

External Quality Assessment Scheme

Pregnancy test Round 1, 2023

Specimens

Please find enclosed 2 fresh liquid human urines S001 and S002, each 1mL.

Caution

Quality control specimens derived from human urine must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases.

Examinations

Choriogonadotropin (urine, qualitative), U -hCG-O

Storage and use

Analyze samples immediately after arrival. Analyse as patient samples.
The samples can be stored one week in refrigerator (2 ... 8 °C).

Result reporting

Please enter the results and methods via LabScala. If you can't find your method from the dropdown menu, please contact the EQA Coordinator.

S001:



S002:



2023-03-06

INSTRUCTIONS

Product no. 3270
LQ744323011-012/FI

Subcontracting: Sample
preparation, Sample pretesting

If the kit is incomplete or contains
damaged specimens, please report
immediately to info@labquality.fi.

The results should be
reported no later than
March 31, 2023.

Inquiries

EQA Coordinator
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Labquality

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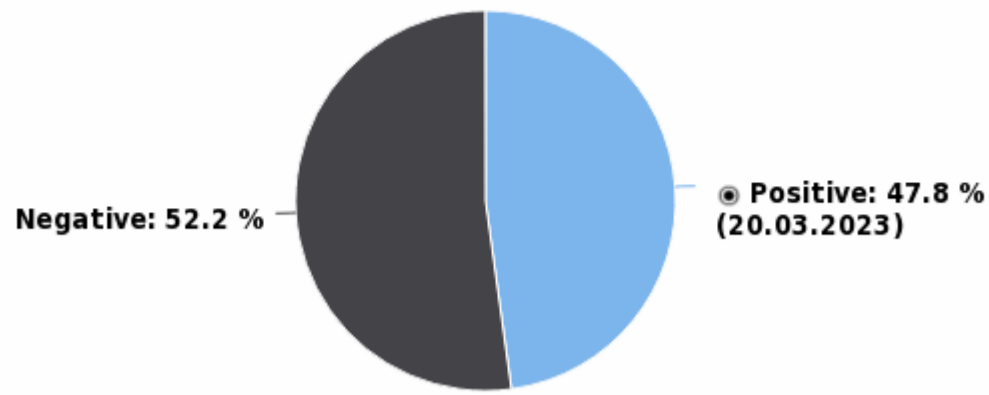
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www.labquality.com

