LABQUALITY

External Quality Assessment Scheme

# *Streptococcus agalactiae* (GBS), culture Round 1, 2023

**Specimens**
Please find enclosed 2 lyophilized samples S001 and S002 (in foil packages) and blue-capped vials of rehydration fluid, each 1 mL.

**Caution**
The specimens simulate patient samples, and they should be handled in the same way as corresponding samples capable of transmitting infectious disease.

**Examinations**
*Streptococcus agalactiae* (GBS), culture

**Storage and use**
After arrival, the samples should be stored at +2…8 °C. Please follow the handling instructions. Excessive shaking of the vials during the rehydration is not recommendable as it may produce foam and retard the dissolution process.

1. Let the specimens and the rehydration fluids warm up to room temperature.
2. Discard the blue-coloured cap from the vial of rehydration fluid.
3. Transfer the colourless cap (on vial inside the foil package) to the vial of the rehydration fluid. The bacterial specimen is fixed in the black particles inside the colourless cap (the paper pad inside the vial with the colourless cap is a desiccant).
4. Place the vial in an inverted position, tap to be sure the liquid is in contact with the inside of the cap and place it in an incubator at +35…37 °C for 15 minutes to dissolve the preserved microbes.
5. Check that there are no black particles inside the cap to make certain that all the microbes have dissolved into the solution. If necessary, reinvert the vial and continue the rehydration process. Observe closely every 1 to 2 minutes for complete dissolution. Continue to dissolve the specimen until no black particles are left in the cap, however, note that a prolonged rehydration process may affect the bacterial count. To enhance the dissolution of the particles you may gently tap the bottom of the vial when keeping it in an inverted position. Excessive vigorous shaking will produce foam.
6. Proceed immediately with the examination as with a patient sample.

The specimens should be cultured and incubated immediately after the preparations, like patient samples. Preferably use a 1 µL culture loop (both for plate and enrichment culture). Incubate up to 48 h if needed.

**Result reporting**
Please enter the results via LabScala (www.labscala.com). Report the findings and results according to your own test selection, leave the parts empty that are not included in your examinations. If you cannot find your test in the dropdown menu, please contact the EQA Coordinator. Merely the results reported in the “Report to the clinician” part will be scored.

S001

LQ759423011

S002

LQ759423012

**2023-03-28**

**INSTRUCTIONS**

Product no. 5594
LQ759423011-012/US
UN3373

Subcontracting: Sample pretesting

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

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The results should be reported no later than **April 24, 2023**.

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The expected results of the round are published in LabScala in the View reports section by April 26, 2023.

**Inquiries**
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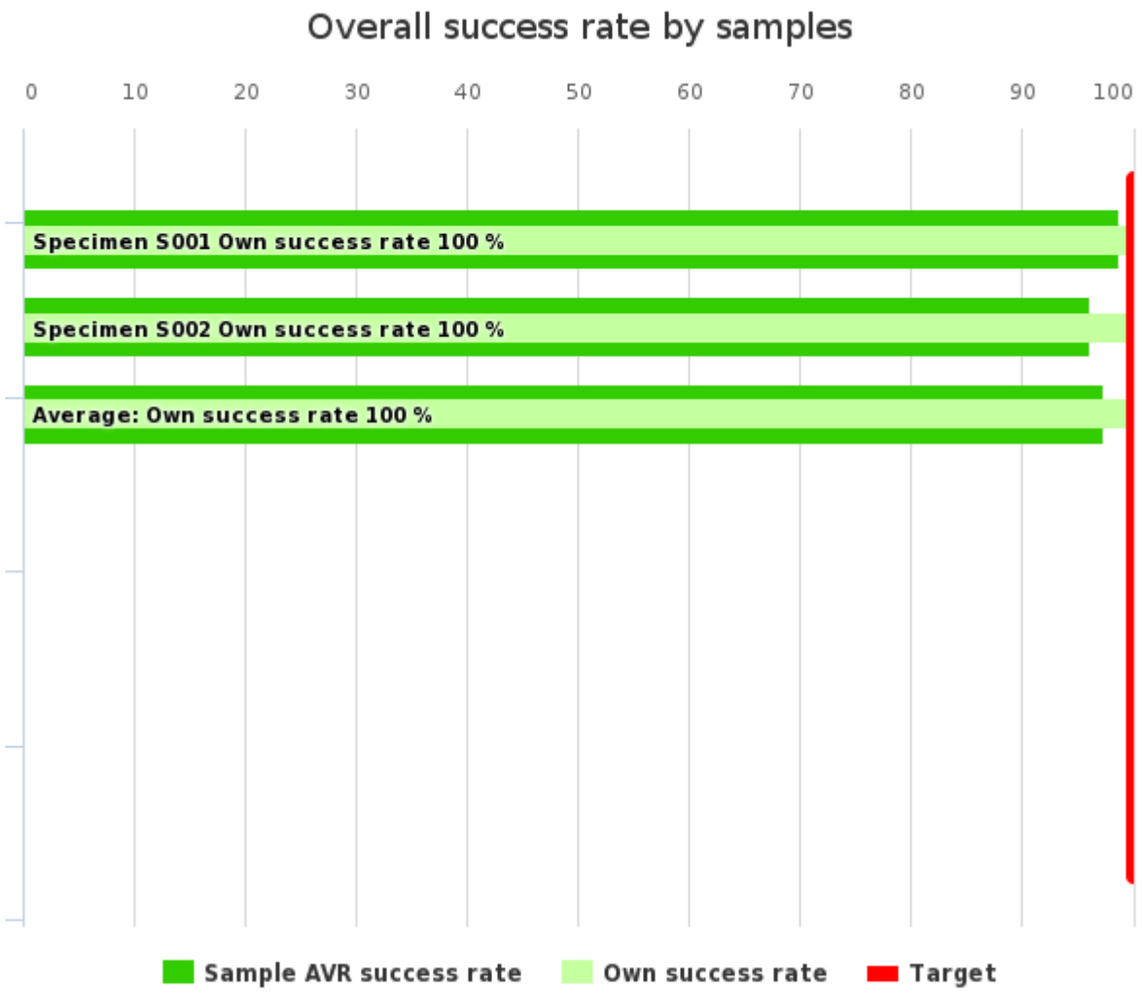
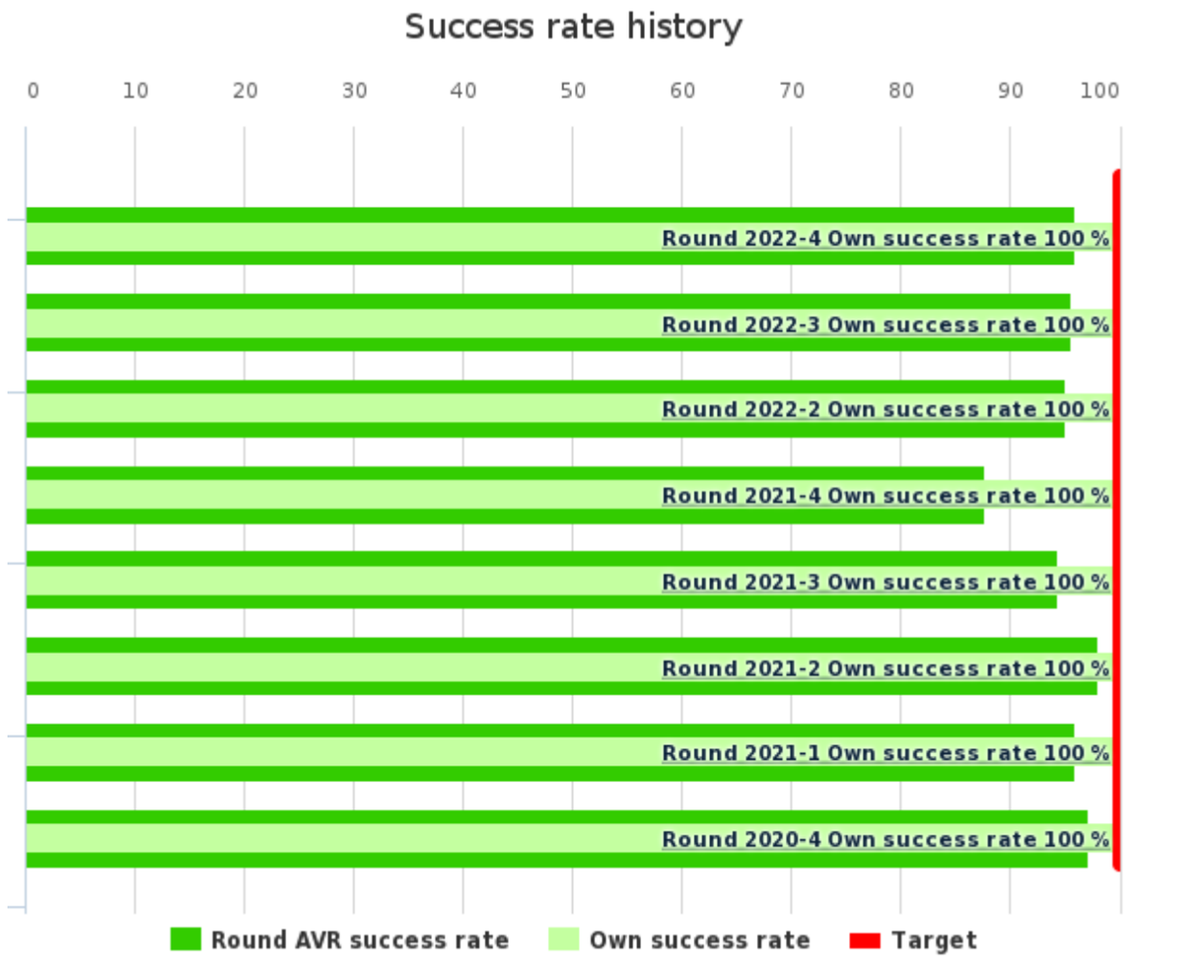
www.labquality.com

