RapidVue® hCG Urine test

A pregnancy test evaluation in hospital laboratory

ordered by

Medinor A/S, Denmark

Report from an evaluation
organised by SKUP

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Evaluation of RapidVue® hCG Urine test

CONTENT

SUMMARY

Background Medinor A/S ordered a SKUP evaluation of the RapidVue® hCG Urine test (RapidVue) in January 2004. This is the second 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 evaluation[1].

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 the 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. 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) hCGβ, (99/708) hCGβcf, and 75/569 hCGα and 75/551 hCGβ). 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 postive.i
Between-observer disagreement: None at 0 IU/L and ≥ 16 IU/L.

3) Percentage invalid tests: 0 %

4) The test turn positive in time, i.e. at 3 minutes that is the specified reading time according to the manual. It becomes more positive during time. False negative: 0 %

User friendliness. 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. 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.

PLANNING OF THE EVALUATION

In January 2004 Medinor A/S had two hCG tests that could be of interest for the primary health care. A protocol was written and an evaluation of RapidVue according to the protocol was performed in April 2004.

This is the 5th evaluation made by SKUP for tests using ordinal scale and the second one for U—hCG. This evaluation was performed in the Department of Clinical Biochemistry, Odense University Hospital (OUH), Denmark.

It has been a wish from the General Practitioners in Denmark that analytical quality and user friendliness are weighted equally in the SKUP evaluation.

The purpose of this evaluation in a hospital laboratory has been to investigate the analytical performance and the user friendliness under standardised and optimal conditions. Tests with false positive or false negative results, a high variation in the readings (within- and between-observers) or a high time consumption for analysis can be sorted out at this point. If the results of this hospital laboratory evaluation are positive a further evaluation in primary health care under "real" conditions is recommended by SKUP.

Esther Jensen, Per Hyltoft Petersen, Per Grinsted and Ole Blaabjerg have written the protocol. The protocol was approved by SKUP and by the supplier Medinor A/S.

Esther Jensen has had the main responsibility for this evaluation. The evaluation was done by the Laboratory Technologists Ann Mains, Nina Brøgger, Ann Jepsen, Anette Knudsen and Secretary Jette Hedelund, Cand Scient Ole Blaabjerg and Medical Doctor Esther Jensen. Samples from women in early pregnancy have been available thanks to assistance from Biologist Karin Erb from the Fertility Clinic, OUH.

SKUP has entered into a contract about this evaluation with the supplier Medinor A/S.

Medinor A/S has supplied SKUP with the equipment necessary for the evaluation. The personnel performing the evaluation were not taught in how to do the test, as this is not planned to be a requirement when supplying the test to customers.

Esther Jensen has made the calculations and written this evaluation report. Per Hyltoft and Ole Blaabjerg approved the report. Then it was sent to the Medinor A/S and to SKUP in Norway and Sweden. They all got the opportunity to discuss and comment the report.

If the test is sold in Scandinavia this report will be published on Internet by SKUP on www.SKUP.NU (and www.SKUP.dk). It will also be available in paper copies.

ADDRESSES

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METHOD

Qualitative detection of U—hCG. An immunochromogen method to determine early pregnancy.

Measurement principle of the test.

To perform the test, urine is collected and the test strip is dipped 10 seconds in the urine. The test strip contains monoclonal antibodies against the beta subunit. If there is hCG in the sample a complex is formed and the complex flows through the test strip by capillary action. Polyclonal rabbit anti-hCG binds to the complex resulting in the formation of a pink-to-purple test line. A blue control line will also appear indicating that the test result is valid. If U—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.

Reagents and materials supplied.

RapidVue® hCG Urine test

Content: 25 individually packaged Test Strips, lot 146206, Expiration date Oct.13th 2004
1 Package Insert.
25 Disposable Droppers

Lot nr. 700891, Expiration date Oct. 13th 2004.

Traceability: 3th International Standard for Chorionic Gonadotropin (75/537)

Producer of RapidVue: Quidel Corporation, Worldwide Headquarters, 10165 McKellar Court, San Diego, Californien 92121 USA, www.quidel.com

Agent in Denmark: Medinor A/S, Postbox 321, Langebjerg 35, DK-4000 Roskilde, Denmark

Test period: April 2004

Writing of Report: May 2004

MATERIAL

4th International Standard for Chorionic Gonadotropin (75/589) 650 IU/ampoule[4]

1st WHO Reference Reagent 2001. (99/650) hCGβ 0.88 nmol/ampoule[5]

1st WHO Reference Reagent 2001. (99/708) hCGβcf 1.02 nmol/ampoule[6]

75/569 hCGα (7mg/L)[7]

75/551 hCGβ (7 mg/l)[8]

Human male urine = hCG-free urine = '0'-urine

Human Serum Albumin (Behring, ORHA 20/21, Reinst)

Urine and blood samples from two women in early pregnancy

Material

Preparation of tests used in the analysis.

