

# Factsheet: E. coli DETECT Kit

Test Kit Specifications	
Sample volume	100 mL
Target cells	<i>E. coli</i> , incl. the Big 6 and <i>E. coli</i> O157
Time to results	First result in 5 hours 30 minutes. All 8 results in 6 hours 30 minutes.
Limit of detection (LOD)	1 cell/100 mL (1 CFU/100 mL)
Sensitivity	93%
Specificity	96%
Working range	Qualitative detection of 3 - 5,000,000 cells/100 mL
Typical test matrices	All types of water (potable, process, env.)

Test Kit Facts	
Unit of results	Detection of viable cells per 100 mL: positive / negative
Main steps in the workflow	Filter 100 mL of sample, resuspend bacteria into 3 mL buffer, await 4 hours 30 minutes incubation time, add 1 mL to reaction tube, await 30 minutes reaction time, add sample to cartridge and start analysis
Daily throughput	Up to 16 samples per day per rqmicro.COUNT instrument
Main areas of application	Microbial control in F&B production, water distribution, wastewater reuse, applied research
Regulatory status of the test kit	The test kit is released for internal quality control, process optimization and risk management. Third-party lab validation is currently ongoing. The production of the test kit is in scope of the ISO 9001 Quality Management System of rqmicro.
Comparison rqmicro test results versus cultivation-based test results	Third-party lab validation is currently ongoing. Internal validations showed very high agreement of 100% between rqmicro test results and cultivation-based test results.
Comparison rqmicro test results versus PCR-based test results	PCR is only able to detect specific types of <i>E. coli</i> such as <i>E. coli</i> O157. PCR is therefore not suitable for general <i>E. coli</i> testing.
Laboratory equipment required	Filtration unit, vacuum pump, incubator, vortex mixer, forceps, pipettes, sample bottle
Shelf life	1.5 years
Storage conditions	Cold storage at 4-8 °C for reagents (reaction tubes, buffer, positive control).

## General Method Description

<b>Technologies used in the rqmicro test method</b>	Specific or unspecific labelling of bacterial cells with staining dyes and subsequent quantification of cells using cartridge-based flow cytometry. Depending on the test kit, the rqmicro method can include cell concentration (filtration), immunomagnetic separation of target cells and/or additional staining to detect membrane integrity.
<b>Laboratory or on-site</b>	Both is feasible using the rqmicro.COUNT instrument. Specific tests (Legionella, E. coli) require additional equipment for sample preparation.

## Frequently Asked Questions

<b>How do I check test results?</b>	Test results are immediately available on the rqmicro.COUNT instrument and on rqmicro's Cloud Solution.
<b>How do you assure the safety of data on the Cloud Solution?</b>	Data produced by rqmicro.COUNT instruments is securely hosted in Europe using market-leading hosting services by Amazon Web Services (AWS). All software services provided by rqmicro are covered by the ISO 9001 quality management system.
<b>How does the method differentiate between live and dead cells?</b>	Flow cytometry is able to assess the viability of single cells at a very high throughput of up to 10,000 cells per second. Membrane-damaged, and therefore, dead cells produce an additional signal that enables a differentiation from viable cells with intact cell membranes.
<b>Could rqmicro rapid test give a positive result whilst the culture test gives a negative result?</b>	Yes, because the rqmicro test also quantifies viable but non-culturable cells (VBNC) which are not detected in cultivation-based methods. Results obtained with the single-cell counting technology deployed in rqmicro.COUNT instruments are therefore more precise and often result in higher cell numbers when compared to cultivation-based tests.
<b>Is the process automated?</b>	Sample preparation takes 1-5 minutes hands-on-time per sample, depending on the test (ICC, TCC, Legionella, E. coli). The analysis on rqmicro.COUNT is fully automated.
<b>Does rqmicro provide training?</b>	New rqmicro.COUNT customers typically receive a 1 day training on the instrument and benefit from continued support by rqmicro Application Specialists.
<b>Does rqmicro provide service contracts?</b>	The rqmicro.COUNT Service Contract offers instrument service, extended warranty, software packages and continued application support for recurring test kit customers.



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