

RapidVue® hCG Urine test



Summary of an evaluation under the direction of SKUP Report SKUP/2004/34*

Background

Medinor A/S ordered a SKUP evaluation of the RapidVue® hCG Urine test (RapidVue) in January 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.

Measurement principle

RapidVue is an immunochromogen dipstick method to determine early pregnancy, using monoclonal antibodies against the beta subunit of human chorionic gonadotropin (hCG). The test strip is dipped in urine for 10 seconds. If hCG is present in concentrations of 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 strip. 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 RapidVue at different concentrations we used serial dilutions of the 4th International Standard for Chorionic Gonadotropin (75/589) 650 IU/ampoule, in five different concentrations. One hCG-free urine, 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 were also tested. 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, ≤ 4 IU/L: 77.5 % (124 of 160, 10 doubtful, 26 positive)*
- 1b) *Percentage positive results at high level, ≥ 40 IU/L: 100 % (240 positive of 240)*
- 1c) *The concentration that gives 50 % positive results is 5.7 IU/L*
- 2) *Disagreement of readings:*
 - Within-observer disagreement: in 20 tests at 4 IU/L the 4 test persons considered from 1 to 17 results as positive.*
 - Between-observer disagreement: None at 0 IU/L and ≥ 16 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. The test becomes more positive during time. False negative: 0 %*

User friendliness

The insert information and Quality Control of the test was evaluated 'satisfactory' and time factors and operation 'very satisfactory'.

Conclusion

RapidVue does not fulfil the analytical requirements in this evaluation. 0 IU/L was negative, but 4 IU/L gave positive results. The user friendliness was fine. All test readers liked the test; it was easy to decide the result. How the test will perform under less standardised conditions in the hands of primary health care personnel is not known. We expect that false positive results will create problems also in the primary health care.

The complete report is found at www.skup.nu