

External Quality Assessment Scheme

Faecal occult blood, qualitative Round 1, 2023

Specimens

Please find enclosed 2 samples S001 and S002 (artificial liquids), each 0.5 mL.

Caution

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAgAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Examinations

F -Hb-O

Storage and use

Specimens are artificial liquids that may contain human haemoglobin, they do not contain faeces. Analyse as patient samples. Analysis is requested to be done immediately after arrival of the samples. If this is not possible, please store the samples at +2 ... +8 °C before use. Please mark the date of analysis to LabScala.

Please note!

Use 40 µL of the sample at room temperature for the test and follow the test kit instructions.

NOTE:

- If you use Actim Faecal Blood test and the volume of the buffer tube is 3 mL, please put 12 µL EQA sample to the buffer tube, thank you.

Result reporting

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

S001:



S002:



2023-01-31

INSTRUCTIONS

Product no. 2750
LQ747523011-012/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 **February 23, 2023.**

Inquiries

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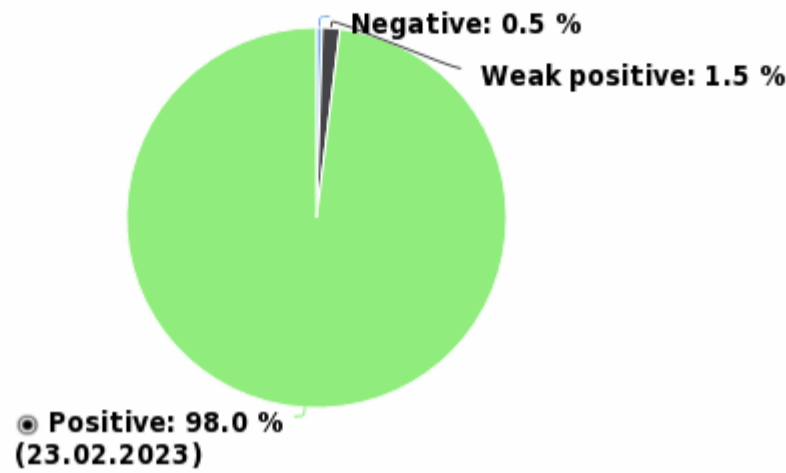
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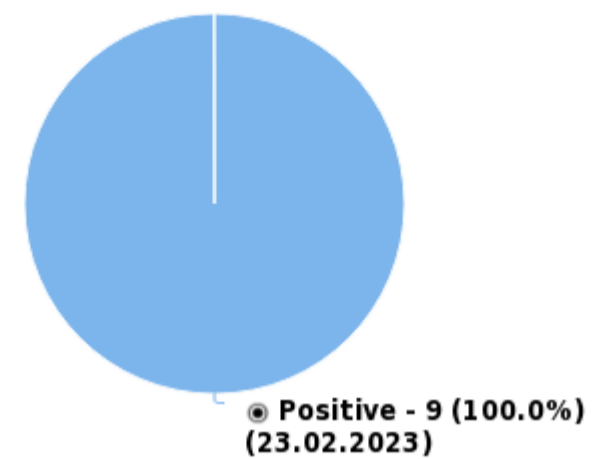


