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**QuickVue® One-Step hCG Urine**  
**A pregnancy test evaluation in hospital laboratory**  
**ordered by**  
**Medinor A/S, Denmark**

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Report from an evaluation  
organised by SKUP

# Evaluation of QuickVue® One-Step hCG Urine

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## SUMMARY

**Background** Medinor AS ordered a SKUP evaluation of the QuickVue® One-Step hCG Urine (QuickVue hCG) test 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 evaluation<sup>1</sup>.

**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 4<sup>th</sup> 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. (1<sup>st</sup> WHO Reference Reagent 2001. ((99/650) hCG $\beta$ , (99/708) hCG $\beta$ cf, and 75/569 hCG $\alpha$  and 75/551 hCG $\beta$ ). 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,  $\geq 40$  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  $\leq 4$  IU/L and  $\geq 40$  IU/L.  
Between-observer disagreement: None  $\leq 4$  IU/L and  $\geq 40$  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 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 goes 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.

## PLANNING OF THE EVALUATION

In January 2004 Medinor had two hCG tests that could be of interest for the primary health care. A protocol was written and an evaluation according to the protocol was performed in April 2004. This is the 5<sup>th</sup> evaluation made by SKUP for tests using ordinal scale and the first 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 reading (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](http://www.SKUP.NU) (and [www.SKUP.dk](http://www.SKUP.dk)). It will also be available in paper copies.

## ADDRESSES

### Producer

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Worldwide Headquarters  
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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 three drops are added into the sample chamber of the test cassette. The test strip contains monoclonal antibodies against the beta subunit of hCG. If there is hCG in the sample an immuno complex is formed. The complex flows through the test strip by capillary action.

At the ‘T’ the complex will pass polyclonal rabbit anti-hCG, which binds the complex resulting in the formation of a pink-to-purple test line. A blue control line will also appear next to the letter “C” on the test cassette indicating that

- the reagents were mixed and added properly,
- proper volume of fluid entered the test cassette and that
- capillary flow occurred.

A blue control line should always appear in a properly functioning test cassette.

If U—hCG is not present or present at lower levels than 25 IU/L, only a blue control line will be visible. The test should be read after 3 minutes at 15 —30°C.

**Reagents and materials supplied.**

QuickVue® One-Step hCG Urine test

Contents: 25 individually wrapped test cassettes, lot no. 148656

1 Package Insert

1 Procedure Card.

25 Disposable Droppers

Lot no. 701179

Expiration date July 29th 2005.

Traceability: 4<sup>th</sup> International Standard for Chorionic Gonadotropin (75/589)

Agent in Denmark: Medinor A/S, Postbox 321, DK-4000 Roskilde. +45 7015 1041

Agent in Norway: Medinor A/S, P.O Box 94 Bryn, N-0611 Oslo, Phone 47 2207 6500

Agent in Sweden: Medinor AB, Box 1215, SE-181 24 Lidingö, Phone: +46 8 544 812 00

**Test period:** April 2004

**Writing of Report:** May 2004

## Material

4<sup>th</sup> International Standard for Chorionic Gonadotropin (75/589) 650 IU/ampoule<sup>4</sup>

1<sup>st</sup> WHO Reference Reagent 2001. (99/650) hCG $\beta$  0.88 nmol/ampoule<sup>5</sup>

1<sup>st</sup> WHO Reference Reagent 2001. (99/708) hCG $\beta$ cf 1.02 nmol/ampoule<sup>6</sup>

75/569 hCG $\alpha$  (7mg/L)<sup>7</sup>

75/551 hCG $\beta$  (7 mg/l)<sup>8</sup>

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

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

Urine and blood sample 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 tests very late, the cross-reaction experiment was changed to the following:

1<sup>st</sup> WHO Reference Reagent 2001, (99/650) hCG $\beta$ , (99/708) hCG $\beta$ cf ,75/569 hCG $\alpha$  and 75/551 hCG $\beta$  were 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  $\geq 2$  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,  $\leq 5$  IU/L, (Negative results) / (All results)
- 1b) Percentage of positive results at high level,  $\geq 40$  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.****Control features built-in in the test.**

The QuickVue hCG test contains built-in control features. Still the manufacturer recommends that the first samples each day are the quality control samples and that these results are documented.