## Client report

| | No of participants | No of responded participants | Response percentage |
|---|---|---|---|
| Streptococcus agalactiae (GBS), culture, April, 1-2023 | 82 | 76 | 92.7 % |

## Summary

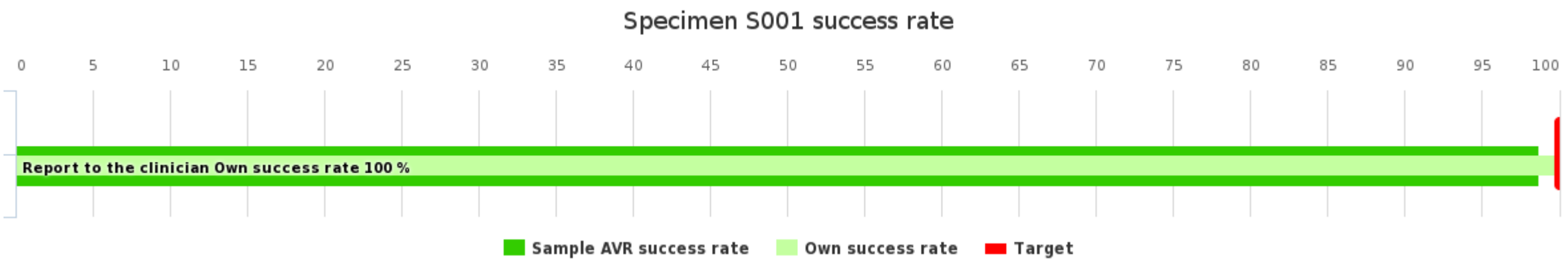


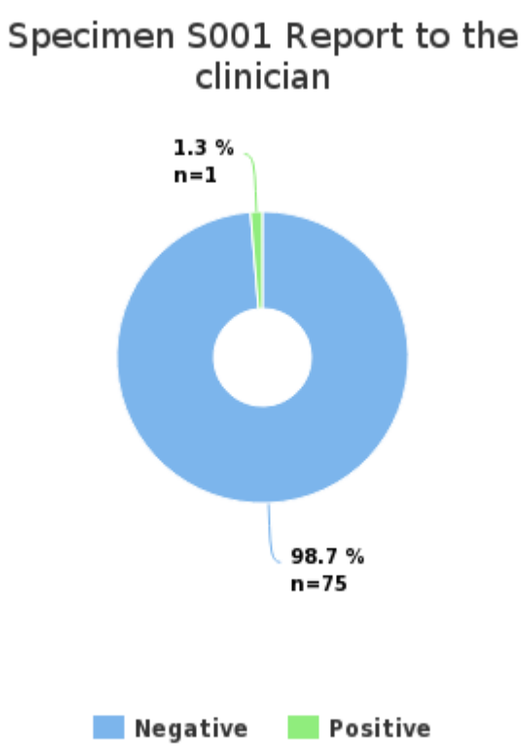

| Summary | Own score | Max score | Own success rate | Difference | AVR success rate |
|---|---|---|---|---|---|
| Specimen S001 | 4 | 4 | 100 % | 1.3 % | 98.7 % |
| Specimen S002 | 4 | 4 | 100 % | 3.9 % | 96.1 % |
| Average: | | | 100 % | 2.6 % | 97.4 % |

| History | Test nr. | Own success rate | Difference | AVR success rate |
|---|---|---|---|---|
| Round 2022-4 | 1 | 100 % | 4 % | 96 % |
| Round 2022-3 | 1 | 100 % | 4.3 % | 95.7 % |
| Round 2022-2 | 1 | 100 % | 4.9 % | 95.1 % |
| Round 2021-4 | 1 | 100 % | 12.3 % | 87.7 % |
| Round 2021-3 | 1 | 100 % | 5.7 % | 94.3 % |
| Round 2021-2 | 1 | 100 % | 1.9 % | 98.1 % |
| Round 2021-1 | 1 | 100 % | 4 % | 96 % |
| Round 2020-4 | 1 | 100 % | 2.8 % | 97.2 % |

**Specimen S001 | Streptococcus agalactiae (GBS): negative**



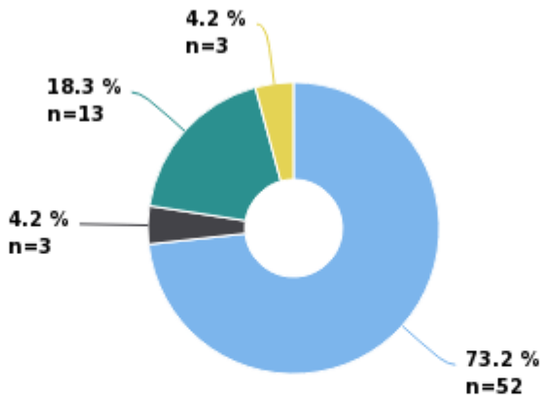

| Specimen S001 results | Responded | Count |
|---|---|---|
| | Report to the clinician | 76 |
| | Plate Culture | 71 |
| | Agglutination test | 8 |
| | Commercial identification kits and analyzers | 3 |
| | Identification tests: MALDI-TOF | 18 |
| | Identification tests on colony: NAT | 8 |
| | Chromogenic medium | 25 |
| | Identification tests: Ag detection | 2 |




**REPORT TO THE CLINICIAN**

| Report to the clinician | Interpretation | Interpretation count | Own score | Max score | Own success rate | Difference | AVR success rate |
|---|---|---|---|---|---|---|---|
| | ◉ Negative | 75 | 4 | 4 | 100 % | 0 % | 100 % |
| | Positive | 1 | - | | | | 0 % |
| | Total: | 76 | 4 | 4 | 100 % | 1.3 % | 98.7 % |

Specimen S001 Plate Culture




Specimen S001 Agglutination test

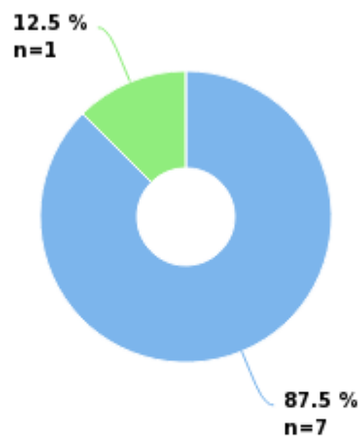


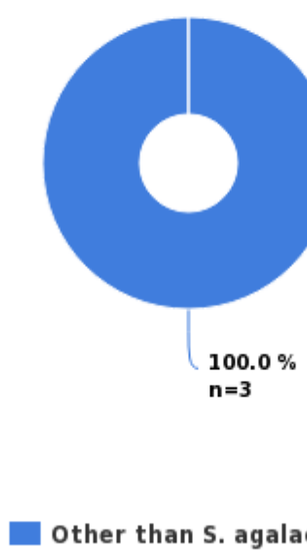

**PLATE CULTURE**

| Method | No growth (-) | Scarce growth (+) | Moderate growth (++) | Heavy growth (+++) | Total: |
|---|---|---|---|---|---|
| Chromogenic medium | 35 | 1 | 10 | 1 | 47 |
| Selective medium | 17 | 2 | 3 | 2 | 24 |
| Total: | 52 | 3 | 13 | 3 | 71 |