Sample S001|F -Hb-O| 1

Sample S001 - All methods



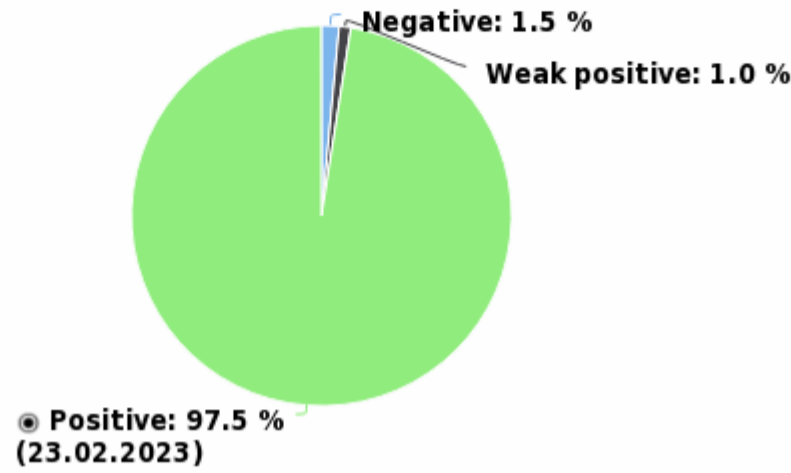
Sample S001 - My method



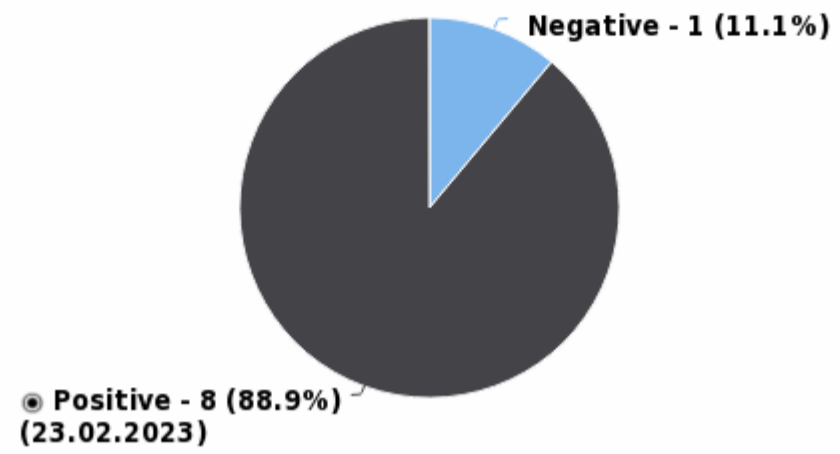
Methodics name	Total	Negative	Weak positive	Positive
Aidian (Orion Diagnostica), QR go iFOBT	1	0	0	1
Aidian (Orion Diagnostica), QuikRead FOB	3	0	0	3
All Diag, COMBO Hb & Tf	1	0	0	1
Ameritek, Occult Blood tests	1	0	0	1
Assure Tech (Hangzhou) Co., Ltd., Ecotest FOB	1	0	0	1
BioGnost, HemoGnost	1	0	0	1
Biohit, Colonview	1	0	0	1
Biomaxima, FOB Cassette	9	0	0	9
Biosynex HEMOTEST	4	0	0	4
Biosynex HEMOTRUST	23	0	0	23
Biotech, ChemTrue	2	0	0	2
CARE diagnostica, ImmoCARE-C	1	0	0	1
CerTest FOB ONE STEP human haemoglobin CARD TEST	2	0	1	1
CerTest FOB-Transferrin	1	0	0	1
CTKBiotech, OnSite FOB	9	0	0	9
Dedisio FOB test cassette	1	0	0	1
Hangzhou AllTest Biotech, FOB Test kit	1	0	0	1
Healgen, iFOB Faecal Occult Blood Rapid Test	1	0	0	1
Healgen Scientific, One Step Rapid Test Kit-iFOB	4	0	0	4
Hemosure iFOB Test	1	0	0	1
Human, Hexagon OBTi	3	1	0	2
Hydrex Diagnostics, FOB Test	7	0	0	7
Immunostics, Hema screen	5	0	0	5
In House Method	2	0	1	1
Koroglu Medical, Laboquick FOB test	3	0	0	3
Medix Biochemica, Actim Faecal Blood	54	0	0	54
Med-Kjemi, hemo FEC	3	0	0	3
Monlab, FOB Monlab test	7	0	0	7
Nal von Minden, Nadal FOB	19	0	0	19
Salofa Oy, Analyz FOB Test	1	0	0	1
Sentinel Diagnostics, FOB Gold	1	0	0	1
Servibio, HEMSIGN 4	14	0	0	14
Stamar, Hemotest	2	0	0	2
Standard Diagnostics, SD Bioline FOB	3	0	0	3
SureScreen, FOB One step faecal occult blood	1	0	0	1
Teco Diagnostics Faecal Occult Blood Cassette	1	0	0	1
Türklab Tibbi Malzemeler San Tic, hHb FOB TOYO Diagn	1	0	0	1
Ultimed, Faecal occult blood test cassette	3	0	0	3
Vitassay FOB	1	0	0	1
YD Diagnostics, OcculTech Faecal Occult Blood Rapid Test	1	0	1	0
Zhejiang, Faecal Occult Blood test	2	0	0	2
Not responded	5			
Total	202	1	3	198