For the serial dilutions the reference material 4th International Standard for Chorionic Gonadotropin (75/589) 650 IU/ampoule was used. One ampoule was dissolved in 25 ml of buffer (26 000 IU/L.)

The hCG-free urine was centrifuged and 0.2 % albumin. (1 g albumin per 0.5 L of urine was added).

Urines with the concentrations of 4, 8 16, 40 and 100 IU/L hCG were prepared by diluting the hCG standard with hCG-free urine. The hCG-free urine and the dilutions were measured on AutoDelfia to assure that no major mistake had occurred in the production of the urines. The urine of each concentration was divided into 20 samples.

The genuine samples, one serum and one urine sample from each pregnant woman were also first measured on AutoDelfia and then divided into 20 glasses.

As we received the RapidVue tests very late, the cross-reaction experiment was carried out the following day:

1st WHO Reference Reagent 2001, (99/650) hCGβ, (99/708) hCGβcf ,75/569 hCGα and 75/551 hCGβ was measured in duplicates in buffer and in combination with 7 and 90 IU/L of IS 75/589.

REQUIREMENTS FOR ANALYTICAL QUALITY AND USER FRIENDLINESS

There is no international (Golden) Standard for evaluation of U—hCG tests in a hospital laboratory or in primary health care. In Denmark a committee settled by the Health Department has decided that a good U—hCG test should show 100 % negative test results at the concentration of 5 IU/L or less and 100 % positive results at 40 IU/L and above. Norway and Sweden have no similar national requirements.

The analytical quality and the user friendliness are regarded equally important in the SKUP evaluation. Each of the sub-areas within Analytical quality and User friendliness has to achieve ≥ 2 points (= satisfactory).
Each area is subdivided and each subdivision has the possible outcome.

(-		not relevant)
0	Point	unsatisfactory
1	Point	less satisfactory
2	Points	satisfactory
3	Points	very satisfactory

Analytical quality. Parameters evaluated:

1) Percentage of negative results at low level, ≤ 4 IU/L, (Negative results) / (All results)

1b) Percentage of positive results at high level, ≥ 40 IU/L, (Positive results) / (All results)

1c) The concentration that gives 50 % positive results.

2) Disagreement of readings. Within-observer disagreement and Between-observer disagreement. Four observers read the hCG samples at eight different concentrations in a random order. Each observer made 20 independent readings at each concentration.

3) Percentage of invalid tests, as defined by test package insert, i.e. no control line and/or diffuse background.

4) Robustness. Does the test turn positive at the time specified in the test manual? The reading time is specified to 3 minutes. Do the results change after the specified reading time? The test is read also after 10 minutes, which is the time the patient usually spend at the doctor.

User friendliness. Parameters evaluated

- manual /insert
- time factors
- quality control
- operation of the test

Quality Control.

Built-in Control Features.

The RapidVue contains built-in control features.

The two test lines provides a clear-cut readout for positive and negative results. The appearance of a blue Control Line indicates that a proper volume of fluid absorbed into the Test Strip and that a capillary flow occurred. If the Control Line does not develop within 3 minutes, the test result is invalid.

If a background colour appears which interferes with your ability to read the test result your result may be invalid. In this case, review the procedure and repeat test with a new test strip.

Positive and negative Quality Control.

External controls may be used to assure that the reagents and assay procedure are performing properly, if required by the laboratory's quality assurance plan. Positive control material can be bought separately and is not evaluated in this evaluation. It is recommended that the positive control used should be traceable to WHO standards.

Positive and negative control samples should be tested with each new lot or shipment of test kits, with each test kit package of 25 tests, and with each new operator within the test kit package, and in addition as required by your laboratory's standard quality control procedures.

If control samples do not perform as expected, do not use the test results. Repeat the test or contact Quidel Technical Assistance.

EVALUATION PROCEDURES

(under standardised and optimal conditions in the hospital laboratory)

192 U—hCG test samples were produced by Cand. Scient Ole Blaabjerg and two laboratory technologists from KKA, OUH.

The 0-sample and 5 concentrations of the 4th International Standard for Chorionic Gonadotropin (75/589), 650 IU/ampoule was each divided into 20 glasses and so were the two genuine samples from the women in early pregnancy.
A further 32 samples containing 1st WHO Reference Reagent 2001, (99/650) hCGβ, (99/708) hCGβcf, 75/569 hCGα or 75/551 hCGβ was investigated. In total 20 × 8 + 32 test.
The WHO standards in buffer and in combinations with concentration 7 and 90 were measured in duplicates with high levels of (99/650) hCGβ, (99/708) hCGβcf or 75/569 hCGα.