- The two windows in the test provide a clear-cut readout for positive and negative results. The appearance of a blue line in the Control Window next to the letter "C" provides several forms of control. First, detection of components from the specimen and the internal control are processed concurrently using identical procedures; therefore, the appearance of the control line ensures that functional activity of the detection of the component is maintained. Secondly, the appearance of the control line also ensures that the foil pouch integrity has been maintained and that the test cassette has been stored properly to not compromise its functionality. Third, the appearance of the control line indicates that the proper volume of fluid has entered the test cassette and capillary flow occurred. This would indicate that the test cassette was assembled properly, by acting as a check for all membrane interfaces and proper positioning of components. If the control line does not develop within 3 minutes, the test result is invalid.

A clear background colour in the Result Window indicates that there were no substances in the specimen interfering with the immunological reaction. This area should be white to light pink when reading the test result. If there is a remaining background colour in the Result Window the test result may be invalid. In this case, the user is told to contact the supplier.

**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 users quality assurance plan. A positive control can be bought from the supplier separately and is not part of the test kit. It is recommended that the positive control used should be traceable to the WHO standard.

One positive and one negative control sample should be tested once for each test kit (25 tests), and with each new operator within the test kit, or as otherwise required by the users standard quality control procedures.

If controls 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 women in early pregnancy.

A further 32 samples containing 1<sup>st</sup> WHO Reference Reagent 2001, (99/650) hCG $\beta$ , (99/708) hCG $\beta$ cf, 75/569 hCG $\alpha$  or 75/551 hCG $\beta$  was investigated. In total  $20 \times 8 + 32$  test.

The WHO standards in buffer and in combinations with concentration 7 and 90 were measured in duplicates with high levels of (99/650) hCG $\beta$ , (99/708) hCG $\beta$ cf or 75/569 hCG $\alpha$ .

Four persons from the department of clinical chemistry, OUH, read the 192 U—hCG samples at 3 and 10 minutes. The observer 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		person 1	person 2	person 3	person 4	In total	In total	In total
3 minutes	Concentration IU/L	positive	positive	positive	positive	positive	negative	in doubt
	n=20	n=	n=	n=	n=	n=	n=	n=
	0	0	0	0	0	0	80	0
	4	0	0	0	0	0	76	4
	8	6	2	4	12	24	41	15
	16	19	18	12	20	69	6	5
	Pregnancy '26'	9	4	3	14	30	35	15
	40	20	20	20	20	80	0	0
	100	20	20	20	20	80	0	0
	Pregnancy '233'	20	20	20	20	80	0	0

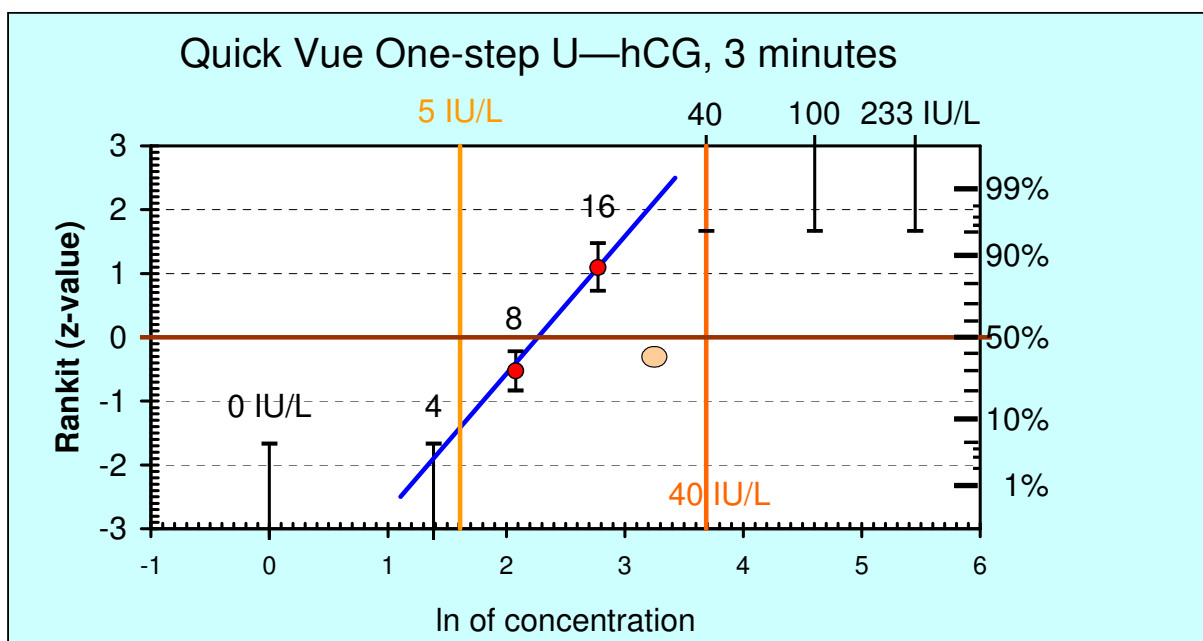
10 minutes		person 1	person 2	person 3	person 4	In total	In total	In total
	Concentration IU/L	positive	positive	positive	positive	positive	Negative	in doubt
	n=20	n=	n=	n=	n=	n=	n=	n=
	0	0	0	0	0	0	80	0
	4	0	0	0	0	0	77	3
	8	10	10	6	14	40	35	5
	16	20	20	16	20	76	2	2
	Pregnancy '26'	4	4	2	11	21	53	6
	40	20	20	20	20	80	0	0
	100	20	20	20	20	80	0	0
	Pregnancy '233'	20	20	20	20	80	0	0