Sample S002|F -Hb-O| 1

Sample S002 - All methods



Sample S002 - My method



Methodics name	Total	Negative	Weak positive	Positive
Aidian (Orion Diagnostica), QR go iFOBT	1	0	0	1
Aidian (Orion Diagnostica), QuikRead FOB	3	0	0	3
All Diag, COMBO Hb & Tf	1	0	0	1
Ameritek, Occult Blood tests	1	0	0	1
Assure Tech (Hangzhou) Co., Ltd., Ecotest FOB	1	0	0	1
BioGnost, HemoGnost	1	0	0	1
Biohit, Colonview	1	0	0	1
Biomaxima, FOB Cassette	9	1	0	8
Biosynex HEMOTEST	4	0	0	4
Biosynex HEMOTRUST	23	0	0	23
Biotech, ChemTrue	2	0	0	2
CARE diagnostica, ImmoCARE-C	1	0	0	1
CerTest FOB ONE STEP human haemoglobin CARD TEST	2	0	0	2
CerTest FOB-Transferrin	1	0	0	1
CTKBiotech, OnSite FOB	9	1	0	8
Dedisio FOB test cassette	1	0	1	0
Hangzhou AllTest Biotech, FOB Test kit	1	0	0	1
Healgen, iFOB Faecal Occult Blood Rapid Test	1	0	0	1
Healgen Scientific, One Step Rapid Test Kit-iFOB	4	0	0	4
Hemosure iFOB Test	2	0	0	2
Human, Hexagon OBTi	3	0	0	3
Hydrex Diagnostics, FOB Test	7	0	0	7
Immunostics, Hema screen	5	0	0	5
In House Method	1	0	0	1
Koroglu Medical, Laboquick FOB test	3	0	0	3
Medix Biochemica, Actim Faecal Blood	54	0	0	54
Med-Kjemi, hemo FEC	3	0	0	3
Monlab, FOB Monlab test	7	0	0	7
Nal von Minden, Nadal FOB	19	0	0	19
Salofa Oy, Analyz FOB Test	1	0	0	1
Sentinel Diagnostics, FOB Gold	1	0	0	1
Servibio, HEMSIGN 4	14	0	0	14
Stamar, Hemotest	2	0	0	2
Standard Diagnostics, SD Bioline FOB	3	1	0	2
SureScreen, FOB One step faecal occult blood	1	0	0	1
Teco Diagnostics Faecal Occult Blood Cassette	1	0	0	1
Türklab Tibbi Malzemeler San Tic, hHb FOB TOYO Diagn	1	0	0	1
Ultimed, Faecal occult blood test cassette	3	0	0	3
Vitassay FOB	1	0	0	1
YD Diagnostics, OcculTech Faecal Occult Blood Rapid Test	1	0	1	0
Zhejiang, Faecal Occult Blood test	2	0	0	2
Not responded	5			
Total	202	3	2	197

Sample S001|F -Hb-O

Methodics name	Total	Negative	Weak positive	Positive
Aidian (Orion Diagnostica), QR go iFOBT	1	0	0	1
Aidian (Orion Diagnostica), QuikRead FOB	3	0	0	3
All Diag, COMBO Hb & Tf	1	0	0	1
Ameritek, Occult Blood tests	1	0	0	1
Assure Tech (Hangzhou) Co., Ltd., Ecotest FOB	1	0	0	1
BioGnost, HemoGnost	1	0	0	1
Biohit, Colonview	1	0	0	1
Biomaxima, FOB Cassette	9	0	0	9
Biosynex HEMOTEST	4	0	0	4
Biosynex HEMOTRUST	23	0	0	23
Biotech, ChemTrue	2	0	0	2
CARE diagnostica, ImmoCARE-C	1	0	0	1
CerTest FOB ONE STEP human haemoglobin CARD TEST	2	0	1	1
CerTest FOB-Transferrin	1	0	0	1
CTKBiotech, OnSite FOB	9	0	0	9
Dedisio FOB test cassette	1	0	0	1
Hangzhou AllTest Biotech, FOB Test kit	1	0	0	1
Healgen, iFOB Faecal Occult Blood Rapid Test	1	0	0	1
Healgen Scientific, One Step Rapid Test Kit-iFOB	4	0	0	4
Hemosure iFOB Test	1	0	0	1
Human, Hexagon OBTi	3	1	0	2
Hydrex Diagnostics, FOB Test	7	0	0	7
Immunostics, Hema screen	5	0	0	5
In House Method	2	0	1	1
Koroglu Medical, Laboquick FOB test	3	0	0	3
Medix Biochemica, Actim Faecal Blood	54	0	0	54
Med-Kjemi, hemo FEC	3	0	0	3
Monlab, FOB Monlab test	7	0	0	7
Nal von Minden, Nadal FOB	19	0	0	19
Salofa Oy, Analyz FOB Test	1	0	0	1
Sentinel Diagnostics, FOB Gold	1	0	0	1
Servibio, HEMSIGN 4	14	0	0	14
Stamar, Hemotest	2	0	0	2
Standard Diagnostics, SD Bioline FOB	3	0	0	3
SureScreen, FOB One step faecal occult blood	1	0	0	1
Teco Diagnostics Faecal Occult Blood Cassette	1	0	0	1
Türklab Tibbi Malzemeler San Tic, hHb FOB TOYO Diagn	1	0	0	1
Ultimed, Faecal occult blood test cassette	3	0	0	3
Vitassay FOB	1	0	0	1
YD Diagnostics, OcculTech Faecal Occult Blood Rapid Test	1	0	1	0
Zhejiang, Faecal Occult Blood test	2	0	0	2
Not responded	5			
Total	202	1	3	198