Four persons from the department of clinical chemistry, OUH, read the 192 U—hCG samples at 3 and 10 minutes. The observers didn't know which samples that had the same concentration and the observer didn't know the results of the other observers.
All together were 384 (2 x 192) readings done per observer, in total 1536 (4 x 384) readings. See table 1, table A and table 3. All readings were done at the specified time (plus maximum 15 seconds). The readings were done on a sunny day in a room with daylight combined with artificial light. At the time the temperature in the room was 23°C.

The Cross-reaction/Interference experiment was carried out the following day. Table 3

RESULTS

4 persons read 20 samples at each of 8 concentrations in a random order at the time 3 and 10 minutes.

Table 1 3 minutes **Concentration IU/L**	person 1 positive	person 2 positive	person 3 positive	person 4 positive	**In total positive**	**In total negative**	**In total in doubt**
n=20	n=	n=	n=	n=	**n=**	**n=**	**n=**
0	0	0	0	0	**0**	**80**	**0**
4	1	4	4	17	**26**	**44**	**10**
8	13	13	16	19	**61**	**13**	**6**
16	20	20	20	20	**80**	**0**	**0**
’26’	20	20	19	20	**79**	**0**	**1**
40	20	20	20	20	**80**	**0**	**0**
100	20	20	20	20	**80**	**0**	**0**
’233’	20	20	20	20	**80**	**0**	**0**

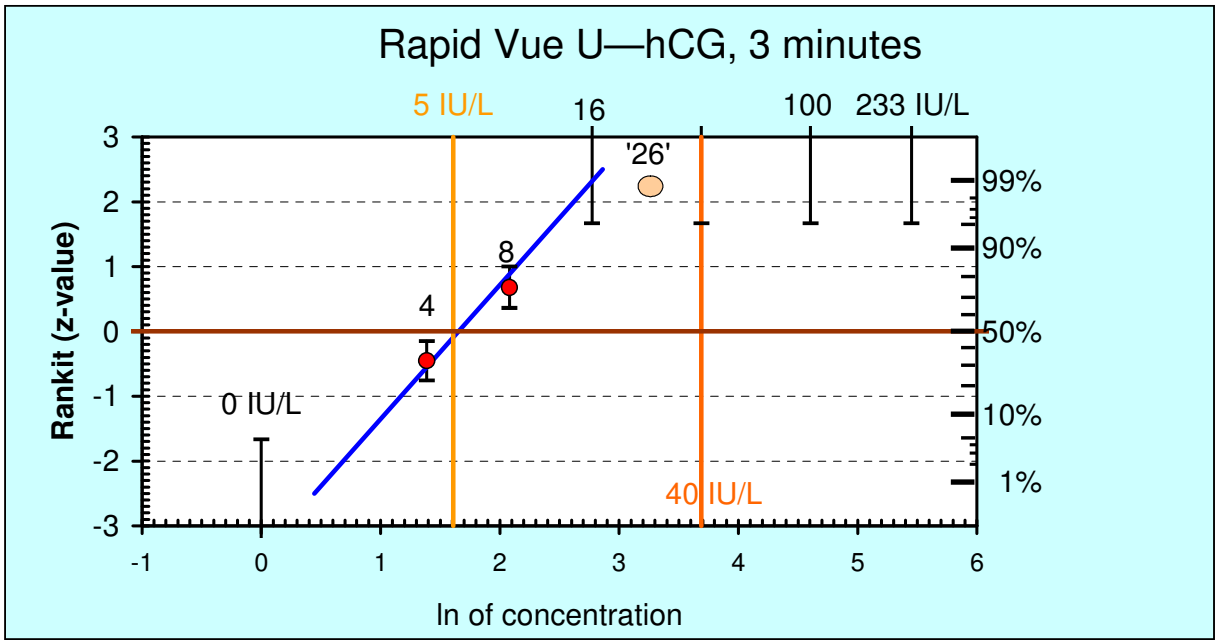
10 minutes **Concentration IU/L**	person 1 positive	person 2 positive	person 3 positive	person 4 positive	**In total positive**	**In total Negative**	**In total In doubt**
n=20	n=	n=	n=	n=	**n=**	**n=**	**n=**
0	0	0	0	0	**0**	**80**	**0**
4	19	20	17	20	**76**	**4**	**0**
8	20	20	20	20	**80**	**0**	**0**
16	20	20	20	20	**80**	**0**	**0**
’26’	20	20	20	20	**80**	**0**	**0**
40	20	20	20	20	**80**	**0**	**0**
100	20	20	20	20	**80**	**0**	**0**
’233’	20	20	20	20	**80**	**0**	**0**

Comments to data in table 1 and table A.