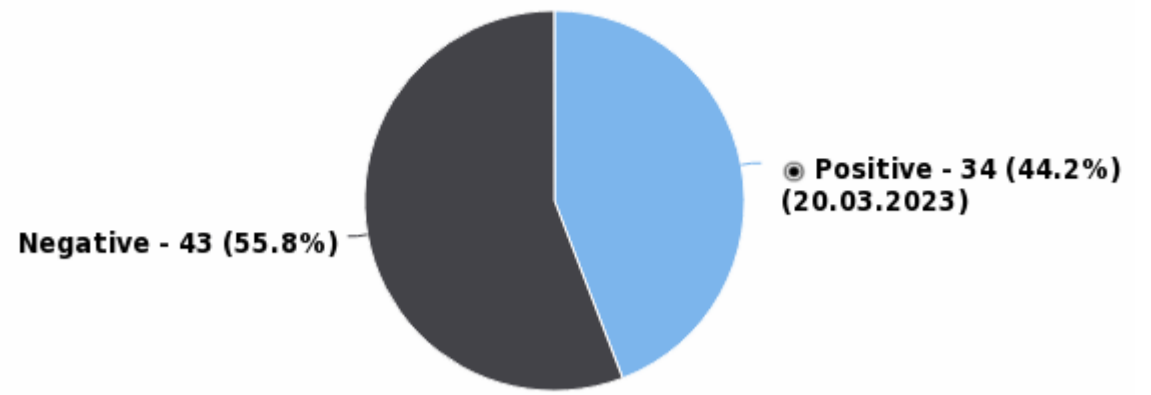


Sample S001|Choriogonadotropin| 1

Sample S001 - All methods



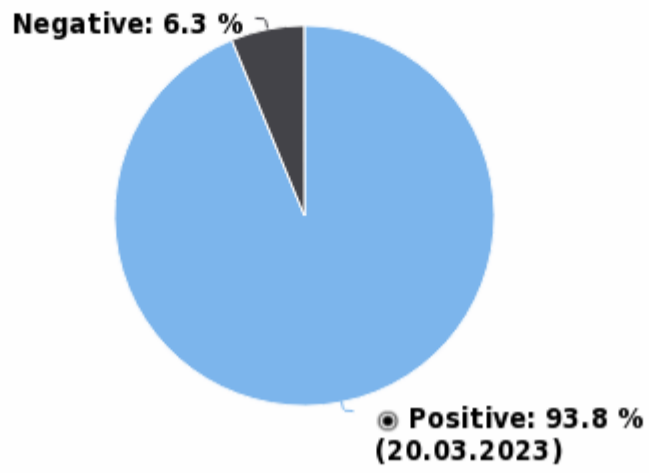
Sample S001 - My method



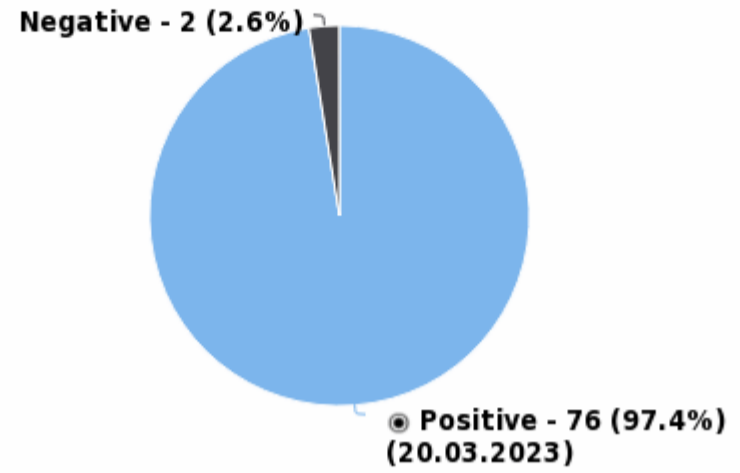
Methodics name	Total	Positive	Negative
Alere hCG Cassette (U 25 IU/l)	4	3	1
Alere hCG Combo Cassette (S+U 25 IU/l)	2	2	0
Alere TestPack +Plus hCG Combo (25 IU/l)	1	0	1
Alere TestPack +Plus hCG with OBC (S+U 25 IU/l)	5	3	2
Alltest FHC-202	34	6	28
Atlas link One Step Strip Style hCG Pregnancy Test (25 IU/l)	1	0	1
Beortek S.A., hCG s&u BALEA	1	0	1
Biognost, GraviGnost Ultra hCG (10 mIU/l)	1	1	0
Biomaxima hCG test (25 IU/l)	2	2	0
Biosynex Exacto rapid urine pregnancy test (10 mU/ml)	1	1	0
Biosynex Fumouze hCG Combo Cassette 20	2	1	1
Biosynex Fumouze minitest hCG 10	2	2	0
Biosynex hcg Strip test	1	0	1
Biosynex hCG 10 BSS (10 U/l)	5	3	2
Biosynex hCG 20	10	6	4
Biotech hCG Rapid Strip (25 IU/l)	2	2	0
Dipro hCG strip	1	0	1
Hangzhou AllTest Biotech hCG Pregnancy Rapid Test Cassette	14	6	8
Hangzhou AllTest Biotech hCG Pregnancy Rapid Test Dipstick	2	1	1
Hangzhou Alltest Biotech Pregnancy (hCG) Enhanced Sensitivity Rapid Test Cassette (10 mIU/mL)	1	1	0
Hydrex hCG Combo Test (20 IU/l)	2	0	2
Koroglu Medical Devices Ltd., Laboquick	1	1	0
Mexacare, hCG testkassette (10 mIU/mL)	1	1	0
MONLAB hCG Pregnancy Rapid Test Cassette (S+U 10 IU/l)	5	4	1
Nal von Minden Nadal hCG Tests (S+U 10 IU/l)	4	4	0
Nal von Minden Nadal hCG Tests (S+U 25 IU/l)	6	4	2
Quidel QuickVue One Step hCG Combo (U+S 25 IU/l)	14	7	7
Siemens Clinitest hCG (25 IU/l)	3	3	0
Stamar, hCG (25 IU/L)	1	0	1
Sure Screen Diagn. hCG One Step (U+S 25 IU/l)	1	1	0
Ultimed hCG	77	34	43
Not responded	5		
Total	207	99	108