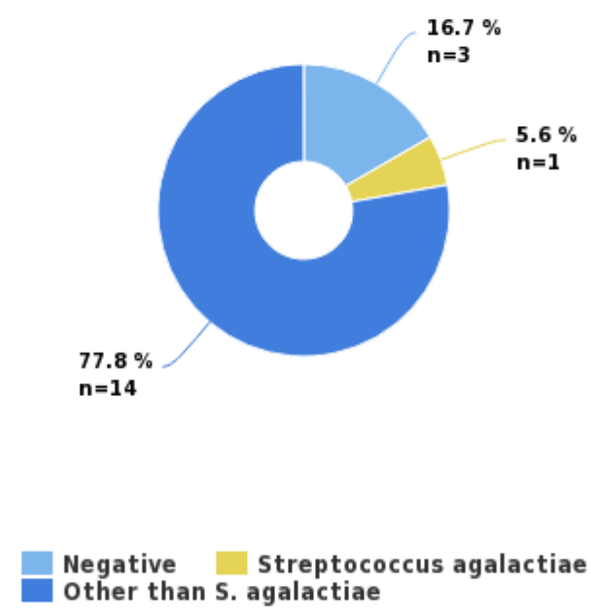
**AGGLUTINATION TEST**

| Method | Negative | Positive | Total: |
|---|---|---|---|
| Microgen Strep Rapid Test (Microgen Bioproducts) | 1 | - | 1 |
| Oxoid Streptococcal Grouping Kit (Thermo Scientific) | 2 | - | 2 |
| Pastorex Strep (Bio-Rad) | 1 | 1 | 2 |
| Prolex Streptococcal Grouping Kit (Pro-Lab Diagnostics) | 2 | - | 2 |
| Remel PathoDxtra Strep Grouping Kit (Thermo Scientific) | 1 | - | 1 |
| Total: | 7 | 1 | 8 |

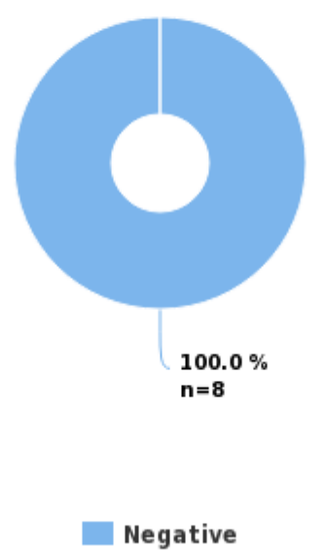
Specimen S001 Commercial identification kits and analyzers




Specimen S001 Identification tests: MALDI-TOF




Specimen S001 Identification tests on colony: NAT




**COMMERCIAL IDENTIFICATION KITS AND ANALYZERS**

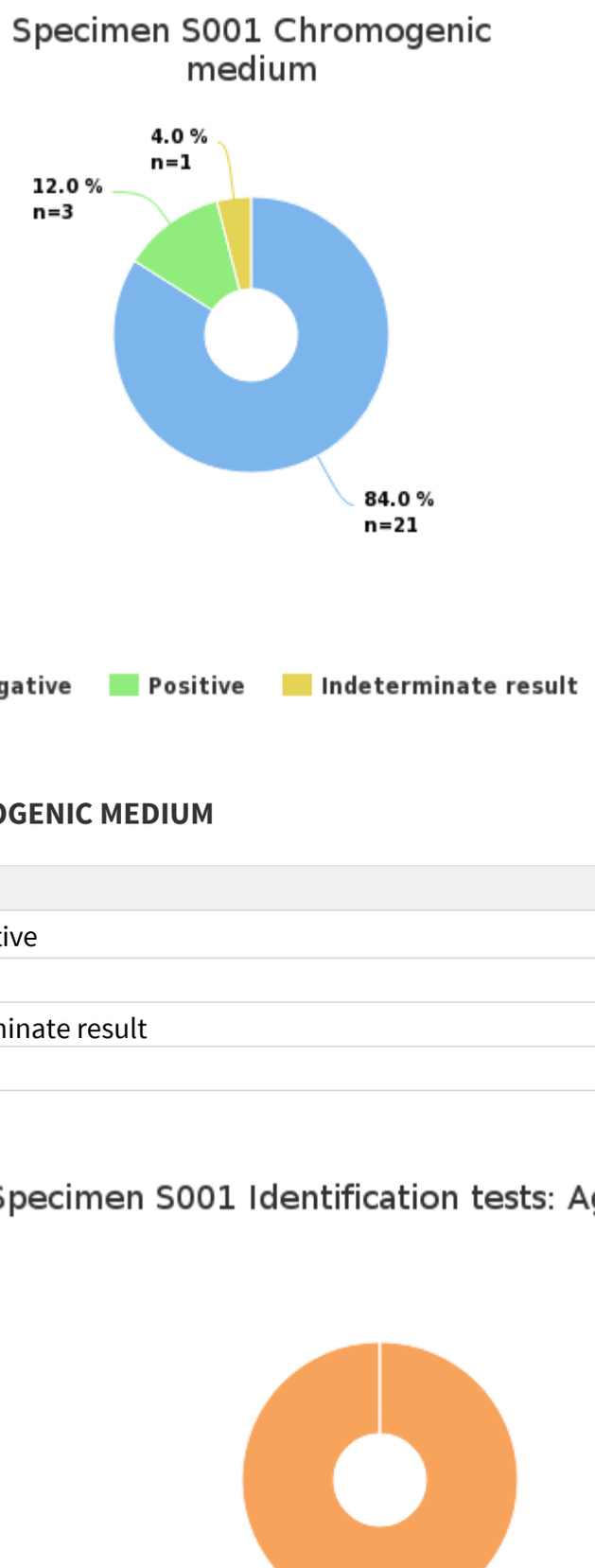
| Method | Result | count |
|---|---|---|
| VITEK 2 (bioMerieux) | | |
| | Other than S. agalactiae | 2 |
| VITEK 2 Compact 60 (bioMerieux) | | |
| | Other than S. agalactiae | 1 |
| Total: | | 3 |

**IDENTIFICATION TESTS: MALDI-TOF**

| Method | Result | count |
|---|---|---|
| Autof MALDI-ToF (Chirus) | | |
| | Streptococcus agalactiae | 1 |
| MALDI Biotyper (Bruker) | | |
| | Negative | 3 |
| | Other than S. agalactiae | 8 |
| VITEK MS (bioMérieux) | | |
| | Other than S. agalactiae | 6 |
| Total: | | 18 |

**IDENTIFICATION TESTS ON COLONY: NAT**

| Method | Result | count |
|---|---|---|
| PCR (In-house) | | |
| | Negative | 1 |
| Xpert GBS (Cepheid) | | |
| | Negative | 5 |
| Xpert Xpress GBS (Cepheid) | | |
| | Negative | 2 |
| Total: | | 8 |



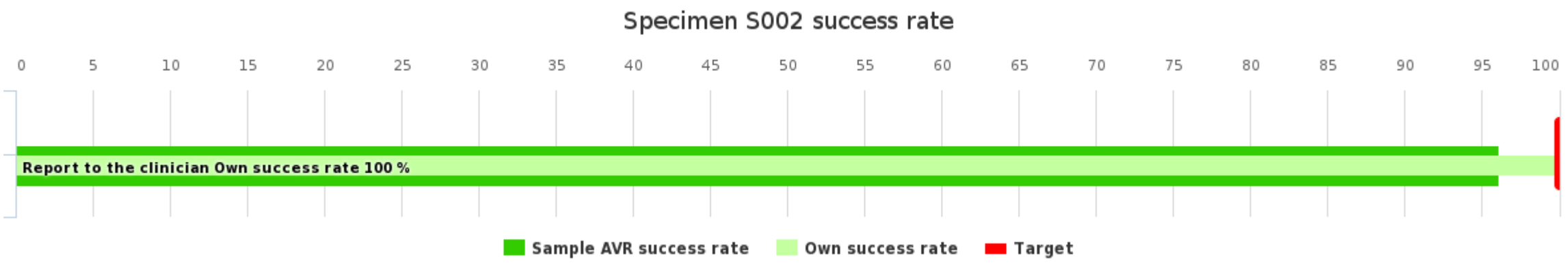

**CHROMOGENIC MEDIUM**

| Result | Result count |
|---|---|
| ◉ Negative | 21 |
| Positive | 3 |
| Indeterminate result | 1 |
| Total: | 25 |