16.3 % (26 of 160) of the tests at the concentrations 0 and 4 IU/L and all tests at the concentrations 16 IU/L and above were positive after 3 minutes.

Figure 1

Fractions of positive results for eight samples



The fractions of positive results at different U—hCG concentrations in a dilution series is shown in a Rankit-plot (Rankit is a linearization of the Gaussian distribution, where z is the distance, expressed in standard deviations, from the mean value). The corresponding percentages could be read on the right Y-axis and the abscissa shows the natural logarithms (ln = log e) of the U—hCG concentrations in IU/L. For each concentration the 95 % confidence interval is plotted.
The figure shows that some tests are positive in the concentrations 4 IU/L and above. 50 % of the tests are positive at the concentration 5.2 IU/L (geometric mean=50 %=(z=0)). The red point is from dilutions of the WHO standard, while the beige point is from a woman in early pregnancy. All concentrations are read after 3 minutes.

Evaluation of user friendliness

The ratings of the test persons are marked with coloured fields. At evaluations in general practice only the white lines are filled in. At testing in a hospital laboratory, all lines are filled in. Any free comments belonging to the four sub-areas will be placed below the table concerning the area.
An average rating is made for each of the four sub-areas: Insert, Time factors, Quality Control and Operation. The summary of the user friendliness is based on the rating of all sub-areas. 2 or 3 points fulfil the expectations, 0 or 1 point do not fulfil the expectations. If 0 or 1 point is given the reason is explained in the text.

Table 2. User friendliness

Information in manual / insert about:	0 point	1 point	2 point	3 point
Content, clearness in presentation	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Specimen collection	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Materials required, provided/not provided	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Pre-analytic/test procedure	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Interpretation of the results	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Measurement principle	Unsatisfactory	Less satisfactory*	Satisfactory	Very satisfactory
Error sources	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Troubleshooting	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Available insert in Danish, Norwegian, Swedish	No	Partly	Yes	English + Scandinavian
Easy to read?	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Rating of the manual / insert			Satisfactory	

Time factors	0 point	1 point	2 point	3 point
Pre-analytic time	>10 min	6 to 10 min.	3 to 5 min.	≤ 2 min.
Analytic time	>10 min	6 to 10 min.	3 to 5 min.	≤ 2 min.
Training / Education	Very difficult	Difficult	Easy	Very easy
Stability of test, unopened, (no/package)	≤ 3 months	3 — 5 months	6 — 12 months	> 12 months
Stability of control material	≤ 3 months	3 — 5 months	6 — 12 months	> 12 months
Storage conditions of tests, unopened	-20^{0}C	2 — 8^{0}C	15 — 30^{0}C	2 — 30^{0}C
Storage conditions of control material	-20^{0}C	2 — 8^{0}C	15 — 30^{0}C	2 — 30^{0}C
Rating of time factors				Very satisfactory

Quality Control	0 point	1 point	2 point	3 point
Internal quality control	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
External quality control	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Interpretation of the Quality Control	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Rating of quality control			Satisfactory	

Operation	0 point	1 point	2 point	3 point
To prepare the test / instrument	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
To prepare the sample	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Application of sample	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Amount of sample	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Procedure step	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Interpretation of the test	Very difficult	Difficult	Easy	Very easy
Sources of errors	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Cleaning/maintenance	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Hygiene, using the test	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Environmental requirements	Poison	Special arrangement	Biohazard	Daily renovation
Demands to education	Lab technician	Course	GP personal	None
Demands to training	days	> 2 hours	½-2 hours	0-30 minutes
Size and weight of package	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Rating of operation				Very satisfactory

* The measurement principle of the test is not described in detail.

Comments: The test was easy to use and to read.

Summary of user friendliness

The ratings of the Information in Manual / Insert and the Quality control were ‘satisfactory’ and the ratings of Time factors and Operation were ‘very satisfactory’.