Sample S002|Choriogonadotropin| 1

Sample S002 - All methods



Sample S002 - My method



Methodics name	Total	Positive	Negative
Alere hCG Cassette (U 25 IU/l)	4	4	0
Alere hCG Combo Cassette (S+U 25 IU/l)	2	2	0
Alere TestPack +Plus hCG Combo (25 IU/l)	1	1	0
Alere TestPack +Plus hCG with OBC (S+U 25 IU/l)	5	5	0
Alltest FHC-202	34	29	5
Atlas link One Step Strip Style hCG Pregnancy Test (25 IU/l)	1	1	0
Beortek S.A., hCG s&u BALEA	1	1	0
Biognost, GraviGnost Ultra hCG (10 mIU/l)	1	1	0
Biomaxima hCG test (25 IU/l)	2	2	0
Biosynex Exacto rapid urine pregnancy test (10 mU/ml)	1	1	0
Biosynex Fumouze hCG Combo Cassette 20	2	2	0
Biosynex Fumouze minitest hCG 10	2	2	0
Biosynex hcg Strip test	1	1	0
Biosynex hCG 10 BSS (10 U/l)	5	5	0
Biosynex hCG 20	10	9	1
Biotech hCG Rapid Strip (25 IU/l)	2	2	0
Dipro hCG strip	1	1	0
Hangzhou AllTest Biotech hCG Pregnancy Rapid Test Cassette	14	12	2
Hangzhou AllTest Biotech hCG Pregnancy Rapid Test Dipstick	2	2	0
Hangzhou Alltest Biotech Pregnancy (hCG) Enhanced Sensitivity Rapid Test Cassette (10 mIU/mL)	1	1	0
Hydrex hCG Combo Test (20 IU/l)	2	2	0
Koroglu Medical Devices Ltd., Laboquick	1	1	0
Mexacare, hCG testkassette (10 mIU/mL)	1	1	0
MONLAB hCG Pregnancy Rapid Test Cassette (S+U 10 IU/l)	5	5	0
Nal von Minden Nadal hCG Tests (S+U 10 IU/l)	4	4	0
Nal von Minden Nadal hCG Tests (S+U 25 IU/l)	6	4	2
Quidel QuickVue One Step hCG Combo (U+S 25 IU/l)	14	14	0
Siemens Clinitest hCG (25 IU/l)	3	3	0
Stamar, hCG (25 IU/L)	1	0	1
Sure Screen Diagn. hCG One Step (U+S 25 IU/l)	1	1	0
Ultimed hCG	78	76	2
Not responded	4		
Total	208	195	13

Sample S001|Choriogonadotropin

Methodics name	Total	Positive	Negative
Alere hCG Cassette (U 25 IU/l)	4	3	1
Alere hCG Combo Cassette (S+U 25 IU/l)	2	2	0
Alere TestPack +Plus hCG Combo (25 IU/l)	1	0	1
Alere TestPack +Plus hCG with OBC (S+U 25 IU/l)	5	3	2
Alltest FHC-202	34	6	28
Atlas link One Step Strip Style hCG Pregnancy Test (25 IU/l)	1	0	1
Beortek S.A., hCG s&u BALEA	1	0	1
Biognost, GraviGnost Ultra hCG (10 mIU/l)	1	1	0
Biomaxima hCG test (25 IU/l)	2	2	0
Biosynex Exacto rapid urine pregnancy test (10 mU/ml)	1	1	0
Biosynex Fumouze hCG Combo Cassette 20	2	1	1
Biosynex Fumouze minitest hCG 10	2	2	0
Biosynex hcg Strip test	1	0	1
Biosynex hCG 10 BSS (10 U/l)	5	3	2
Biosynex hCG 20	10	6	4
Biotech hCG Rapid Strip (25 IU/l)	2	2	0
Dipro hCG strip	1	0	1
Hangzhou AllTest Biotech hCG Pregnancy Rapid Test Cassette	14	6	8
Hangzhou AllTest Biotech hCG Pregnancy Rapid Test Dipstick	2	1	1
Hangzhou Alltest Biotech Pregnancy (hCG) Enhanced Sensitivity Rapid Test Cassette (10 mIU/mL)	1	1	0
Hydrex hCG Combo Test (20 IU/l)	2	0	2
Koroglu Medical Devices Ltd., Laboquick	1	1	0
Mexacare, hCG testkassette (10 mIU/mL)	1	1	0
MONLAB hCG Pregnancy Rapid Test Cassette (S+U 10 IU/l)	5	4	1
Nal von Minden Nadal hCG Tests (S+U 10 IU/l)	4	4	0
Nal von Minden Nadal hCG Tests (S+U 25 IU/l)	6	4	2
Quidel QuickVue One Step hCG Combo (U+S 25 IU/l)	14	7	7
Siemens Clinitest hCG (25 IU/l)	3	3	0
Stamar, hCG (25 IU/L)	1	0	1
Sure Screen Diagn. hCG One Step (U+S 25 IU/l)	1	1	0
Ultimed hCG	77	34	43
Not responded	5		
Total	207	99	108

