

# Factsheet: Legionella COUNT Kits

### **Test Kit Specifications**

Sample volume	100 mL
Target cells	Legionella pneumophila SG 1 or Legionella pneumophila SG 1-15
Time to results	First result in 1 hour 27 minutes. All 4 results in 2 hours.
Limit of detection (LOD)	Drinking water: 50 cells/100 mL (0 - 80 CFU/100 mL) Process water: 150 cells/100 mL (0 - 240 CFU/100 mL)
Sensitivity	100%
Specificity	98%
Quantitative working range (without dilution)	Drinking water: 150 - 5,000,000 cells/100 mL Process water: 500 - 5,000,000 cells/100 mL
Typical test matrices	All types of water (potable, process, env.)

#### **Test Kit Facts**

Unit of results	Number of viable cells per 100 mL
Main steps in the workflow	Filter 100 mL sample, resuspend bacteria in 1 mL buffer, add 200 $\mu$ L to reaction tube, await 60 minutes reaction time, add sample to cartridge and start analysis
Daily throughput	Up to 28 samples per day per rqmicro.COUNT instrument
Main areas of application	Cooling tower monitoring, microbial control, wastewater reuse, applied research, water safety concept, outbreak management, Legionella risk assessment
Regulatory status of the test kit	The Legionella pneumophila SG 1 Kit has received the AOAC Performance-Tested-Method (PTM) certification. The method has been adopted by the Association of German Engineers (VDI) for Legionella monitoring during disinfection procedures (42. BlmSchV, VDI-Richtlinie 4250 Blatt 2). 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 validations confirmed high correlation of rqmicro results to cultivation-based tests according to ISO 11731:2017 in spiking experiments. In practice, a large and highly variable share of viable but non-culturable cells (VBNC) of Legionella remains undetected by cultivation-based methods but is included in the single-cell counting method used by rqmicro.
Comparison rqmicro test results versus PCR-based test results	Third-party lab validations confirmed high correlation of rqmicro results to PCR results in spiking experiments. In practice, the viability assessment of PCR-based tests is prone to failure and correlation to the rqmicro method is therefore lower.
Laboratory equipment required	Filtration unit, vacuum pump, vortex mixer, rotator/roller mixer, forceps, pipettes, sample bottle
Shelf life	1 year
Storage conditions	Cold storage at 4 - 8 °C for reagents (reaction tubes, buffers, positive control)



# **General Method Description**

Technologies used in the rqmicro test method	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 includes cell concentration (filtration), immunomagnetic separation of target cells and/or additional staining to detect membrane integrity.
Laboratory or on-site	Both is feasible using the rqmicro.COUNT instrument. Specific tests (Legionella, E. coli) require additional equipment for sample preparation.

## **Frequently Asked Questions**

How do I check test results?	Test results are immediately available on the rqmicro.COUNT instrument and on rqmicro's Cloud Solution.
How do you assure the safety of data on the Cloud Solution?	Data produced by rqmicro.COUNT instruments is securely hosted in Europe using market-leading hosting services by AWS. All software services provided by rqmicro are covered by the ISO 9001 quality management system.
How does the method differentiate between live and dead cells?	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.
Could rqmicro rapid test give a positive result whilst the culture test gives a negative result?	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.
Is the process automated?	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.
Does rqmicro provide training?	New rqmicro.COUNT customers typically receive a 1 day training on the instrument and benefit from continued support by rqmicro Application Specialists.
Does rqmicro provide service contracts?	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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