INTERFERENS and CROSS-REACTIONS

WHO	concentration	content	RapidVue, n=4
75/569	70 µg/L	alfa hCG	0
75/569	700 µg/L	alfa hCG	0
75/589 + 75/569	7 IU/L+ 700 µg/L	alfa hCG	1
75/589 + 75/569	90 IU/L+ 700 µg/L	alfa hCG	1
99/708	0.4 nmol/L	Core fragment	0
99/708	4.1 nmol/L	Core fragment	0
75/589 + 99/708	7 IU/L + 4.1 nmol/L	Core fragment	1
75/589 + 99/708	90 IU/L + 4.1 nmol/L	Core fragment	1
75/551	70 µg/L	free beta hCG	1
75/551	700 µg/L	free beta hCG	1
75/589 + 75/551	7 IU/L+ 700 µg/L	free beta hCG	1
75/589 + 75/551	90 IU/L+ 700 µg/L	free beta hCG	1
99/650	78 µg/L	free beta hCG	1
99/650	19.5 µg/L	free beta hCG	1
99/650	7.8 µg/L	free beta hCG	1
99/650	1.9 µg/L	free beta hCG	1

Explanation of the results:

1) RapidVue detects free subunits of beta hCG. It also detects beta subunits in intact hCG. It does not detect alfa hCG or core fragment beta hCG.
2) High levels of different WHO standards do not produce false negative results when combined with total hCG
3) The use of (99/650) in very low concentration shows, that RapidVue is very sensitive.

Conversion factors [4,5]						
WHO	content	Molecular weigth	IU/L	µg/L	nmol/L	per ampul nmol/L
75/589	intact hCG	36700	7		0.02014	
75/589	intact hCG	36700	70		0.2014	
99/688	intact hCG	36700				1.88
75/569	alfa hCG	14500	700	700	48.3	
75/551	beta hCG	22200	700	700	31.5	
99/650	beta hCG	22200		78	3.52	0.88
99/708	core fragment				4.1	1.02

EVALUATION OF ANALYTICAL QUALITY AFTER 3 MINUTES

Results, *analytical quality.*

1a) ***Percentage negative results at low level, ≤ 4 IU/L:*** *77,5 %, 80 of 80 readings were negative for 0 IU/L but only 44 of 80 readings were negative for 4 IU/L. All the test observers read at least 1 of 20 tests 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 5.2 IU/L*

2) ***Disagreement of readings:***

Within-observer disagreement: All 4 observers read both positive and negative results in the 20 tests at the concentration 4 IUL/., There were no problems for concentrations ≥ 16 IU/L. Between-observer disagreement: None for 0 IU/L and for ≥ 16 IU/L. In the area from 4 to 8 IU/L the test can produce either positive or negative result. The four observers read the tests a bit differently at these concentrations, but this is expected for all ordinal scale tests close to the concentration that gives 50 % positive results.

3) ***Invalid tests:*** *0 % . The blue control line appeared in all test and the background was clear.*

4) ***Robustness****: The test turns positive at the specified time, i.e. at 3 minutes. False positive at 3 minutes: 32.5 %. The test becomes more positive after the specified reading time.*

At 10 minutes: False negative: 0 %

Summary of analytical quality

Under standardised conditions the analytical quality does not fulfil the Danish criteria that at 5 IU/L should all tests be negative.

Conclusion

RapidVue ® hCG Urine test does not fulfil the criteria for good analytical quality in this evaluation. Under standardised conditions 32.5 % of the tests were positive at the concentration 4 IU/L For the different test readers this percentage varied from 5 % to 85 %.

The user friendliness of the test was good. All the persons participating in this evaluation liked the test.

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.

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Clin Chem 2004 50: 798-800

6) NIBSC indlægsseddel til 4th International Standard for Chorionic Gonadotropin (75/589) 650 IU/ampoule

7) NIBSC indlægsseddel 1st WHO Reference Reagent 2001. (99/650) hCGβ 0.88 nmol/ampoule

8) NIBSC indlægsseddel 1st WHO Reference Reagent 2001. (99/708) hCGβcf 1.02 nmol/ampoule

9) NIBSC indlægsseddel 75/569 hCGα (7mg/L)

10) NIBSC indlægsseddel 75/551 hCGβ (7 mg/l)

11) A Model for setting Analytical Quality Specifications and Design of Control for Measurements on the Ordinal Scale. Per Hyltoft Petersen, Sverre Sandberg, Callum Fraser and Henk Goldschmidt.
Clin Chem Lab Med 2000; 38 (6): 545-551.