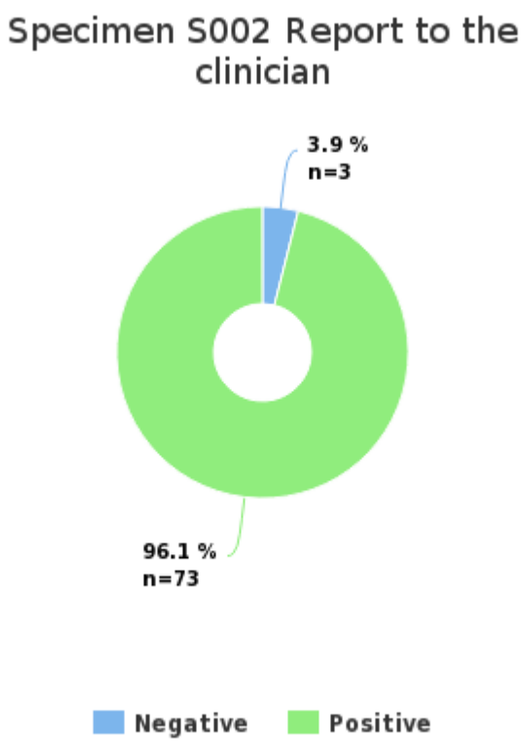
**IDENTIFICATION TESTS: AG DETECTION**

| Method | Result | count |
|---|---|---|
| Nadal Strep B Test (nal von minden) | | |
| | Negative | 1 |
| StrepBStick (Novamed) | | |
| | Negative | 1 |
| Total: | | 2 |

**Specimen S002 | Streptococcus agalactiae (GBS): positive**



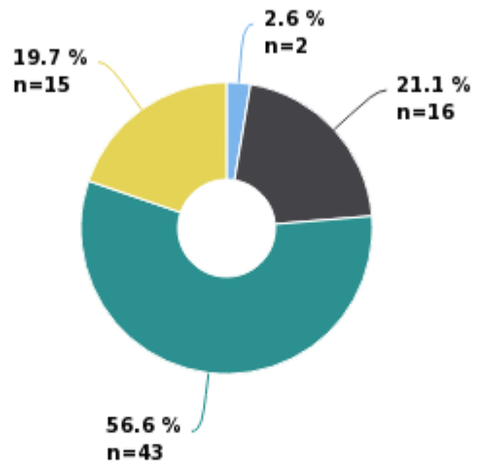

| Specimen S002 results | Responded | Count |
|---|---|---|
| | Report to the clinician | 76 |
| | Plate Culture | 76 |
| | Agglutination test | 32 |
| | Commercial identification kits and analyzers | 13 |
| | Identification tests: MALDI-TOF | 50 |
| | Identification tests on colony: NAT | 12 |
| | Chromogenic medium | 31 |
| | Identification tests: Ag detection | 3 |




**REPORT TO THE CLINICIAN**

| Report to the clinician | Interpretation | Interpretation count | Own score | Max score | Own success rate | Difference | AVR success rate |
|---|---|---|---|---|---|---|---|
| | Negative | 3 | - | | | | 0 % |
| | ◉ Positive | 73 | 4 | 4 | 100 % | 0 % | 100 % |
| | Total: | 76 | 4 | 4 | 100 % | 3.9 % | 96.1 % |

Specimen S002 Plate Culture




Specimen S002 Agglutination test

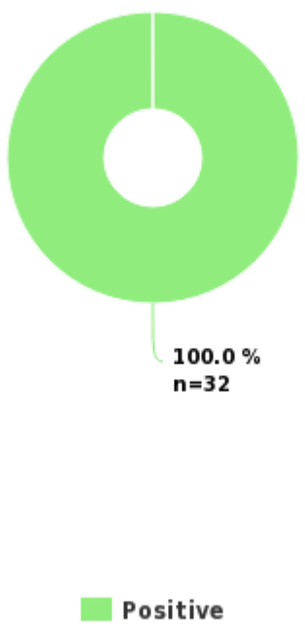


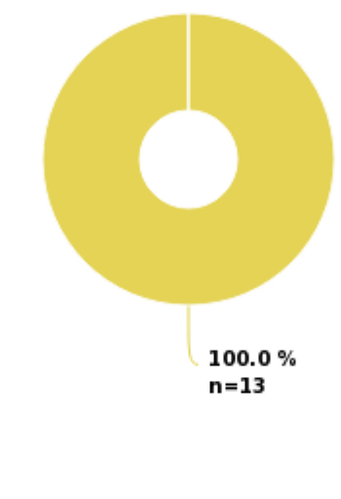

**PLATE CULTURE**

| Method | No growth (-) | Scarce growth (+) | Moderate growth (++) | Heavy growth (+++) | Total: |
|---|---|---|---|---|---|
| Chromogenic medium | 1 | 11 | 28 | 11 | 51 |
| Selective medium | 1 | 5 | 15 | 4 | 25 |
| Total: | 2 | 16 | 43 | 15 | 76 |

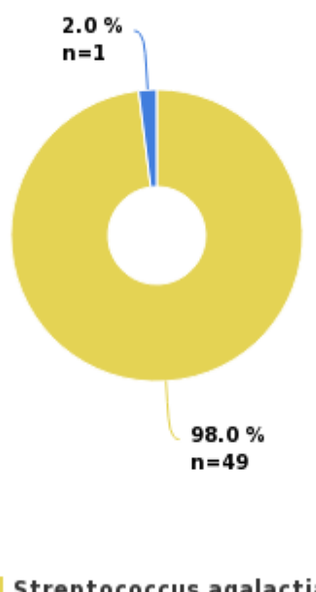
**AGGLUTINATION TEST**

| Method | Positive |
|---|---|
| Microgen Strep Rapid Test (Microgen Bioproducts) | 1 |
| Oxoid Streptococcal Grouping Kit (Thermo Scientific) | 13 |
| Pastorex Strep (Bio-Rad) | 4 |
| Prolex Streptococcal Grouping Kit (Pro-Lab Diagnostics) | 7 |
| Remel PathoDx Strep Grouping Kit (Thermo Scientific) | 2 |
| Remel PathoDxtra Strep Grouping Kit (Thermo Scientific) | 4 |
| Streptex Rapid Latex Agglutination (Thermo Scientific) | 1 |
| Total: | 32 |

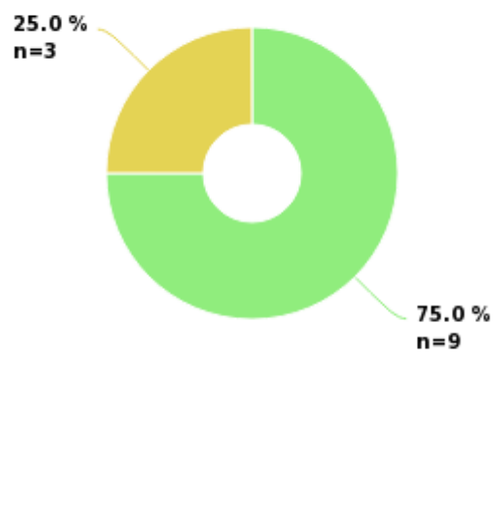
Specimen S002 Commercial identification kits and analyzers




Specimen S002 Identification tests: MALDI-TOF




Specimen S002 Identification tests on colony: NAT




**COMMERCIAL IDENTIFICATION KITS AND ANALYZERS**

| Method | Result | count |
|---|---|---|
| VITEK 2 (bioMerieux) | | |
| | Streptococcus agalactiae | 6 |
| VITEK 2 Compact 15 (bioMerieux) | | |
| | Streptococcus agalactiae | 3 |
| VITEK 2 Compact 60 (bioMerieux) | | |

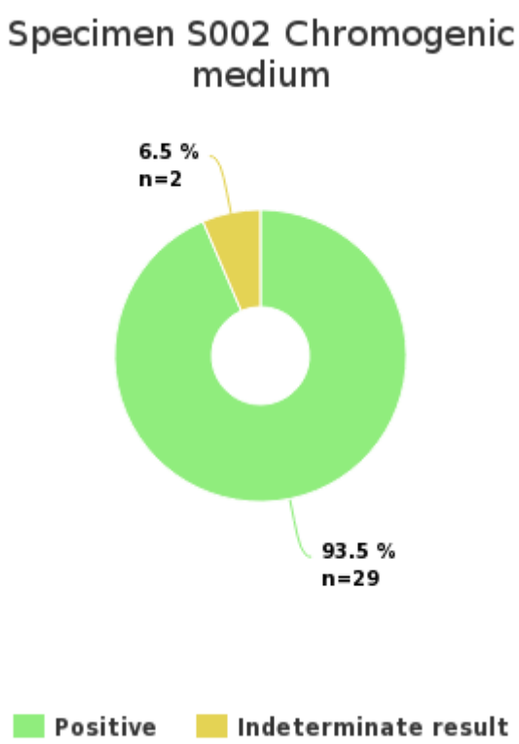
| | | |
|---|---|---|
| | Streptococcus agalactiae | 4 |
| Total: | | 13 |