Sample S002|F -Hb-O

Methodics name	Total	Negative	Weak positive	Positive
Aidian (Orion Diagnostica), QR go iFOBT	1	0	0	1
Aidian (Orion Diagnostica), QuikRead FOB	3	0	0	3
All Diag, COMBO Hb & Tf	1	0	0	1
Ameritek, Occult Blood tests	1	0	0	1
Assure Tech (Hangzhou) Co., Ltd., Ecotest FOB	1	0	0	1
BioGnost, HemoGnost	1	0	0	1
Biohit, Colonview	1	0	0	1
Biomaxima, FOB Cassette	9	1	0	8
Biosynex HEMOTEST	4	0	0	4
Biosynex HEMOTRUST	23	0	0	23
Biotech, ChemTrue	2	0	0	2
CARE diagnostica, ImmoCARE-C	1	0	0	1
CerTest FOB ONE STEP human haemoglobin CARD TEST	2	0	0	2
CerTest FOB-Transferrin	1	0	0	1
CTKBiotech, OnSite FOB	9	1	0	8
Dedisio FOB test cassette	1	0	1	0

Hangzhou AllTest Biotech, FOB Test kit	1	0	0	1
Healgen, iFOB Faecal Occult Blood Rapid Test	1	0	0	1
Healgen Scientific, One Step Rapid Test Kit-iFOB	4	0	0	4
Hemosure iFOB Test	2	0	0	2
Human, Hexagon OBTi	3	0	0	3
Hydrex Diagnostics, FOB Test	7	0	0	7
Immunostics, Hema screen	5	0	0	5
In House Method	1	0	0	1
Koroglu Medical, Laboquick FOB test	3	0	0	3
Medix Biochemica, Actim Faecal Blood	54	0	0	54
Med-Kjemi, hemo FEC	3	0	0	3
Monlab, FOB Monlab test	7	0	0	7
Nal von Minden, Nadal FOB	19	0	0	19
Salofa Oy, Analyz FOB Test	1	0	0	1
Sentinel Diagnostics, FOB Gold	1	0	0	1
Servibio, HEMSIGN 4	14	0	0	14
Stamar, Hemotest	2	0	0	2
Standard Diagnostics, SD Bioline FOB	3	1	0	2
SureScreen, FOB One step faecal occult blood	1	0	0	1
Teco Diagnostics Faecal Occult Blood Cassette	1	0	0	1
Türklab Tibbi Malzemeler San Tic, hHb FOB TOYO Diagn	1	0	0	1
Ultimed, Faecal occult blood test cassette	3	0	0	3
Vitassay FOB	1	0	0	1
YD Diagnostics, OcculTech Faecal Occult Blood Rapid Test	1	0	1	0
Zhejiang, Faecal Occult Blood test	2	0	0	2
Not responded	5			
Total	202	3	2	197

External Quality Assessment Scheme

Faecal occult blood, qualitative Round 1, 2023

Specimens

Sample S001 (LQ747523011) and Sample S002 (LQ747523012) were liquid artificial specimens that may contain human haemoglobin. Based on the previous tests (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: LQ747523011 positive

Specimen S002: LQ747523012 positive

The Hb concentrations were quantitated by Actim Fecal Blood method.

Report info

It is important to read the Final report first, because it contains important information of the samples and results in each round. The laboratory-specific histograms and global reports contain the results listed by the method information. The superiority or sensitivity of the tests should not be compared on the basis of this quality assessment sample, as for practical reasons the same amount of hemoglobin is added to all tests and the number of sample and dilution required for the test is not taken into account. In actual patient samples, different tests take different grams of stool sample and the sensitivity of the tests is calculated accordingly.

Your own result should be compared only with other results in the same method group. If the EQA sample is higher than the sensitivity limit of your own test (cut off, which can be inquired from the kit manufacturer), the sample should in principle be interpreted as positive.

Comments - Expert

On this round both the samples S001 and S002 were strong positive. Of the participants, 98% reported sample S001 as positive and 98% reported S002 as positive. Clients reporting results outside consensus are asked to check their methods and procedures as well as the detection limit of the test they are using.

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.

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2023-03-07

FINAL REPORT

Product no. 2750

Subcontracting: Sample preparation,
sample pretesting

Samples sent	2023-01-31
Round closed	2023-02-23
Final report	2023-03-07

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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