12) Dansk, Norsk, Svensk og Engelsk indlægsseddel

13) SKUP rapport nr 24

TABLE A

Raw data

RapidVue®Urine hCG test

	IU/L		3 min				10 min			
	Concentration	Test No	person1	person2	person3	person4	person1	person2	person3	person4
'0' Urine	0	4	0	0	0	0	0	0	0	0
'0' Urine	0	21	0	0	0	0	0	0	0	0
'0' Urine	0	31	0	0	0	0	0	0	0	0
'0' Urine	0	40	0	0	0	0	0	0	0	0
'0' Urine	0	47	0	0	0	0	0	0	0	0
'0' Urine	0	62	0	0	0	0	0	0	0	0
'0' Urine	0	67	0	0	0	0	0	0	0	0
'0' Urine	0	77	0	0	0	0	0	0	0	0
'0' Urine	0	84	0	0	0	0	0	0	0	0
'0' Urine	0	91	0	0	0	0	0	0	0	0
'0' Urine	0	101	0	0	0	0	0	0	0	0
'0' Urine	0	107	0	0	0	0	0	0	0	0
'0' Urine	0	117	0	0	0	0	0	0	0	0
'0' Urine	0	123	0	0	0	0	0	0	0	0
'0' Urine	0	136	0	0	0	0	0	0	0	0
'0' Urine	0	145	0	0	0	0	0	0	0	0
'0' Urine	0	150	0	0	0	0	0	0	0	0
'0' Urine	0	157	0	0	0	0	0	0	0	0
'0' Urine	0	172	0	0	0	0	0	0	0	0
'0' Urine	0	179	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	13	0	0	0	0	1	1	0	1
'0'+ 4th IS 75/589	4	24	s	0	0	s	1	1	1	1
'0'+ 4th IS 75/589	4	28	0	0	0	0	0	s	0	s
'0'+ 4th IS 75/589	4	37	0	s	0	1	1	1	1	1
'0'+ 4th IS 75/589	4	43	0	?	0	s	1	1	1	1
'0'+ 4th IS 75/589	4	51	0	s	0	s	1	1	1	1
'0'+ 4th IS 75/589	4	60	0	s	0	s	1	s	1	1
'0'+ 4th IS 75/589	4	69	0	?	0	s	1	1	1	1
'0'+ 4th IS 75/589	4	78	0	?	0	s	1	1	1	1
'0'+ 4th IS 75/589	4	95	0	s	1	1	1	1	1	1
'0'+ 4th IS 75/589	4	103	0	?	0	1	1	1	1	1
'0'+ 4th IS 75/589	4	114	0	0	0	0	1	s	1	1
'0'+ 4th IS 75/589	4	119	0	?	1	s	1	s	1	1
'0'+ 4th IS 75/589	4	121	0	0	?	s	1	1	1	1
'0'+ 4th IS 75/589	4	129	0	0	0	s	1	1	1	1
'0'+ 4th IS 75/589	4	142	0	?	1	s	1	1	1	1
'0'+ 4th IS 75/589	4	148	0	0	0	s	1	1	1	1
'0'+ 4th IS 75/589	4	158	0	?	0	s	1	1	1	1
'0'+ 4th IS 75/589	4	165	0	?	0	s	1	1	0	1
'0'+ 4th IS 75/589	4	174	0	?	1	s	1	1	1	1
'0'+ 4th IS 75/589	8	5	0	?	?	1	1	1	1	1
'0'+ 4th IS 75/589	8	9	s	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	17	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	25	s	s	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	44	s	s	0	1	1	1	1	1
'0'+ 4th IS 75/589	8	49	s	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	63	s	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	74	s	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	80	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	90	0	?	0	1	1	1	1	1
'0'+ 4th IS 75/589	8	93	0	?	0	1	1	1	1	1
'0'+ 4th IS 75/589	8	100	0	?	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	111	1	s	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	131	0	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	137	0	0	1	s	1	1	1	1
'0'+ 4th IS 75/589	8	147	0	0	1	0	1	1	1	1
'0'+ 4th IS 75/589	8	153	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	161	1	1	1	1	1	1	1	1