**Comments to data in table 1 and table A.**

It seems correct to read the test after 3 minutes. 97,5 % (156 of 160) of the test results at the concentrations 0 and 4 IU/L were negative and all test results at the concentrations of 40 IU/L and above were positive.

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 percentages could be read on the right Y-axis and the abscissa shows the natural logarithms ( $\ln = \log e$ ) of the the U—hCG concentrations in IU/L.. For each oncentration the 95 % confidence interval is plotted. The figure shows that QuickVue is negative in the concentrations 0 and 4 IU/L and positive for concentrations of 40 IU/L and above. QuickVue is 50 % positive in the concentration 10 IU/L (geometric mean=50 %=( $z=0$ )). The red points are from dilutions of the WHO standard, while the beige point is from a urine sample of a woman in early pregnancy.

## Evaluation of user friendliness

The ratings of the test persons are marked with coloured fields. At evaluations in general practice only the white fields are filled in. At testing in a hospital laboratory, all fields are filled in. Any free comments belonging to the four sub-areas will be placed under 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**

<b>Information in manual / insert about:</b>	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
<b>Rating of the manual / insert</b>			Satisfactory	

<b>Time factors</b>	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 <sup>0</sup> C	2 — 8 <sup>0</sup> C	15 — 30 <sup>0</sup> C	2 — 30 <sup>0</sup> C
Storage conditions of control material	-20 <sup>0</sup> C	2 — 8 <sup>0</sup> C	15 — 30 <sup>0</sup> C	2 — 30 <sup>0</sup> C
<b>Rating of time factors</b>				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
<b>Rating of quality control</b>			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
<b>Rating of operation</b>				Very satisfactory

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

Comments: The test was difficult to read for low borderline positive U—hCG concentrations.

When the test turns positive a band without colour is seen. Then a weak red band appears. It becomes stronger with time. For the concentrations (4), 8, 16 IU/L and for the genuine sample “k1-day 17” there were great individual differences in how to interpret the results. All tests on dilutions 8 and 16 IU/L showed maximum colour at 3 minutes, whereas the genuine samples showed maximum colour after 10 minutes.

There was no doubt or difficulties for the readers at the concentrations 0, 40 and above 40 IU/L.

### 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’.



**INTERFERENCES and CROSS REACTIONS****Table 3**

WHO	concentration	content	QuickVue, n=4
75/569	70 mikrog/L	alfa hCG	0
75/569	700 mikrog/L	alfa hCG	0
75/589 + 75/569	7 IU/L+ 700 mikrog/L	alfa hCG	1
75/589 + 75/569	90 IU/L+ 700 mikrog/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 mikrog/L	free beta hCG	1
75/551	700 mikrog/L	free beta hCG	1
75/589 + 75/551	7 IU/L+ 700 mikrog/L	free beta hCG	1
75/589 + 75/551	90 IU/L+ 700 mikrog/L	free beta hCG	1
99/650	78 mikrog/L	free beta hCG	1
99/650	19.5 mikrog/L	free beta hCG	1
99/650	7.8 mikrog/L	free beta hCG	1
99/650	1.9 mikrog/L	free beta hCG	0

Explanation of the results:

- 1) The QuickVue hCG test measures free beta subunits of hCG. It also measures beta subunits of intact hCG. It does not measure alfa hCG or core fragment of beta hCG.
- 2) High levels of different non-beta hCG from WHO standards do not cause false negative results when added to samples containing hCG

Conversion factors <sup>4,5</sup>						
WHO	content	Molecular weight	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, 0 and 4 IU/L:** 97.5 % (156 negative of 160, 4 doubtful)

1b) **Percentage positive results at high level,  $\geq 40$  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  $\leq 4$  IU/L and none  $\geq 40$  IU/L. In the interval from 8 to 26 IU/L the test can give both positive and negative results.*

*Between-observer disagreement: None  $\leq 4$  IU/L and none  $\geq 40$  IU/L. Four different persons read the tests a bit differently, 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.*

*The colour does not change after the specified reading time.*

*At 10 minutes: False positive: 0 %. False negative: 0 %*

Under standardised conditions the analytical quality fulfils the Danish criteria set for analytical quality of hCG tests.

## **Conclusion**

QuickVue® One-Step hCG test does fulfil the criteria for good performance in this evaluation. Under standardised conditions the analytical quality fulfils the Danish criteria set for analytical quality of 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 is also regarded as satisfactory even if the test was difficult to read for low borderline positive U—hCG concentrations. The lowest concentrations gave a visible band without colour. For higher concentrations a weak red band appeared, it became stronger with time. For the concentrations (4), 8, 16 IU/L and for the genuine sample 'k1' there were great individual differences in how to interpret the results. All tests of 8 and 16 IU/L were generally more positive as time went on, whereas the genuine samples became less positive after 10 minutes compared to 3 minutes.

How the test will perform under less standardised conditions in the primary health care has not been evaluated.

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- 6) NIBSC indlægsseddel 1<sup>st</sup> WHO Reference Reagent 2001. (99/708) hCG $\beta$ cf 1.02 nmol/ampoule
- 7) NIBSC indlægsseddel 75/569 hCG $\alpha$  (7mg/L)
- 8) NIBSC indlægsseddel 75/551 hCG $\beta$  (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

**TABLE A**

Raw data

**QuickVue One-Step Urine hCG test**

	IU/L Concentration	Test No	3 minutes				10 minutes			
			person1	person2	person3	person4	person1	person2	person3	person4
'0'- urine	0	4	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	0	0	0	?
'0'+ 4th IS 75/589	4	24	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	28	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	37	0	?	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	43	0	?	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	51	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	60	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	69	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	78	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	95	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	103	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	114	0	0	0	?	0	0	0	?
'0'+ 4th IS 75/589	4	119	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	121	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	129	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	142	0	0	0	?	0	0	0	?
'0'+ 4th IS 75/589	4	148	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	158	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	165	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	4	174	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	8	5	s	1	1	1	s	s	1	1
'0'+ 4th IS 75/589	8	9	0	?	1	1	0	0	1	1
'0'+ 4th IS 75/589	8	17	0	?	0	0	0	0	0	1
'0'+ 4th IS 75/589	8	25	0	0	0	1	0	0	0	1
'0'+ 4th IS 75/589	8	44	0	0	0	1	s	s	0	1
'0'+ 4th IS 75/589	8	49	0	?	0	1	s	s	1	1
'0'+ 4th IS 75/589	8	63	s	0	0	0	0	0	0	?
'0'+ 4th IS 75/589	8	74	0	0	1	1	0	0	1	?
'0'+ 4th IS 75/589	8	80	0	?	0	1	0	0	0	1
'0'+ 4th IS 75/589	8	90	0	?	?	1	1	1	?	1
'0'+ 4th IS 75/589	8	93	s	0	0	0	s	s	0	0
'0'+ 4th IS 75/589	8	100	1	?	0	?	s	s	0	1
'0'+ 4th IS 75/589	8	111	0	0	1	0	0	0	1	0
'0'+ 4th IS 75/589	8	131	0	?	0	0	0	0	0	1
'0'+ 4th IS 75/589	8	137	s	?	0	?	1	1	0	1
'0'+ 4th IS 75/589	8	147	0	0	0	0	0	0	0	0
'0'+ 4th IS 75/589	8	153	0	?	0	1	0	0	0	1
'0'+ 4th IS 75/589	8	161	s	?	0	1	s	s	1	1

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

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

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

*Figure 2*

*Example of 4 positive test (beta hCG, 75/551)*

