Quick Response® hCG test

A pregnancy test evaluation in hospital laboratory

ordered by

Perivita A/S

Report from an evaluation
organised by SKUP

SKUP i Danmark, Afdeling KKA, Odense Universitetshospital, 5000 Odense C, tlf. 65412865, www.SKUP.dk

SKUP/2004/37*

CONTENT

SUMMARY

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 evaluation[1]. The result of the test should be read after 5 minutes at 15-30^0 C. The supplier wanted to know, if it could be read earlier.

Measurement principle Quick Response hCG test is an immunochromogen 'hCG Urine Midstream' test method to determine early pregnancy. The test strip is in this testing 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) 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 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 that gives 50 % positive results is 25 IU/L

2) Disagreement of readings: Within-observer disagreement: None < 16 IU/L and ≥ 67 IU/L.
Between-observer disagreement: None for 0-8 IU/L and ≥ 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 Operation of the test were evaluated 'satisfactory', and Time factors '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 a requirement is that 100 % of the tests at 40 IU/L should be positive. How the test will perform in the hands of women that wants to know if they are pregnant has not been evaluated.

PLANNING OF THE EVALUATION

In June 2004 Perivita A/S ordered a U—hCG laboratory evaluation of Quick Response to decide if the test should be marketed in Norway for home testing. The protocol was approved the same month and the evaluation according to the protocol was performed in July 2004. This is the 3rd evaluation made by SKUP for hCG tests using ordinal scale. The evaluation was performed in the Department of Clinical Biochemistry (afd. KKA), 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 important 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 readings (within- and between-observers) or a high time consumption for analysis can be sorted out at this point. If this hospital laboratory evaluation gets good results 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 Perivita 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 Perivita A/S.

Perivita 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 Perivita 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

Producer

Wondsfo Biotech
South China University of Technology
Tianhe, Guangzhou
China

Supplier

Perivita A/S
P. O. Box 57
1403 Langhus

Norway
Phone +47 64879500
Fax +47 64 87 93 47
perivita @perivita.no

Responsible from SKUP

Esther Jensen
Phone +45 6541 2865
Fax +45 6541 1911

Co-workers

Ole Blaabjerg
Ann Jepsen
Nina Brøgger
Phone +45 6541 1955
E-mail SKUP-KKA@ouh.fyns-amt.dk

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 or the test is held in the urine stream for 10 – 15 seconds. The principle of the test is not explained in the insert.

A red control line will appear within a minute indicating that the strip is valid. If there is hCG in the sample, another red test line will appear later. If U—hCG is not present or present at lower levels, only a red control line will be visible. The result of the test should be read after 5 minutes at 15-30 °C.

Reagents and materials supplied.

Quick Response hCG test

Content: Individually packed Test Strips, lot W1040413, Expiration date March 5th 2006
1 Package Insert.

Traceability: no information

Agent in Norway: Perivita A/S

Agent in Denmark: None

Agent in Sweden: None

Test period: July 2004

Writing of Report: August 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 sample from one woman early in pregnancy

Materials

Preparation of tests used in the evaluation

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, 67 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 Auto-Delfia 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 (pt '233') from a pregnant woman, were also first measured on AutoDelfia and then apportioned in 20 glasses and frozen. Before testing they were thawed at room temperature.

The cross reaction experiment was carried out after the protocol:
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 4th International Standard for Chorionic Gonadotropin (75/589).
The cross reaction samples were read randomly together with the samples described above.

REQUIREMENTS TO ANALYTICAL QUALITY AND TO 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[1] 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 hCG 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 as equally important in the SKUP evaluation. Each of the sub-areas within analytical quality and user friendliness ought to achieve ≥ 2 points (= satisfactory).

Each area is subdivided, and each subdivision has the following 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, ≤ 5 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 seven 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 5 minutes. The supplier believes, that the test can be read after 3 minutes. Do the results change after the specified reading time? The test is read also after 10 minutes, which is approximately the time the patient spends at the doctor.

User friendliness

Parameters evaluated

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

Quality Control

Built-in Control Features

The Quick Response hCG test contains built-in control features. The appearance of a red Control Line indicates that a proper volume of fluid was absorbed into the Test Strip and capillary flow occurred. If the Control Line does not develop within 2 minutes, the test result is invalid.

If a background colour that interferes with the ability to read the test result appears, the test result may be invalid. The procedure then has to be reviewed and the test repeated with a new test strip.

External quality control

External positive or negative quality control is possible, but it is not a part of the test package.