'0'+ 4th IS 75/589	8	166	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	8	178	s	?	1	s	1	1	1	1
'0'+ 4th IS 75/589	16	1	1	1	1	1	1	1	2	1
'0'+ 4th IS 75/589	16	7	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	11	s	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	23	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	29	s	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	35	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	45	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	46	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	52	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	57	1	1	1	1	1	1	2	1
'0'+ 4th IS 75/589	16	72	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	88	1	1	1	1	1	1	2	1
'0'+ 4th IS 75/589	16	99	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	108	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	113	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	127	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	135	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	140	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	155	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	16	168	1	1	1	1	1	1	1	1
U-k1	'26'	8	s	1	1	1	1	1	1	1
U-k1	'26'	27	1	1	1	1	1	1	1	1
U-k1	'26'	33	s	1	?	s	1	1	1	1
U-k1	'26'	41	1	1	1	1	1	1	1	1
U-k1	'26'	54	1	1	1	1	1	1	1	1
U-k1	'26'	55	1	1	1	1	1	1	2	1
U-k1	'26'	61	s	1	1	1	1	1	2	1
U-k1	'26'	68	s	s	1	1	1	1	1	1
U-k1	'26'	75	1	1	1	1	1	1	1	1
U-k1	'26'	81	1	1	1	1	1	1	2	1
U-k1	'26'	98	1	1	1	1	1	1	2	1
U-k1	'26'	105	s	1	1	1	1	1	1	1
U-k1	'26'	112	1	1	1	1	1	1	1	1
U-k1	'26'	115	1	1	1	1	1	1	1	1
U-k1	'26'	122	1	1	1	1	1	1	1	1
U-k1	'26'	130	1	1	1	1	1	1	2	1
U-k1	'26'	141	1	1	1	1	1	1	1	1
U-k1	'26'	149	1	1	1	1	1	1	1	1
U-k1	'26'	163	1	1	1	1	1	1	1	1
U-k1	'26'	173	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	40	3	1	1	2	1	2	2	2	1
'0'+ 4th IS 75/589	40	12	1	1	1	1	1	1	2	1
'0'+ 4th IS 75/589	40	16	1	1	2	1	1	2	2	1
'0'+ 4th IS 75/589	40	34	1	1	2	1	1	1,5	2	1
'0'+ 4th IS 75/589	40	39	1	1	1	1	1	2	2	1
'0'+ 4th IS 75/589	40	48	1	1	1	1	1	1	2	1
'0'+ 4th IS 75/589	40	56	1	1	2	1	2	1,5	2	1
'0'+ 4th IS 75/589	40	66	1	1	2	1	1	1	2	1
'0'+ 4th IS 75/589	40	76	1	1	2	1	1	1	2	1
'0'+ 4th IS 75/589	40	86	1	1	2	1	1	1	2	1
'0'+ 4th IS 75/589	40	94	1	1	2	1	1	1,5	2	1
'0'+ 4th IS 75/589	40	102	1	1	2	1	1	1,5	2	1
'0'+ 4th IS 75/589	40	106	1	1	2	1	1	1,5	2	1
'0'+ 4th IS 75/589	40	120	1	1	1	1	1	2	2	1
'0'+ 4th IS 75/589	40	125	1	1	2	1	1	1,5	2	1
'0'+ 4th IS 75/589	40	139	1	1	2	1	1	1,5	2	1
'0'+ 4th IS 75/589	40	152	1	1	2	1	1	1,5	2	1
'0'+ 4th IS 75/589	40	164	1	1	1	1	1	1	2	1
'0'+ 4th IS 75/589	40	171	1	1	2	1	1	1	2	1
'0'+ 4th IS 75/589	40	177	1	1	2	1	1	1,5	2	1
'0'+ 4th IS 75/589	100	15	1	1	2	1	1	1,5	2	1
'0'+ 4th IS 75/589	100	22	1	2	2	1	1	2	2	1

'0'+ 4th IS 75/589	100	30	1	2	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	36	2	2	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	58	2	2	2	2	2	2	2	2
'0'+ 4th IS 75/589	100	64	1	2	2	1	1	2	2	1
'0'+ 4th IS 75/589	100	73	1	2	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	83	1	2	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	89	2	1,5	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	104	1	1	2	1	1	2	2	1
'0'+ 4th IS 75/589	100	109	1	1,5	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	116	1	1	2	1	1	1	2	1
'0'+ 4th IS 75/589	100	124	2	2	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	132	1	2	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	146	1	1	2	1	1	1,5	2	1
'0'+ 4th IS 75/589	100	154	1	1	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	156	1	2	2	2	2	2	2	2
'0'+ 4th IS 75/589	100	162	1	2	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	169	2	1,5	2	1	2	2	2	1
'0'+ 4th IS 75/589	100	175	1	1	2	1	1	1,5	2	1
U- k2	'233'	2	2	2	2	2	2	2	2	2
U- k2	'233'	10	2	2	2	2	2	2	2	2
U- k2	'233'	18	2	2	2	2	2	2	2	2
U- k2	'233'	20	2	2	2	1	2	2	2	1
U- k2	'233'	42	2	2	2	2	2	2	2	2
U- k2	'233'	50	2	2	2	1	2	2	2	1
U- k2	'233'	59	2	2	2	2	2	2	2	2
U- k2	'233'	65	2	2	2	1	2	2	2	1
U- k2	'233'	70	2	2	2	2	2	2	2	2
U- k2	'233'	79	2	2	2	1	2	2	2	2
U- k2	'233'	85	2	2	2	2	2	2	2	2
U- k2	'233'	97	2	2	2	1	2	2	2	1
U- k2	'233'	110	2	2	2	2	2	2	2	2
U- k2	'233'	118	2	2	2	2	2	2	2	2
U- k2	'233'	126	2	2	2	1	2	2	2	1
U- k2	'233'	133	1	2	2	1	2	2	2	1
U- k2	'233'	144	2	2	2	1	2	2	2	1
U- k2	'233'	159	2	2	2	2	2	2	2	2
U- k2	'233'	170	2	2	2	2	2	2	2	2
U- k2	'233'	180	2	2	2	2	2	2	2	2