**IDENTIFICATION TESTS: MALDI-TOF**

| Method | Result | count |
|---|---|---|
| Autof MALDI-ToF (Chirus) | | |
| | Streptococcus agalactiae | 2 |
| MALDI Biotyper (Bruker) | | |
| | Streptococcus agalactiae | 27 |
| | Other than S. agalactiae | 1 |
| VITEK MS (bioMérieux) | | |
| | Streptococcus agalactiae | 20 |
| Total: | | 50 |

**IDENTIFICATION TESTS ON COLONY: NAT**

| Method | Result | count |
|---|---|---|
| PCR (In-house) | | |
| | Positive | 1 |
| | Streptococcus agalactiae | 2 |
| Xpert GBS (Cepheid) | | |
| | Positive | 5 |
| Xpert Xpress GBS (Cepheid) | | |
| | Positive | 3 |
| | Streptococcus agalactiae | 1 |
| Total: | | 12 |




**CHROMOGENIC MEDIUM**

| Result | Result count |
|---|---|
| ◉ Positive | 29 |
| Indeterminate result | 2 |
| Total: | 31 |

Specimen S002 Identification tests: Ag detection


**IDENTIFICATION TESTS: AG DETECTION**

| Method | Result | count |
|---|---|---|
| Nadal Strep B Test (nal von minden) | | |
| | Weak positive | 1 |
| StrepBStick (Novamed) | | |
| | Positive | 2 |
| Total: | | 3 |

## Report Info

### PARTICIPANTS

Altogether 82 laboratories from 13 countries participated in this EQA round.

### REPORT INFO

On the front page you can see a summary of the overall average success rate and sample specific success rates which have been calculated from the scores. The reported results and the scores are presented in separate tables.
In general, the expected results are marked with green color. Accepted results may also be indicated with yellow color. Laboratory's own results are indicated with a black radio button ◉. In the participant specific report, the participant's own success is shown both as scores and as success rates (%) generated from the score values.
If you have not reported results, you will get a note: "You have not responded in time, only global report is available".
For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

### SCORING

The results in the "Report to the clinician" part can be scored when at least 60% of the participants have reported the correct/expected result and when there are at least three reported results.
Laboratory's scores have been converted to percentage (own success rate, % from maximum scores) with a target at 100%. Own success rate is compared with the success rate of all results.

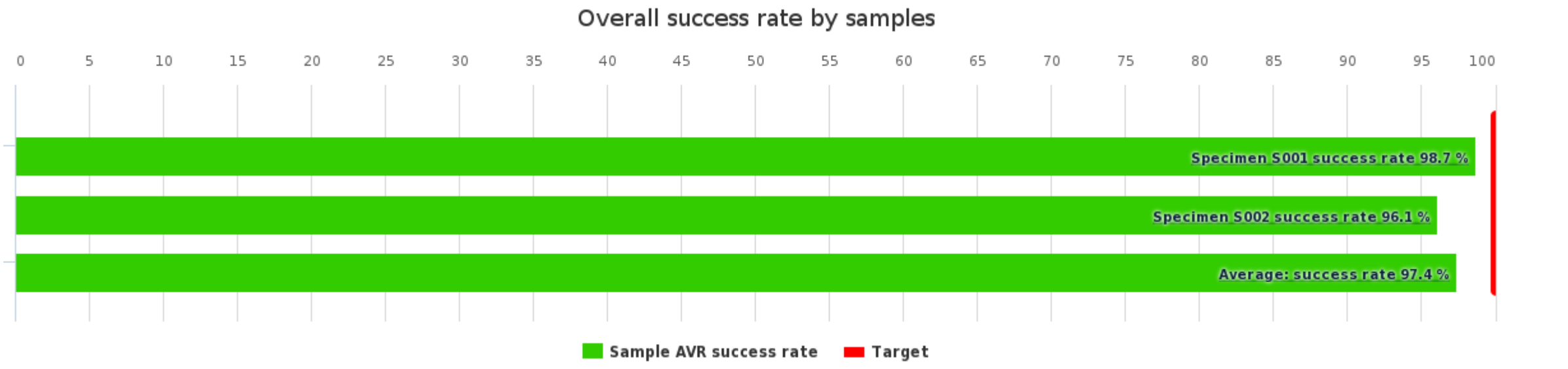
The following general rules are applied:
4 points is reached by reporting the expected correct result
1-3 points is given to results that are partly correct/insufficient regarding the expected finding
0 points is given for an incorrect/false result

# Streptococcus agalactiae (GBS), culture, April, 1-2023

## GLOBAL REPORT

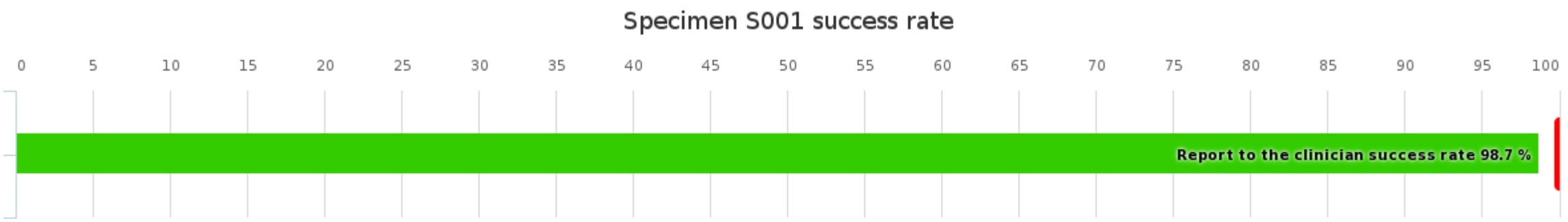
| | No of participants | No of responded participants | Response percentage |
|---|---|---|---|
| Streptococcus agalactiae (GBS), culture, April, 1-2023 | 82 | 76 | 92.7 % |

## Summary

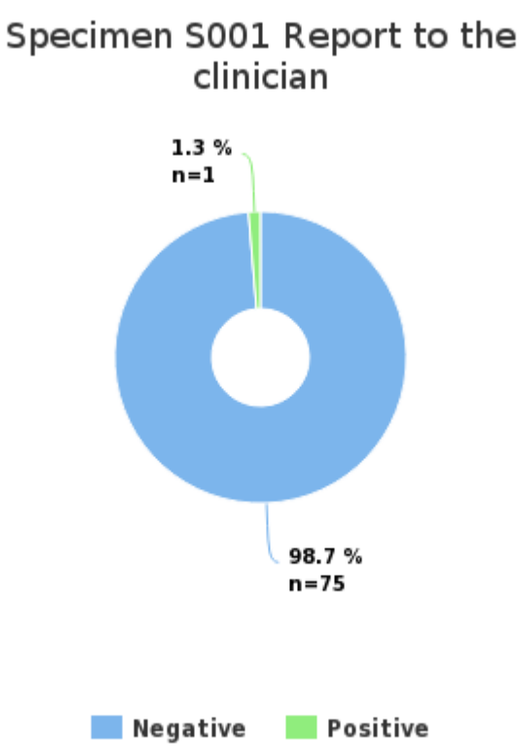



| Summary | AVR success rate |
|---|---|
| Specimen S001 | 98.7 % |
| Specimen S002 | 96.1 % |
| Average: | 97.4 % |

**Specimen S001 | Streptococcus agalactiae (GBS): negative**




| Specimen S001 results | Responded | Count |
|---|---|---|
| | Report to the clinician | 76 |
| | Plate Culture | 71 |
| | Agglutination test | 8 |
| | Commercial identification kits and analyzers | 3 |
| | Identification tests: MALDI-TOF | 18 |
| | Identification tests on colony: NAT | 8 |
| | Chromogenic medium | 25 |
| | Identification tests: Ag detection | 2 |