Sample S002|Choriogonadotropin

Methodics name	Total	Positive	Negative
Alere hCG Cassette (U 25 IU/l)	4	4	0
Alere hCG Combo Cassette (S+U 25 IU/l)	2	2	0
Alere TestPack +Plus hCG Combo (25 IU/l)	1	1	0
Alere TestPack +Plus hCG with OBC (S+U 25 IU/l)	5	5	0
Alltest FHC-202	34	29	5
Atlas link One Step Strip Style hCG Pregnancy Test (25 IU/l)	1	1	0
Beortek S.A., hCG s&u BALEA	1	1	0
Biognost, GraviGnost Ultra hCG (10 mIU/l)	1	1	0
Biomaxima hCG test (25 IU/l)	2	2	0
Biosynex Exacto rapid urine pregnancy test (10 mU/ml)	1	1	0
Biosynex Fumouze hCG Combo Cassette 20	2	2	0
Biosynex Fumouze minitest hCG 10	2	2	0
Biosynex hcg Strip test	1	1	0
Biosynex hCG 10 BSS (10 U/l)	5	5	0
Biosynex hCG 20	10	9	1
Biotech hCG Rapid Strip (25 IU/l)	2	2	0
Dipro hCG strip	1	1	0
Hangzhou AllTest Biotech hCG Pregnancy Rapid Test Cassette	14	12	2
Hangzhou AllTest Biotech hCG Pregnancy Rapid Test Dipstick	2	2	0
Hangzhou Alltest Biotech Pregnancy (hCG) Enhanced Sensitivity Rapid Test Cassette (10 mIU/mL)	1	1	0
Hydrex hCG Combo Test (20 IU/l)	2	2	0
Koroglu Medical Devices Ltd., Laboquick	1	1	0
Mexacare, hCG testkassette (10 mIU/mL)	1	1	0
MONLAB hCG Pregnancy Rapid Test Cassette (S+U 10 IU/l)	5	5	0
Nal von Minden Nadal hCG Tests (S+U 10 IU/l)	4	4	0
Nal von Minden Nadal hCG Tests (S+U 25 IU/l)	6	4	2

Quidel QuickVue One Step hCG Combo (U+S 25 IU/l)	14	14	0
Siemens Clinitest hCG (25 IU/l)	3	3	0
Stamar, hCG (25 IU/L)	1	0	1
Sure Screen Diagn. hCG One Step (U+S 25 IU/l)	1	1	0
Ultimed hCG	78	76	2
Not responded	4		
Total	208	195	13

External Quality Assessment Scheme

Pregnancy test (urine) Round 1, 2023

Specimens

Sample S001 (LQ744323011) and Sample S002 (LQ744323012) were fresh liquid human urine (pool). Based on the pretesting and the results of this round, the samples are homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

Specimen S001: LQ744323011 13 IU/L

Specimen S002: LQ744323012 32 IU/L

The hCG concentrations were measured with hCG STAT (cobas e411/Roche Diagnostics).

Report info

The laboratory-specific reports and global reports contain the results listed by the method information. It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments - Expert

The hCG concentration in sample S001 was 13 IU/L. Based on the concentration of the sample, the result was expected to be negative for tests with a sensitivity limit of 20/25 IU/L and positive for tests with a sensitivity limit of 10 IU/L. The reported results were partly negative and partly positive, and did not follow the nominal sensitivity limit in all respects.

The measured hCG concentration of sample S002 was 32 IU/L. As expected due to the concentration, the reported results were mostly positive.

Annex

Annex 1. POCT interpretation guidelines.

End of report

Annex 1.

Own result outside acceptable results of own method group

- Please read the test manual.
- Check that the device is working properly and tests/reagents are the correct ones and in right temperature. Check your measurement technique.
- The tests/device's own or unit's internal controls should be used regularly as instructed by the meter manufacturer / laboratory.
- Contact the person in charge at the support laboratory or the device manufacturer.

2023-04-20

FINAL REPORT

Product no. 3270

Subcontracting: Sample preparation,
sample pretesting

Samples sent	2023-03-06
Round closed	2023-03-31
Final report	2023-04-20

Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

Authorized by

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