EVALUATION PROCEDURES

(under standardised and optimal conditions in the hospital laboratory)

184 U—hCG test samples produced by Cand. Scient Ole Blaabjerg and two Laboratory Technologists from KKA, OUH.

The 0-sample and 6 concentrations of the 4th International Standard for Chorionic Gonadotropin (75/589), 650 IU/ampoule, were each divided into 20 glasses and so was the genuine sample from a woman in early pregnancy (in total 20 × 8=160).
A further 24 samples containing 1st WHO Reference Reagent 2001, (99/650) hCGβ, (99/708) hCGβcf, 75/569 hCGα or 75/551 hCGβ was investigated in the cross reaction/interference experiment. See table p 17.
Four persons from the department of clinical chemistry, OUH, read the 184 U—hCG samples at 2, 3, 5 and 10 minutes. The observers didn't know which samples had the same concentration or the results of the other observers. All together 736 (4 x 184) readings per observer, in total 2944 (4 x 736) 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. The room temperature was 23 °C.

RESULTS

4 persons read 20 samples at each of 8 concentrations of U—hCG in a random order at the time 2, 3, 5 and 10 minutes.

Table 1 Quick Response

2 minutes					
Concentration	R1 positive	R2 positive	R3 positive	R4 positive	in total positive
IU/L, n=20	n=	n=	n=	n=	n=
0	0	0	0	1	1
4	0	0	0	0	0
8	0	0	0	0	0
16	0	1	0	1	2
40	7	6	4	6	23
67	16	16	17	17	66
100	19	19	20	20	78
233-pt	19	19	19	20	77

3 minutes					
Concentration	R1 positive	R2 positive	R3 positive	R4 positive	in total positive
IU/L, n=20	n=	n=	n=	n=	n=
0	0	0	0	0	0
4	0	0	0	0	0
8	0	0	0	0	0
16	1	2	1	2	6
40	11	11	6	13	41
67	18	19	20	20	77
100	20	20	20	20	80
233-pt	20	20	20	20	80

5 minutes					
Concentration	R1 positive	R2 positive	R3 positive	R4 positive	in total positive
IU/L, n=20	n=	n=	n=	n=	n=
0	0	0	0	0	0
4	0	0	0	0	0
8	0	0	0	0	0
16	6	6	6	9	27
40	15	15	13	15	58
67	20	20	20	20	80
100	20	20	20	20	80
233-pt	20	20	20	20	80

10 minutes					
Concentration	R1 positive	R2 positive	R3 positive	R4 positive	in total positive
IU/L, n=20	n=	n=	n=	n=	n=
0	0	0	0	0	0
4	0	0	0	0	0
8	1	1	1	3	6
16	7	7	6	9	29
40	15	15	14	16	60
67	20	20	20	20	80
100	20	20	20	20	80
233-pt	20	20	20	20	80