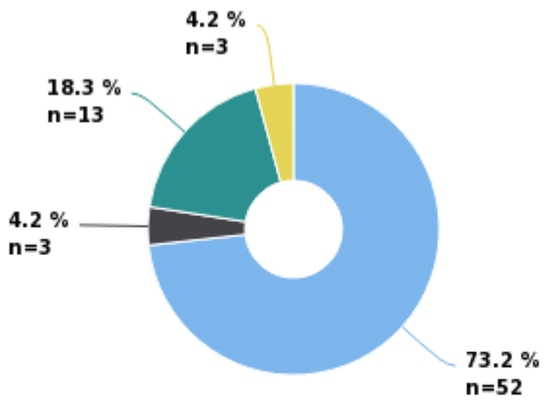



**REPORT TO THE CLINICIAN**

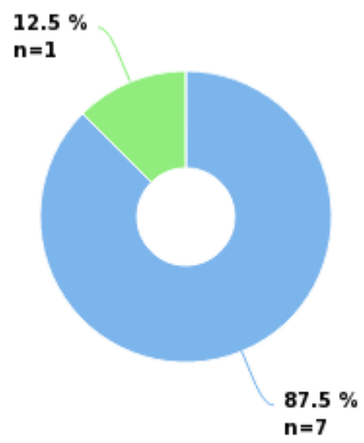
| Report to the clinician | Interpretation | Interpretation count | AVR success rate | Interpretation Score |
|---|---|---|---|---|
| | Negative | 75 | 100 % | 4 |
| | Positive | 1 | 0 % | 0 |
| | Total: | 76 | 98.7 % | |

# Streptococcus agalactiae (GBS), culture, April, 1-2023

Specimen S001 Plate Culture




Specimen S001 Agglutination test



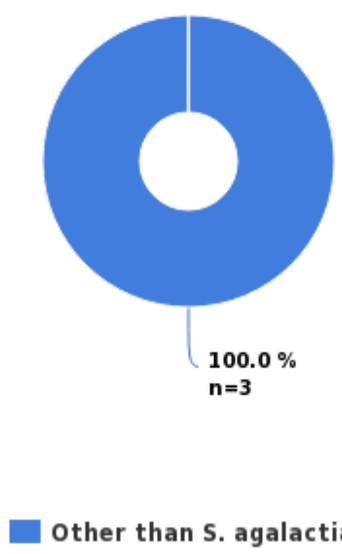

## PLATE CULTURE

| Method | No growth (-) | Scarce growth (+) | Moderate growth (++) | Heavy growth (+++) | Total: |
|---|---|---|---|---|---|
| Chromogenic medium | 35 | 1 | 10 | 1 | 47 |
| Selective medium | 17 | 2 | 3 | 2 | 24 |
| Total: | 52 | 3 | 13 | 3 | 71 |

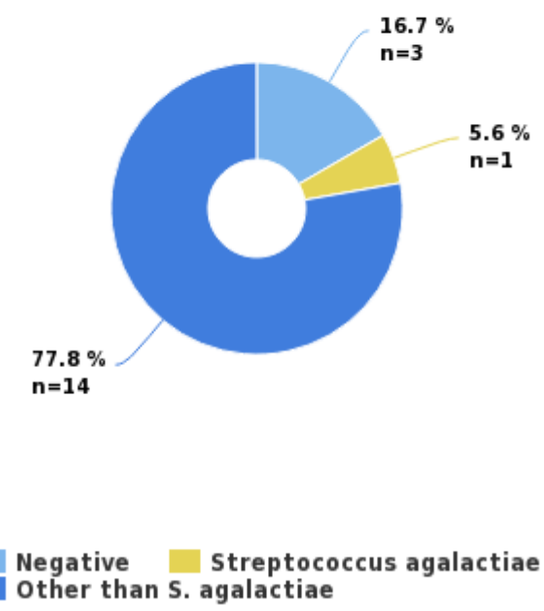
## AGGLUTINATION TEST

| Method | Negative | Positive | Total: |
|---|---|---|---|
| Microgen Strep Rapid Test (Microgen Bioproducts) | 1 | - | 1 |
| Oxoid Streptococcal Grouping Kit (Thermo Scientific) | 2 | - | 2 |
| Pastorex Strep (Bio-Rad) | 1 | 1 | 2 |
| Prolex Streptococcal Grouping Kit (Pro-Lab Diagnostics) | 2 | - | 2 |
| Remel PathoDxtra Strep Grouping Kit (Thermo Scientific) | 1 | - | 1 |
| Total: | 7 | 1 | 8 |

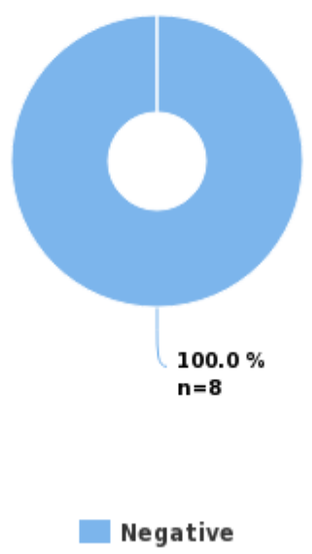
Specimen S001 Commercial identification kits and analyzers




Specimen S001 Identification tests: MALDI-TOF




Specimen S001 Identification tests on colony: NAT




## COMMERCIAL IDENTIFICATION KITS AND ANALYZERS

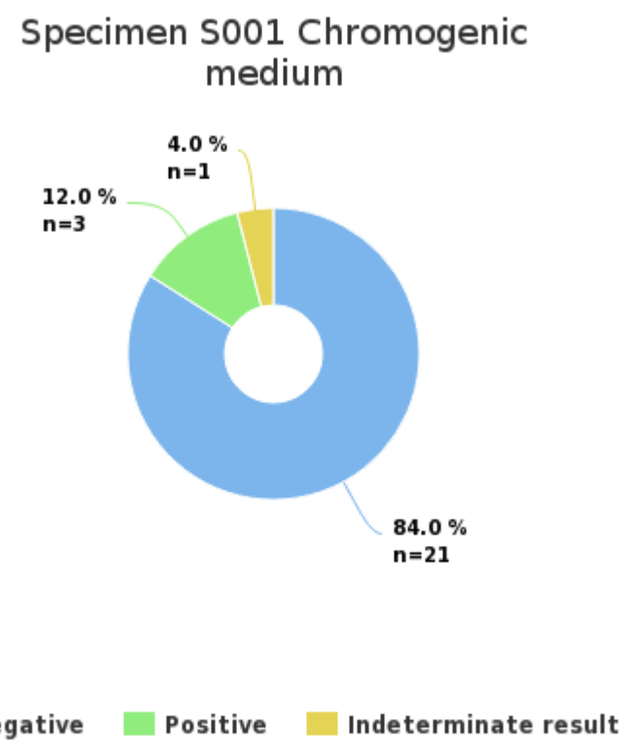
| Method | Result | count |
|---|---|---|
| VITEK 2 (bioMerieux) | | |
| | Other than S. agalactiae | 2 |
| VITEK 2 Compact 60 (bioMerieux) | | |
| | Other than S. agalactiae | 1 |
| Total: | | 3 |

## IDENTIFICATION TESTS: MALDI-TOF

| Method | Result | count |
|---|---|---|
| Autof MALDI-ToF (Chirus) | | |
| | Streptococcus agalactiae | 1 |
| MALDI Biotyper (Bruker) | | |
| | Negative | 3 |
| | Other than S. agalactiae | 8 |
| VITEK MS (bioMérieux) | | |
| | Other than S. agalactiae | 6 |
| Total: | | 18 |

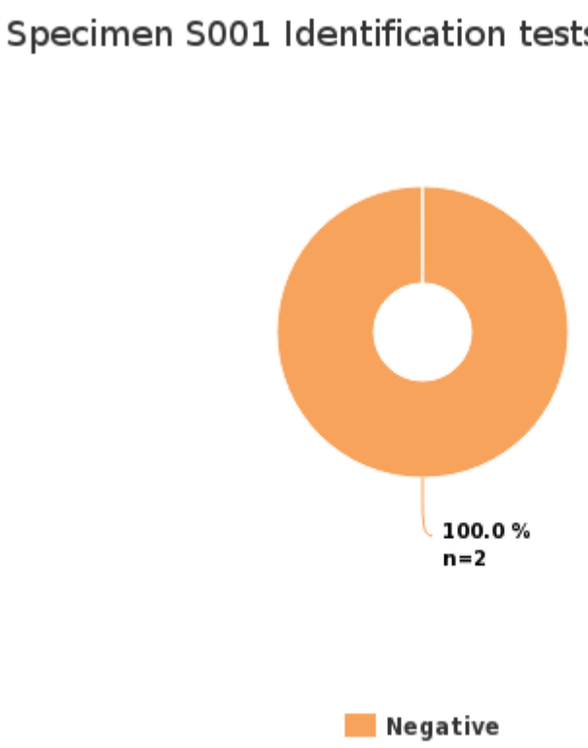
**IDENTIFICATION TESTS ON COLONY: NAT**

| Method | Result | count |
|---|---|---|
| PCR (In-house) | | |
| | Negative | 1 |
| Xpert GBS (Cepheid) | | |
| | Negative | 5 |
| Xpert Xpress GBS (Cepheid) | | |
| | Negative | 2 |
| Total: | | 8 |




