnant	Don't know	
Strip	Pregnant	96	79	48	59.1
	Not Pregnant	2	101	7	
Cassette	Pregnant	120	72	30	69.3
	Not Pregnant	0	111	0	
Store-brand midstream visual	Pregnant	94	85	37	61.2
	Not Pregnant	3	110	4	
Branded midstream visual	Pregnant	142	43	38	75.6
	Not Pregnant	0	110	0	
Branded midstream easy-use visual	Pregnant	214	2	6	97.2
	Not Pregnant	1	110	0	
Branded midstream digital	Pregnant	218	1	0	99.3
	Not Pregnant	1	109	0	

\* The result was not recorded for 2 Pregnant and 2 Not Pregnant test results

Table 3. Percentage of volunteers scoring 1 or 2 for each product when evaluating the tests at the end of the study (7-point Likert questions, where 1 is the most positive response and 7 the most negative; a score of 1 or 2 represents an active preference for the attribute being examined).

Questionnaire evaluation	Strip, %	Cassette, %	Store-brand midstream visual, %	Branded midstream visual, %	Branded midstream easy-use visual, %	Branded midstream digital, %
Certainty of testing correctly	17.43	28.31	33.15	42.21	87.91	98.74
How clear the results were	10.27	26.27	28.19	32.11	83.41	98.65
How easy the results were to read	12.80	25.45	30.31	45.52	87.23	100.00
How accurate the test was believed to be	17.37	29.64	37.74	50.31	92.12	98.03
How much the test was trusted	15.00	22.09	34.62	46.94	91.26	97.34

## Conclusions

- It is important that home pregnancy tests provide an accurate result in consumer hands and that they are easy to use and interpret
- This study found that the midstream digital test was superior to the other tests evaluated and fulfilled these criteria
- Strip and cassette format tests should not be available to consumers, who may misinterpret the results

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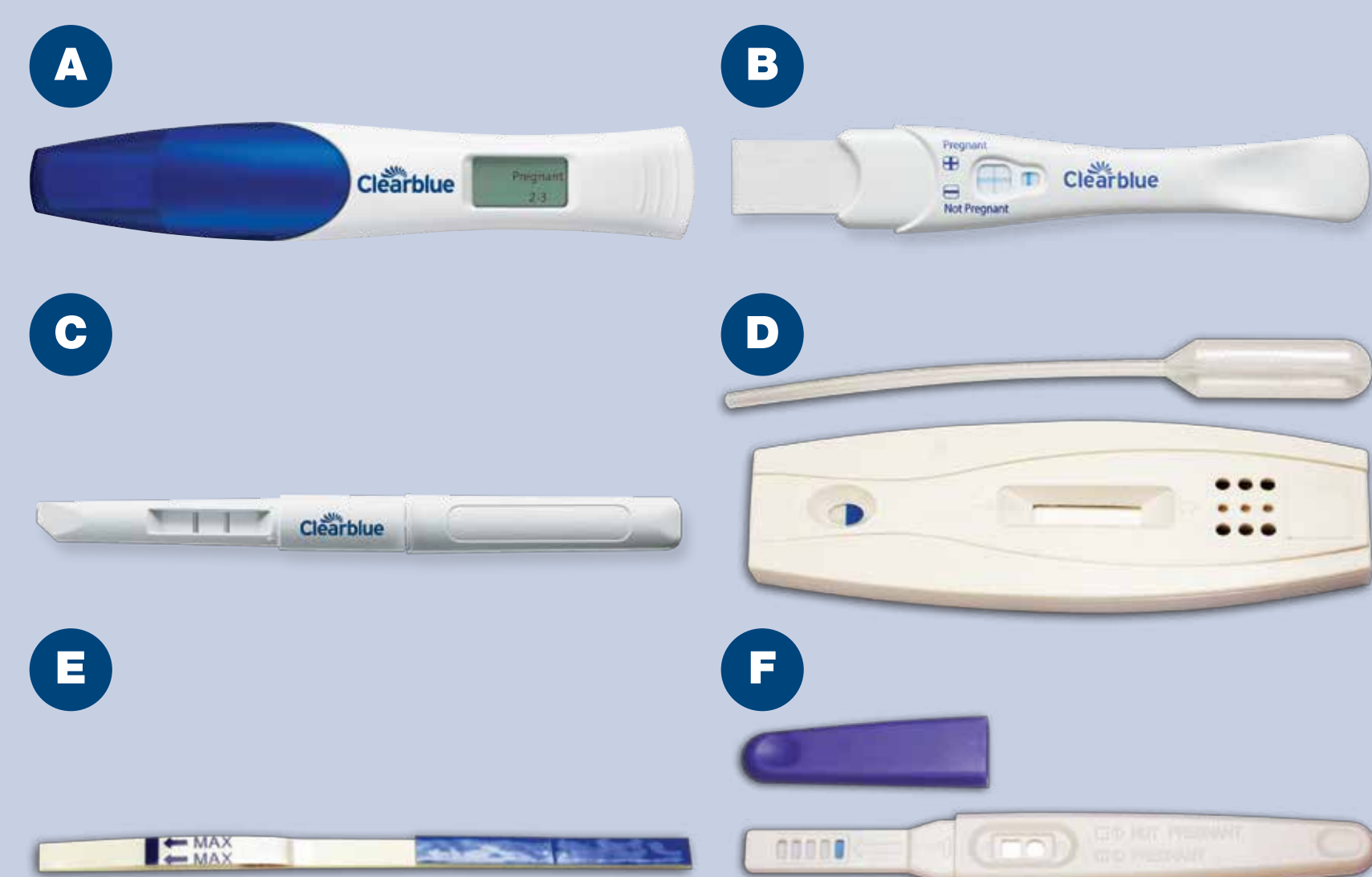


Figure 1. Examples of different pregnancy test formats; A) Digital test; B) Branded midstream easy-use visual test; C) Branded midstream visual test; D) Cassette test; E) Strip test; F) Store-brand midstream visual test.