Performance of nine home urinary hCG (Human chorionic gonadotropin) pregnancy tests.

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Study Question:

Do currently available at home pregnancy tests (HPTs) meet their claimed sensitivity for hCG in early pregnancy testing?

Summary Answer:

Performance claims ranged from plausible (consistent with hCG rise), to unrealistic. Products from manufacturers that also made USA marketed tests (cleared by Food and Drug Administration (FDA)), made realistic claims and laboratory testing found claims were likely to be valid. Whereas, many tests marketed only in Europe, made improper claims that testing found to be invalid.

Introduction:

Current versions of the HPTs are quick and easy to use, utilising immunometric assays that use monoclonal or polyclonal antibodies to bind hCG and then produce a reaction which results in a colour change.

- In a study of 86 pregnant women the mean concentrations of hCG were 0.04, 0.93, 5.03, 13.22mIU/ml for days -7, -6, -5 and -4 days relative to the expected date of next period (day 0)[1].
- A variety of tests are available all with different claimed levels of sensitivity on their packaging as well as different claims regarding how early a woman can test.

Objective:

This study aimed to compare the sensitivity of HPTs available in Germany.

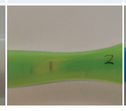
Methodology:

Nine HPTs available in Germany (Clearblue Digital Pregnancy test with Conception Indicator (CBD), Clearblue Plus Pregnancy Test (CBP), Cyclotest (C), Cyclotest supersensitive (CSS), MedVec International (MI), Presense (P), Prima Sicher (PS), Testamed diagnostics Digital (TDD), Testamed diagnostics Sensitive (TDS)), were tested using 5 hCG standards representative of not pregnant and early pregnancy (0, 5, 10, 25 and 50mIU/ml). Each tested was performed as instructed in by the manufacturer's instructions for use. Each type of test was tested on each of the 5 standards (3 tests per standard). Testing was conducted in a randomised, blinded fashion. The tests were read by 3 technicians and the majority decision for each test recorded. Results were compared to the manufacturer's claims. hCG standards were prepared from an initial stock solution (SciPAC P111-6) calibrated to the WHO 4th International standard. The standards were prepared using a pooled urine (negative for hCG) and were all measured by AutoDELFIA (Perkin Elmer) to ensure they were within +/- 5% of target value.

Results:

Important differences in the laboratory performance of urinary hCG tests were found (see table). Four tests (CBD, CBV, PS, TSD) were all able to detect 25mIU/ml, consistent with their respective manufacturers claimed sensitivity of 25mIU/ml and test up to 4 days before the period is due. TDD had an extremely high error rate of 40% and was also unable to reliably detect 25mIU/ml hCG. Although test C has a claimed sensitivity of 25mIU/ml, it gave negative results for all standards tested. MI and CSS made claims of 10mIU/ml sensitivity and test up to 8 days early but neither of these tests had performance consistent with these claims. Of the C and CSS HPTs only 1/6 tests was able to detect 50mIU/ml and these results suggest false negative results may be obtained when testing early or on days around expected period.

Results Table

	Cyclotest (Schwanger-schafts Fruhtest)	MedVec International (Schwanger-schafts Fruhtest)	Clearblue Digital Pregnancy test with conception Indicator	Testamed diagnostics (Schwanger-schafts sensitive)	Cyclotest (Schwanger-schafts Fruhtest supersensitive)	Prima Sicher (Schwanger-schaftstest)	Testamed diagnostics (Schwanger-schafts test Digital)	Presense (Schwanger-schafts Fruhtest)	Clearblue Pregnancy test
Claimed sensitivity	25mIU/ml	10mIU/ml	25mIU/ml	25mIU/ml	12mIU/ml	25mIU/ml	Not stated	10mIU/ml	25mIU/ml
Dipping time for test	3 seconds	10 seconds	20 seconds	20 seconds	3 seconds	3 seconds	15 seconds	10 seconds	5 seconds
Reading time for test	3 minutes	5 minutes	3 minutes	2 minutes	3 minutes	1-3 minutes	5 minutes	3 minutes	3 minutes
Standards (mIU/ml)									
0	0/2 (1error)	0/3	0/3	0/3	0/3	0/3	0/1 (2errors)	0/3	0/3
5	0/3	0/3	0/3	1/3	0/3	0/3	0/2 (1error)	0/3	3/3
10	0/3	0/3	0/3	3/3	0/3	3/3	0/1 (2errors)	2/3	3/3
25	0/3	3/3	3/3	3/3	0/3	3/3	2/2 (1error)	3/3	3/3
50	0/3	3/3	3/3	3/3	1/3	3/3	3/3	3/3	3/3
Did test match sensitivity claim?	No	No	Yes	Yes	No	Yes	Unknown	Borderline	Yes
Example of test at claim sensitivity									

Discussion:

The results from this study and a similar study carried out in Belgium show that some HPTs do not match their claimed levels of sensitivity[2]. In the USA FDA regulations have ensured only home pregnancy tests which meet their performance claims can be sold. The only tests in this study that are sold in the USA are the CBD and CBP HPTs and they met their specifications in this study, as they did in the study carried out in Belgium[2]. In Europe, products appear to be being sold with unrealistic claims, such as "Can already be used 8 days before your period is due[3]" and "Accurate as early as 10 days after possible conception". There is also no standard by which performance can be assessed. Having claims inconsistent with performance could have serious consequences if using these tests to confirm/rule out pregnancy before introducing lifestyle changes for pregnancy. Therefore, a European standard for home pregnancy test performance evaluation should be set in order for women to be certain of the performance of the product

Clearblue

References:

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2. Nickmans, S., Vermeersch, P., Van Eldere, J., & Billen, J. (2014). Performance of qualitative urinary hCG assays. Acta clinica Belgica. e-pub ahead of print
3. Cyclotest Schwangerschafts-Frühtest
4. MedVec International Schwangerschafts-Frühtest

Declaration of Interest:

This study was funded by SPD Development company Ltd. D Broomhead and S Johnson are employees of SDP development company Ltd., a fully owned subsidiary of SPD Swiss Precision Diagnostics GmbH, the manufacturers of Clearblue pregnancy and fertility tests.