

Quick Response hCG test

Summary of an evaluation under the direction of SKUP Report SKUP/2004/37*



Background

Perivita A/S ordered a SKUP evaluation of Quick Response hCG test in June 2004. This evaluation is not complete according to the SKUP model, but includes only the part, which is done under standardised conditions by experienced laboratory personnel. The Danish criteria for good analytical quality were used for the evaluation¹. The result of the test should be read after 5 minutes at 15-30⁰ C. The supplier wanted to know, if the test could be read earlier.

Measurement principle

Quick Response hCG test is an immunochromogen 'hCG Urine Midstream' test method to determine early pregnancy. In this evaluation the test strip is dipped in urine for 10 seconds. According to the manufacturer it can also be held in the urine stream for a few seconds. If hCG is present, a red band is seen together with the red control line. If hCG is not present or present at very low levels, only a red control line will be visible.

Method

To determine the response of the Quick Response hCG test at different concentrations we used serial dilutions of the 4th International Standard for Chorionic Gonadotropin (75/589), 650 IU/ampoule in six different concentrations. We also tested one hCG-free urine, one genuine urine sample from the fertility clinic from a woman in early pregnancy and WHO standards containing alfa hCG, beta-hCG and beta core fragment HCG (1st WHO Reference Reagent 2001, (99/650) hCG β , (99/708) hCG β cf, and (75/569) hCG α and 75/551 hCG β). The tests were read independently by four persons. The analytical quality and the user friendliness are regarded equally important.

Results

Analytical quality at 5 minutes

- 1a) *Percentage negative results at low level, 0 and 4 IU/L: 100 % (160 negative of 160)*
- 1b) *Percentage positive results at high level, 40 IU/L: 72 % (58 positive of 80)*
- 1c) *The concentration where 50 % of the tests show positive results is 25 IU/L*
- 2) *Disagreement of readings: Within-observer disagreement: None < 16 IU/L and \geq 67 IU/L
Between-observer disagreement: None for 0-8 IU/L and \geq 67 IU/L*
- 3) *Percentage invalid tests: 0 %*
- 4) *At 67 IU/L the test turn positive in time, i.e. at 5 minutes that is the specified reading time according to the manual (At 3 minutes 100 IU/L is positive. Reading after the specified reading time does not lead to false results. At 10 minutes: False positive: 0 %. False negative: 0 %)*

User friendliness

The insert information, Quality Control and the Operation of the test were evaluated as 'satisfactory', and Time factors as 'very satisfactory'.

Conclusion

At five minutes the Quick Response hCG test was negative at 0-8 IU/L and positive at 67 IU/L and above. User friendliness was satisfactory. All test readers liked the test; it was easy to decide the result. The test does not fulfil the Danish criteria for good analytical quality because one requirement is that 100 % of the tests at 40 IU/L should be positive. How the test will perform in the hands of women who want to know if they are pregnant has not been evaluated.

The complete report is found at www.skup.nu