**CHROMOGENIC MEDIUM**

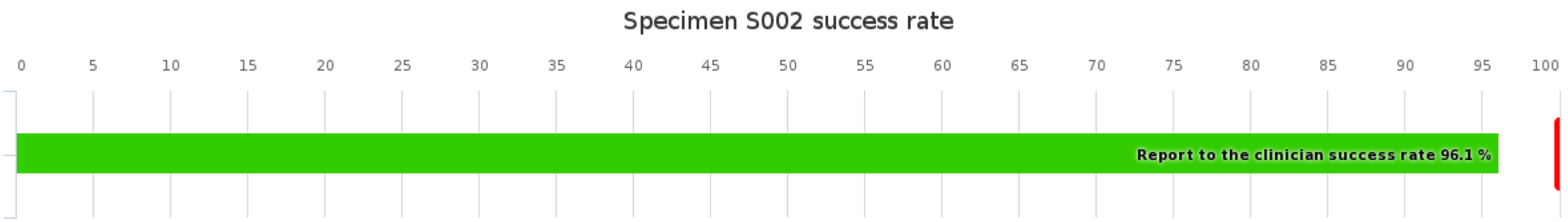
| Result | Result count |
|---|---|
| Negative | 21 |
| Positive | 3 |
| Indeterminate result | 1 |
| Total: | 25 |



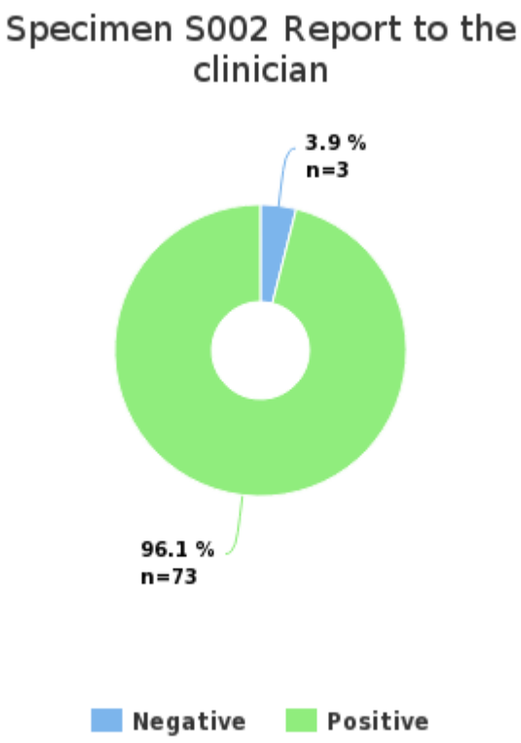
**IDENTIFICATION TESTS: AG DETECTION**

| Method | Result | count |
|---|---|---|
| Nadal Strep B Test (nal von minden) | | |
| | Negative | 1 |
| StrepBStick (Novamed) | | |
| | Negative | 1 |
| Total: | | 2 |

**Specimen S002 | Streptococcus agalactiae (GBS): positive**

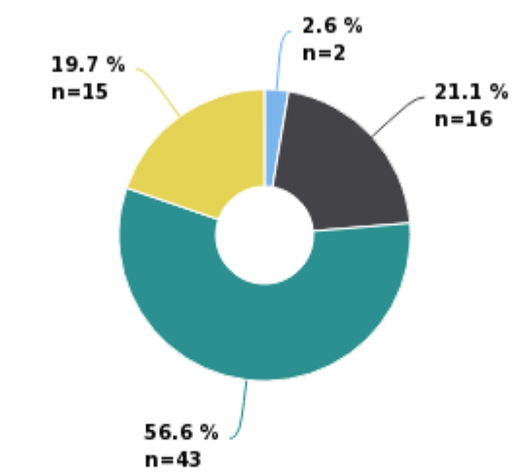



| Specimen S002 results | Responded | Count |
|---|---|---|
| | Report to the clinician | 76 |
| | Plate Culture | 76 |
| | Agglutination test | 32 |
| | Commercial identification kits and analyzers | 13 |
| | Identification tests: MALDI-TOF | 50 |
| | Identification tests on colony: NAT | 12 |
| | Chromogenic medium | 31 |
| | Identification tests: Ag detection | 3 |




**REPORT TO THE CLINICIAN**

| Report to the clinician | Interpretation | Interpretation count | AVR success rate | Interpretation Score |
|---|---|---|---|---|
| | Negative | 3 | 0 % | 0 |
| | Positive | 73 | 100 % | 4 |
| | Total: | 76 | 96.1 % | |



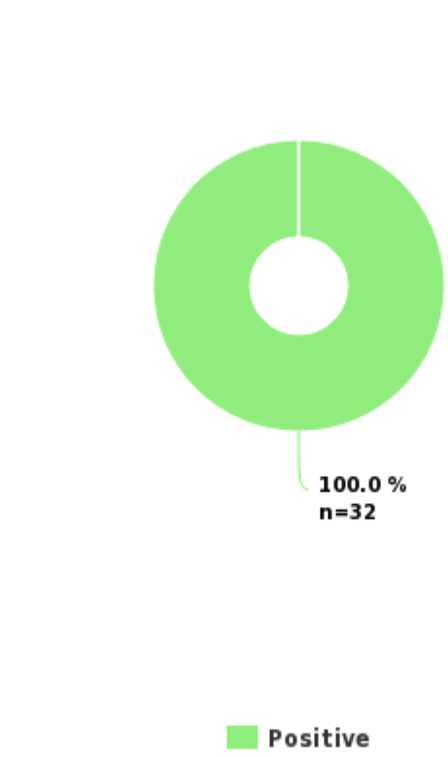
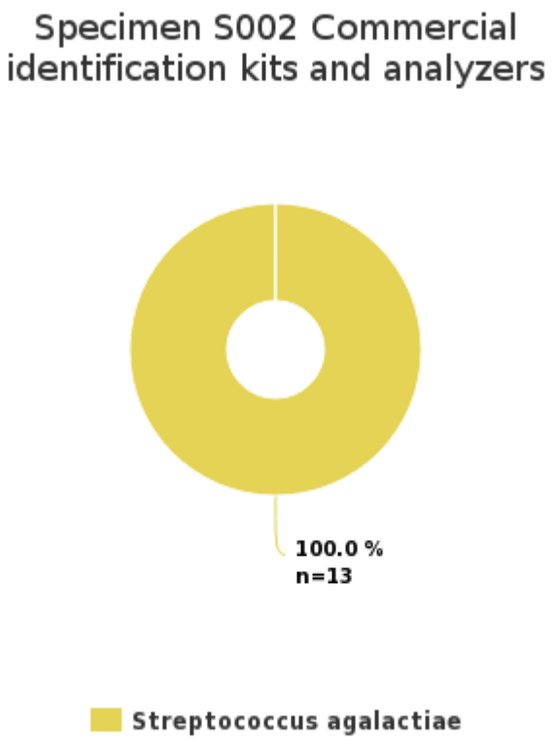