Explanation to the signs in the table above:

B	Not valid
0	Negative
?	Doubtful
s	Weak positive
1	Positive
1,5	Positive
2	Strong positive
1	Positive (unexpected)

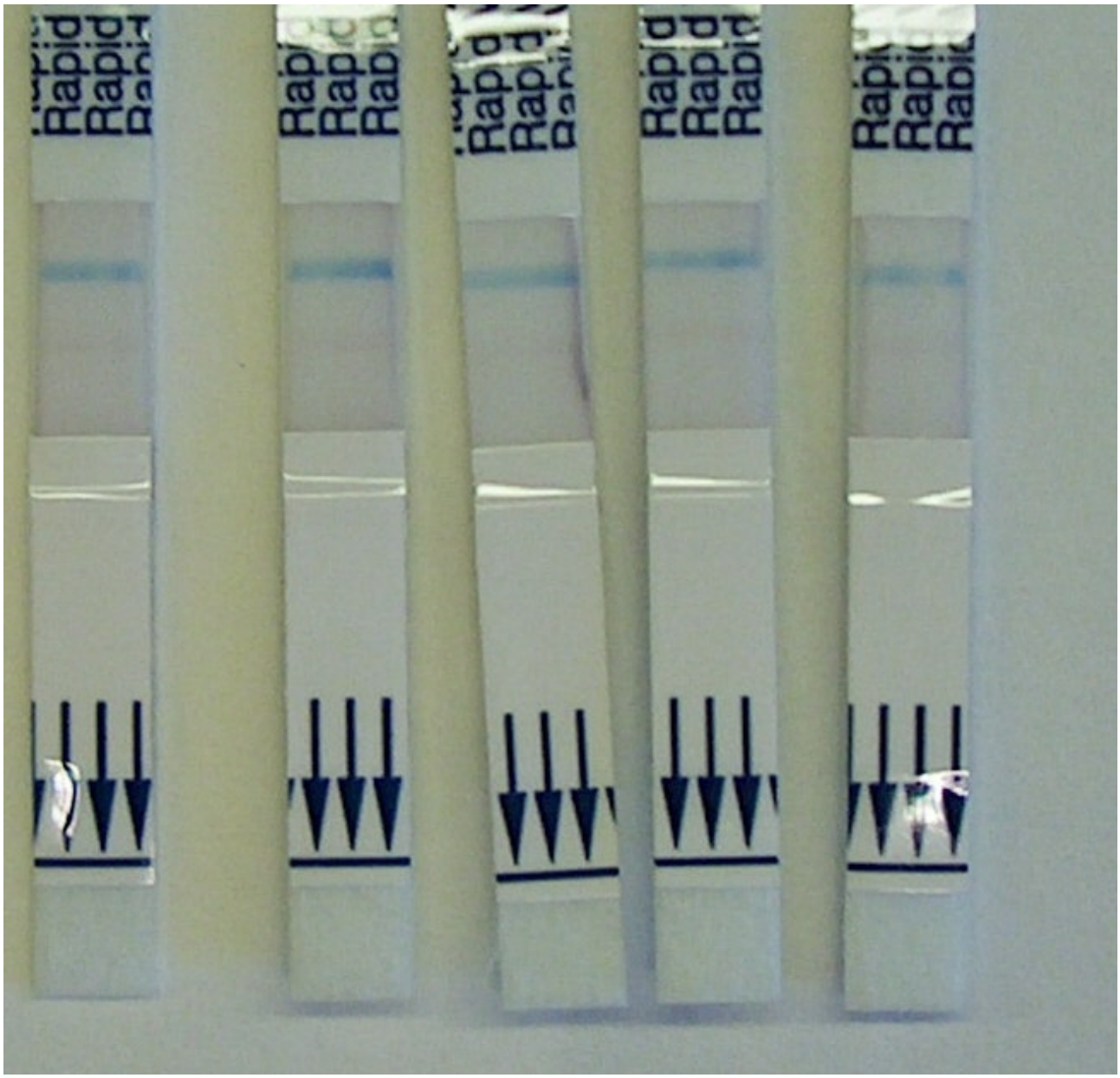

Figure showing RapidVue test strips measuring at the concentration 4 IU/L after 3 minutes.