

1. Qualification Aim

As part of the qualification we wanted to verify the detection range of the color change reaction in the Letz – Test Tube system.

The following tests in this Qualification report for

Letz – Test Tubes (to test your water for fecal bacteria)

were performed and rated with the use of Escherichia coli. (ATTC 8739)

2. Qualification procedure

Two different batches were used in combination with one dilution series of Escherichia coli to fathom out the capability of the Letz – Test tubes in relation to the detection limit of their color indication system from the natural yellow of the medium to black.

The test strain was used as an overnight culture. Diluted in buffer solution and 0,1 ml of the different dilution solutions were used in 20 ml test volume (sterile water). To evaluate the test count of the dilutions 0,1 ml were transferred to TSA with the spreading method.

Incubation temperature at 35 – 37 ° C.

Evaluation was done after 18 - 48 hours.

Summary of Results and Conclusion

The following charts show the assembled data of the evaluation.

Batch May 2018 – less nutrient

Dilution	cfu/0,1 ml	Black coloring 24 hours	Black coloring 48 hours
10 ⁻²	> 200	Black	Black
10 ⁻⁴	> 200	Grey to Black	Black
10 ⁻⁶	116	Grey to Black	Black
10 ⁻⁷	8	Grey	Black
Negative control	0	yellow	yellow

Batch April 2018 – more nutrient

Dilution	cfu/0,1 ml	Black coloring 24 hours	Black coloring 48 hours
10 ⁻²	> 200	Black	Black
10 ⁻⁴	> 200	Black	Black
10 ⁻⁶	116	Grey to Black	Black
10 ⁻⁷	8	Grey to Black	Black
Negative control	0	yellow	yellow

Conclusion

Both batches are able to successfully indicate less than 10/cfu of Escherichia Coli in 20 ml test volume.

The difference between more and less broth is only visible after 24 hours.

Longer incubation times such as 48 hours deliver the exact same results in color change from light yellow to black.

This only represents the color change reaction with an incubation temperature of 35 - 37 ° C.

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Lab Manager, Frank Jansen

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