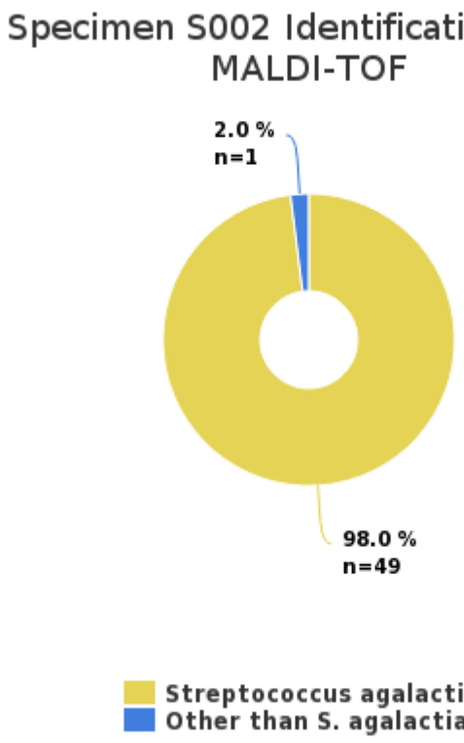

**PLATE CULTURE**

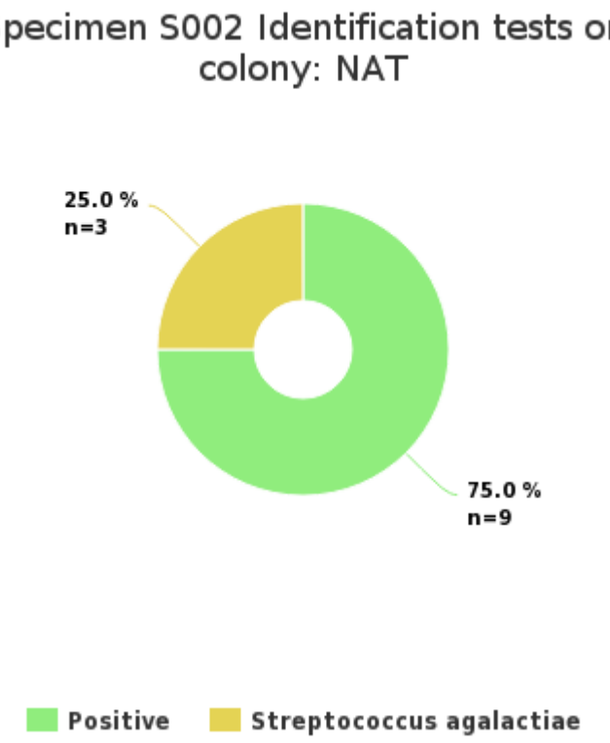
| Method | No growth (-) | Scarce growth (+) | Moderate growth (++) | Heavy growth (+++) | Total: |
|---|---|---|---|---|---|
| Chromogenic medium | 1 | 11 | 28 | 11 | 51 |
| Selective medium | 1 | 5 | 15 | 4 | 25 |
| Total: | 2 | 16 | 43 | 15 | 76 |

**AGGLUTINATION TEST**

| Method | Positive |
|---|---|
| Microgen Strep Rapid Test (Microgen Bioproducts) | 1 |
| Oxoid Streptococcal Grouping Kit (Thermo Scientific) | 13 |
| Pastorex Strep (Bio-Rad) | 4 |
| Prolex Streptococcal Grouping Kit (Pro-Lab Diagnostics) | 7 |
| Remel PathoDx Strep Grouping Kit (Thermo Scientific) | 2 |
| Remel PathoDxtra Strep Grouping Kit (Thermo Scientific) | 4 |
| Streptex Rapid Latex Agglutination (Thermo Scientific) | 1 |
| Total: | 32 |




**COMMERCIAL IDENTIFICATION KITS AND ANALYZERS**

| Method | Result | count |
|---|---|---|
| VITEK 2 (bioMerieux) | | |
| | Streptococcus agalactiae | 6 |
| VITEK 2 Compact 15 (bioMerieux) | | |
| | Streptococcus agalactiae | 3 |
| VITEK 2 Compact 60 (bioMerieux) | | |

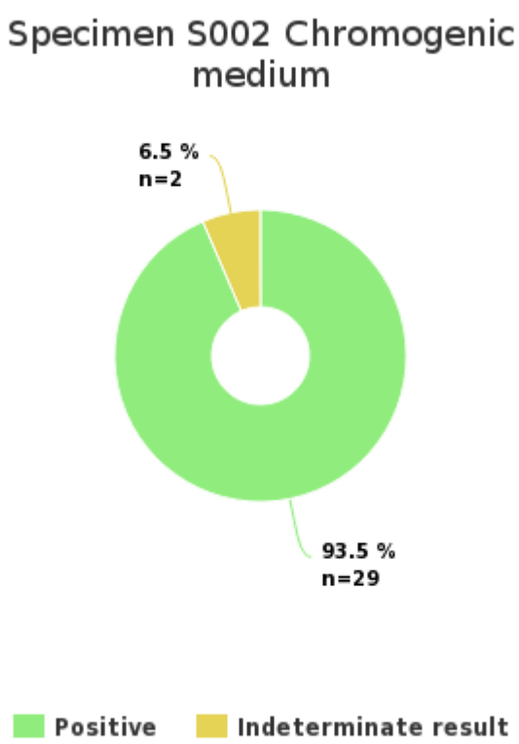
| | | |
|---|---|---|
| | Streptococcus agalactiae | 4 |
| Total: | | 13 |

**IDENTIFICATION TESTS: MALDI-TOF**

| Method | Result | count |
|---|---|---|
| Autof MALDI-ToF (Chirus) | | |
| | Streptococcus agalactiae | 2 |
| MALDI Biotyper (Bruker) | | |
| | Streptococcus agalactiae | 27 |
| | Other than S. agalactiae | 1 |
| VITEK MS (bioMérieux) | | |
| | Streptococcus agalactiae | 20 |
| Total: | | 50 |

**IDENTIFICATION TESTS ON COLONY: NAT**

| Method | Result | count |
|---|---|---|
| PCR (In-house) | | |
| | Positive | 1 |
| | Streptococcus agalactiae | 2 |
| Xpert GBS (Cepheid) | | |
| | Positive | 5 |
| Xpert Xpress GBS (Cepheid) | | |
| | Positive | 3 |
| | Streptococcus agalactiae | 1 |
| Total: | | 12 |




**CHROMOGENIC MEDIUM**

| Result | Result count |
|---|---|
| Positive | 29 |
| Indeterminate result | 2 |
| Total: | 31 |

Specimen S002 Identification tests: Ag detection


**IDENTIFICATION TESTS: AG DETECTION**

| Method | Result | count |
|---|---|---|
| Nadal Strep B Test (nal von minden) | | |
| | Weak positive | 1 |
| StrepBStick (Novamed) | | |
| | Positive | 2 |
| Total: | | 3 |

## Report Info

### PARTICIPANTS

Altogether 82 laboratories from 13 countries participated in this EQA round.

### REPORT INFO

On the front page you can see a summary of the overall average success rate and sample specific success rates which have been calculated from the scores. The reported results and the scores are presented in separate tables.
In general, the expected results are marked with green color. Accepted results may also be indicated with yellow color. Laboratory's own results are indicated with a black radio button ◉. In the participant specific report, the participant's own success is shown both as scores and as success rates (%) generated from the score values.
If you have not reported results, you will get a note: "You have not responded in time, only global report is available".
For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

### SCORING

The results in the "Report to the clinician" part can be scored when at least 60% of the participants have reported the correct/expected result and when there are at least three reported results.
Laboratory's scores have been converted to percentage (own success rate, % from maximum scores) with a target at 100%. Own success rate is compared with the success rate of all results.

The following general rules are applied:
4 points is reached by reporting the expected correct result
1-3 points is given to results that are partly correct/insufficient regarding the expected finding
0 points is given for an incorrect/false result

LABQUALITY

External Quality Assessment Scheme

# *Streptococcus agalactiae* (GBS), culture Round 1, 2023

**Specimens**
The round included two lyophilized samples. Based on the quality controls conducted by the sample material manufacturer and the results obtained in the round, the sample lots are to be considered as homogeneous, stable and suitable for external quality assessment. The materials were sent without temperature control packaging.

The content of the samples was as follows:

Sample S001 (LQ759423011)
*Streptococcus* sp. (viridans group) C020203
*Gardnerella vaginalis* C04701
Expected result: Negative

Sample S002 (LQ759423012)
*Streptococcus agalactiae* C010502
*Gardnerella vaginalis* C04701
Expected result: Positive

**Report info**
Please see the description of the data analysis on the last page of the laboratory-specific reports and global reports. It is important to read the Final report first, because it contains important information of the samples and results in each round.

**Comments – Expert**
Sample S001 was expected to be GBS negative and included high amount of alpha hemolytic streptococci. The sample was reported incorrectly as positive by 1/76 participants.

Sample S002 was expected to be GBS positive but was reported as negative by 3/76 participants.

**Exceptions in scoring**
No exceptions.

**End of report**

**2023-05-05**

**FINAL REPORT**

Product no. 5594

Subcontracting: sample pretesting

| | |
|---|---|
| Samples sent | 2023-03-28 |
| Round closed | 2023-04-24 |
| Expected results | 2023-04-26 |
| Final report | 2023-05-05 |

**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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