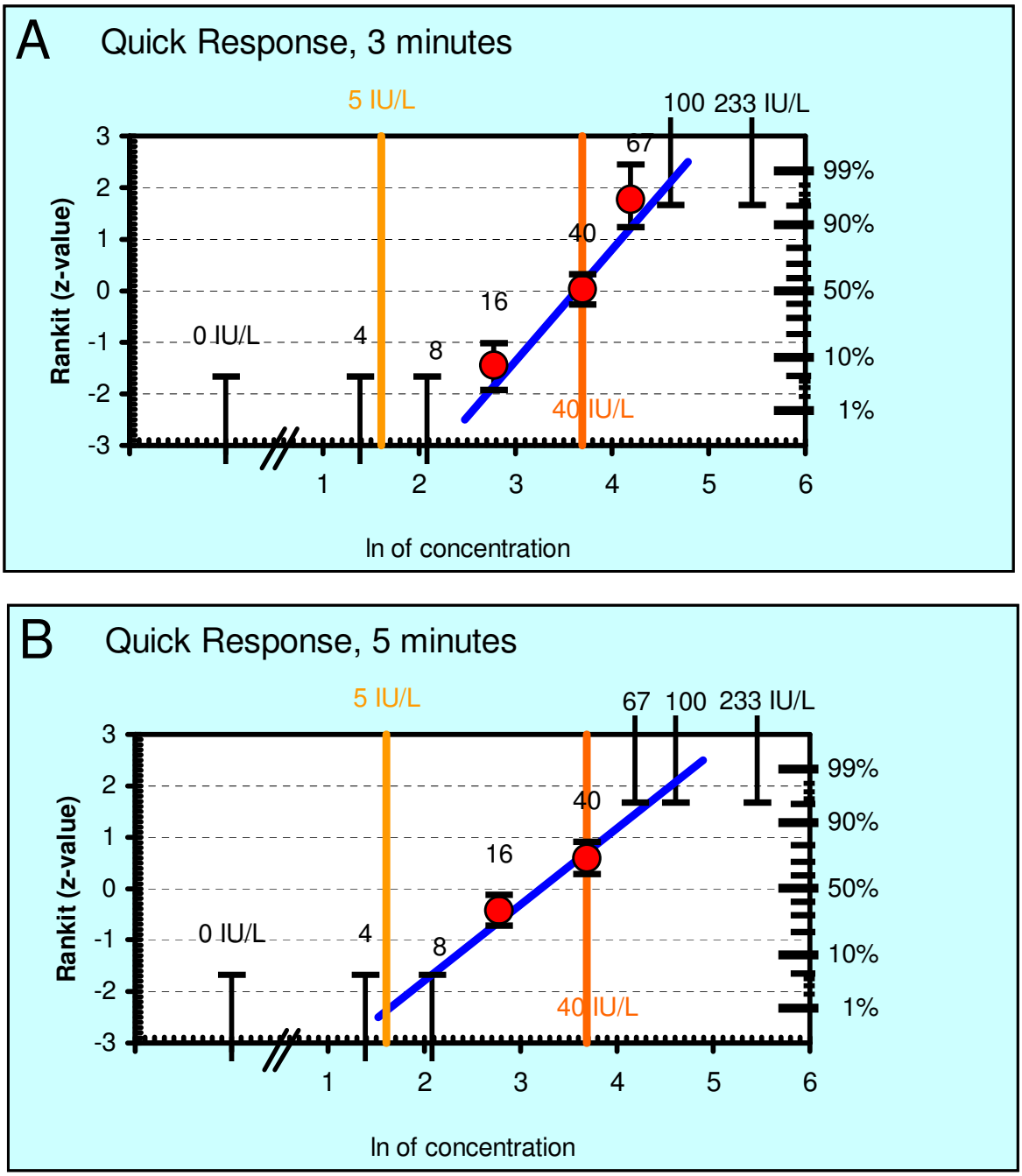
Comments to data in table 1 and table A.

All concentrations of 0, 4 and 8 IU/L is negative after 3, 5 and 10 minutes

All concentrations of 100 and 261 IU/L were positive after 3, 5 and 10 minutes

All concentrations of 67 IU/L were positive after 5 minutes.

Figure 1
Fractions of positive results for eight samples



The fractions of the 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 percents are indicated on the right Y-axis. The abscissa shows the natural logarithms (ln = log e) of the concentration, while the U—hCG concentration IU/L is marked in the plot. For each fraction the 95% confidence interval is plotted.

The figure 1A, after 3 minutes shows that Quick Response hCG test is negative in the concentrations 0, 4 and 8 IU/L and positive for concentrations of 100 IU/L and above. The concentration that gives 50 % positive results is 38 IU/L (geometric mean=50%=(z=0)). The red points are from dilutions of the WHO standard.
Figure 1B, after 5 minutes shows that Quick Response hCG test is negative in the concentrations 0, 4 and 8 IU/L and positive for concentrations of 100 IU/L and above. The concentration that gives 50 % positive results is 25 IU/L (geometric mean=50%=(z=0)). The red points are from dilutions of the WHO standard.

Evaluation of user friendliness

At the evaluation under standardised and optimal conditions in a hospital laboratory, all the fields are filled in. At evaluations in general practice only the white fields are filled in. The ratings of the test persons are marked with coloured fields. Any free comment belonging to the four sub-areas will be placed under the table concerning the area.
A 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 average for the sub-area. 2 or 3 fulfils the expectations, 0 or 1 does 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	-20ºC	2 — 8ºC	15 — 30ºC	2 — 30ºC
Storage conditions of control material	-20ºC	2 — 8ºC	15 — 30ºC	2 — 30ºC
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 is not explained
** Error sources: ‘you have not followed the instructions’ is the only mentioned error
*** The insert is available in Norwegian and English, the test is not to be sold in Denmark and Sweden.

Comments: The Test line and the control line were not always ‘unbroken’. However, it was never a problem for the result. See the picture, page 25.

