

Summary of an evaluation under the direction of SKUP Report SKUP/2004/35*

Background

Medinor AS ordered a SKUP evaluation of the QuickVue® One-Step hCG Urine test (QuickVue hCG) in January 2004. This is the first evaluation of U—hCG made by SKUP. 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.

Measurement principle

The QuickVue hCG test uses an immunochromogen method to determine early pregnancy. Monoclonal antibodies detect the beta subunit of the human chorionic gonadotropin (hCG). Three drops of urine is added to the sample well of the test cassette. If hCG is present in concentrations in 25 IU/L or more it will be seen as a pink-to-purple test line. A blue control line should always appear in a properly functioning test cassette. If hCG is not present or present at lower levels than 25 IU/L, only a blue control line will be visible. The result of the test should be read after 3 minutes at 15 – 30°C.

Method

To determine the response of the QuickVue hCG test at different concentrations we used serial dilutions of the 4th International Standard for Chorionic Gonadotropin (75/589), 650 IU/ampoule in five different concentrations. We also tested one hCG-free urine, two genuine urine samples from the fertility clinic from two women 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.

Results

The analytical quality and the user friendliness are regarded equally important.

Analytical quality

- 1a) Percentage negative results at low level, 0 and 4 IU/L: 97.5 % (156 negative of 160, 4 doubtful)
- 1b) Percentage positive results at high level, ≥ 40 IU/L: 100 % (240 positive of 240)
- 1c) The concentration that gives 50 % positive results is 9.5 IU/L
- 2) Disagreement of readings: Within-observer disagreement: None ≤ 4 IU/L and ≥ 40 IU/L
Between-observer disagreement: None ≤ 4 IU/L and ≥ 40 IU/L
- 3) Percentage invalid tests: 0 %
- 4) The test turns positive in time, i.e. at 3 minutes that is the specified reading time according to the manual. Reading after the specified reading time does not lead to false results.
At 10 minutes: False positive: 0 %. False negative: 0 %

User friendliness

Insert information and Quality Control of the test was evaluated 'satisfactory' and Time factors and Operation 'very satisfactory'. The test persons had some remarks concerning the reading of very low concentrations. See raw data and conclusion.

Conclusion

The QuickVue hCG test fulfils the analytical requirements in this evaluation. 0 and 4 IU/L gave negative results and 40 IU/L and above gave positive results. However, the test was difficult to read for low U—hCG concentrations. For the lowest concentrations a band without colour was seen. At higher concentrations a weak red band appeared. The WHO standard became more positive as time went on; this was not the case for the low genuine sample. How the test will perform in the primary health care has not been evaluated.