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

INTERFERENS and CROSS REACTIONS

Content			2 min				3 min				5min				10 min			
Sub units of hCG		intact hCG IU/L	R1	R2	R3	R4	R1	R2	R3	R4	R1	R2	R3	R4	R1	R2	R3	R4
Core fragment	0.4 nmol/L	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Core fragment	0.4 nmol/L	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Core fragment	4.1 nmol/L	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Core fragment	4.1 nmol/L	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Core fragment	4.1 nmol/L	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Core fragment	4.1 nmol/L	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Core fragment	4.1 nmol/L	90	0	0	0	0	0	0	0	0	1	0	0	1	1	0	1	1
Core fragment	4.1 nmol/L	90	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
alfa hCG	70 µg/L	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
alfa hCG	70 µg/L	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
alfa hCG	700 µg/L	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
alfa hCG	700 µg/L	0	0	0	0	0	1	0	0	0	1	1	1	1	1	1	1	1
alfa hCG	700 µg/L	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
alfa hCG	700 µg/L	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
alfa hCG	700 µg/L	90	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
alfa hCG	700 µg/L	90		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
free beta hCG	70 µg/L	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
free beta hCG	70 µg/L	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
free beta hCG	700 µg/L	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
free beta hCG	700 µg/L	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
free beta hCG	700 µg/L	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
free beta hCG	700 µg/L	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
free beta hCG	700 µg/L	90	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1
free beta hCG	700 µg/L	90	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

1 = positive, 0 = negative.

Explanation of the results:

1) The Quick Response hCG test does not measure core fragment or free beta subunits hCG in any concentration.
2) Alfa hCG in high concentration is measured in 3 samples of 4 possible
3) One sample with core fragment and intact HCG 90 IU/L is negative
4) From this, it is not evident if the test measures alfa hCG or intact hCG (or both)

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: 100 % (160 negative of 160)*

1b) ***Percentage positive results at high level****, 40 IU/L: 51 %. 41 positive of 80. All the test was positive at ≥ 100 IU/L.*

1c) ***The concentration that gives 50 % positive results*** *is 40 IU/L*

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

Within-observer disagreement: None < 16 IU/L and none ≥ 100 IU/L.

Between-observer disagreement: None for 0-8 IU/L and ≥ 100 IU/L. In the area from 16 to 67 IU/L the test can have positive or negative result.

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

4) ***Robustness****: The test turns positive at 100 IU/L at 3 minutes.*

The test becames more positive 7 minutes later. (entall, eller du kan la verbet være i fortid: the test became)

EVALUATION OF ANALYTICAL QUALITY AFTER 5 MINUTES

Results, *analytical quality.*

1a) ***Percentage negative results at low level****, ≤ 4 IU/L: 100 % (160 negative of 160)*

1b) ***Percentage positive results at high level****, 40 IU/L: 72 % positive. 58 of 80. At the concentration 67 IU/L all the tests were positive.*

1c) ***The concentration that gives 50 % positive results*** *is 24.7 IU/L*

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

Within-observer disagreement: None < 16 IU/L and none ≥ 67 IU/L.

Between-observer disagreement: None for 0-8 IU/L and ≥ 67 IU/L. In the area from 16 to 40IU/L the test can have positive or negative result.

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

4) ***Robustness****: The test turns positive at 67 IU/L at 5 minutes.*

The test became more positive 5 minutes later. No false positive or false negative results were seen at 10 minutes.

Summary of Analytical Quality

The Danish criteria for good analytical quality of U—hCG tests claim that at 5 IU/L should 100 % of the tests be negative and at 40 IU/L should 100 % of the tests be positive. These requirements are not fulfilled. With this test 100 % positive results are achieved at ≥ 67 IU/L.

Conclusion

Quick Response hCG test had all the tests of 0-8 IU/L negative after 3, 5 and 10 minutes.

After 5 minutes all tests of 67 IU/L and above were positive.

After 3 minutes all tests of 100 IU/L and above were positive.

Under standardised conditions the analytical quality does not fulfil the Danish criteria set for hCG tests, which is that 0 and 4 IU/L should give negative results and 40 IU/L and above should give positive results.

The user friendliness of the test was satisfactory. All the test persons liked the test.

How the test will perform under less standardised conditions in the home testing is not evaluated.

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5) Standardization of Assays for Human Chorionic Gonadotropin**.** Ulf-Håkan Stenman
Clin Chem 2004 50: 798-800

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

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

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

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

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

9) 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.

10) Dansk, Norsk, Svensk og Engelsk indlægsseddel

11) SKUP rapport nr 24

Enclosure A

TABLE A Raw data

	IU/L	Test No	2 minutes				3 minutes				5 minutes				10 minutes			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
'0' Urine	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	43	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	49	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	53	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	56	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	65	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	73	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	83	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	106	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	113	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	132	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	143	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	154	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	168	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
'0' Urine	0	180	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	32	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	38	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	4	71	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	4	105	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	114	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	118	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	134	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	4	179	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	8	10	0	0	0	0	0	0	0	0	0	0	0	0	0	s	s	0
'0'+ 4th IS 75/589	8	18	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	8	46	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	8	68	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	8	75	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

'0'+ 4th IS 75/589	8	87	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	8	122	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	8	129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	8	140	0	0	0	0	0	0	0	0	0	0	0	0	s	0	0	1
'0'+ 4th IS 75/589	8	145	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	8	157	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	8	164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	8	174	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	8	181	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	16	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	16	30	0	0	0	0	0	0	0	0	s	s	s	1	1	s	1	1
'0'+ 4th IS 75/589	16	36	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	16	37	0	s	0	1	s	s	s	1	s	s	s	1	s	s	1	1
'0'+ 4th IS 75/589	16	40	0	0	0	0	0	0	0	0	0	s	0	1	1	s	1	1
'0'+ 4th IS 75/589	16	45	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	16	62	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	16	81	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	16	109	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	16	126	0	0	0	0	0	0	0	0	0	s	s	1	0	s	s	1
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'0'+ 4th IS 75/589	16	153	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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'0'+ 4th IS 75/589	16	175	0	0	0	0	0	s	0	0	s	s	0	1	1	s	s	1
'0'+ 4th IS 75/589	16	178	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
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'0'+ 4th IS 75/589	40	17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	40	24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	40	26	s	1	s	0	1	1	s	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	40	34	0	0	0	0	0	s	0	1	s	s	s	1	s	s	s	1
'0'+ 4th IS 75/589	40	50	0	s	0	0	0	s	0	1	s	s	0	1	1	s	s	1
'0'+ 4th IS 75/589	40	58	0	0	0	0	s	s	0	1	s	s	s	1	1	s	1	1
'0'+ 4th IS 75/589	40	64	s	0	s	1	s	s	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	40	74	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	40	79	0	0	0	1	0	0	0	1	1	s	s	1	1	s	1	1
'0'+ 4th IS 75/589	40	82	s	s	0	0	1	s	0	1	1	s	1	1	1	s	1	1
'0'+ 4th IS 75/589	40	90	0	0	0	0	s	0	0	0	s	s	s	1	1	s	1	1
'0'+ 4th IS 75/589	40	103	s	s	0	1	1	s	1	1	1	s	1	1	1	s	1	1
'0'+ 4th IS 75/589	40	110	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	40	125	0	0	0	0	0	0	0	0	s	s	0	1	s	s	0	1
'0'+ 4th IS 75/589	40	138	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	40	149	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	40	155	0	0	0	0	s	0	0	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	40	176	1	1	s	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	40	183		0	0	0	1	s	0	1	1	1	s	1	1	1	1	1

'0'+ 4th IS 75/589	67	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	11	s	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	19	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	21	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	29	0	s	0	0	0	s	s	1	s	s	s	1	1	s	1	1
'0'+ 4th IS 75/589	67	63	s	s	s	1	s	s	1	1	s	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	69	0	0	0	0	s	0	s	1	s	s	1	1	1	s	1	1
'0'+ 4th IS 75/589	67	80	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	89	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	98	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	108	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	117	0	0	s	0	0	s	s	1	s	s	1	1	1	s	1	1
'0'+ 4th IS 75/589	67	124	1	s	s	1	1	s	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	130	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	139	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	152	1	s	s	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	159	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	161	1	1	s	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	67	167	s	s	s	1	s	s	s	1	s	s	s	1	1	s	s	1
'0'+ 4th IS 75/589	67	171	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	6	s	1	1	1	s	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	13	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	23	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	39	0	s	1	1	s	s	1	1	1	s	1	1	1	s	1	1
'0'+ 4th IS 75/589	100	57	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	72	s	1	s	1	s	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	85	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	92	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	96	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	112	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	120	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	121	1	s	s	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	128	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	133	1	s	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	142	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
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'0'+ 4th IS 75/589	100	172	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
'0'+ 4th IS 75/589	100	182	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	27	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	31	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	35	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	44	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	47	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	59	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	78	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	91	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	99	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	104	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	107	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	115	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1

U-k2	261	123	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	135	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	147	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	151	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	170	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	177	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
U-k2	261	184	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Signature: s,1, 2 = positive, 0 = negative, ? = In doubt, B = not valid

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

Enclosure B
Quick Response.

The picture shows two positive tests. The test line and the control line is ‘broken’, however the result is clearly positive.