CytoQuant®

Mobile Flow Cytometer

Quantify bacteria and residues in 30 seconds.

Immediate verification of cleaning and disinfection procedures

VENDART
DIAGNOSTICS

Cracking down on bacteria

The presence of bacteria in food and beverage manufacturing facilities can affect product shelf life and quality, while pathogens can even lead to foodborne illness. Cleaning and disinfection is therefore paramount to securing food safety and protecting both your reputation and your business.

But cracking down on something we can't see isn't always easy and straightforward. While visual inspection is a good first step, it isn't enough. Traditional microbiological methods often don't allow for preventive control and preoperational actions as lab results take days. ATP tests, while simple and fast, quantify biological residues, which are not a meaningful proxy for disinfection efficacy.

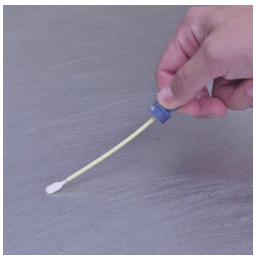
Each one of these methods comes with considerable limitations. Yet you are expected to make informed decisions, fast.

	Visual inspection	Cultural methods	ATP tests	CytoQuant
Fast	++	-	++	++
Simple operation	++	-	++	++
Quantitative	-	++	++	++
Measure residues	+	-	++	++
Measure bacteria	-	++	-	++
Robustness	+	++	-/+	++

Test Procedure

1

Open the swab kit by unscrewing the swab from the vial.



2

Swab the surface to be tested.

3

Return the swab into the vial and screw it closed.

4

Shake to suspend bacteria and particles in the buffer.

5

Insert the swab kit into the vial port, press OK and wait 30 seconds for the results.

6

Read the results displayed on the screen.

Introducing CytoQuant®

The world's first mobile flow cytometer

CytoQuant® is a mobile flow cytometer that enables the immediate, on-site verification of cleaning and disinfection procedures in food production facilities or other areas where hygiene is crucial by directly quantifying bacteria and particles on surfaces.

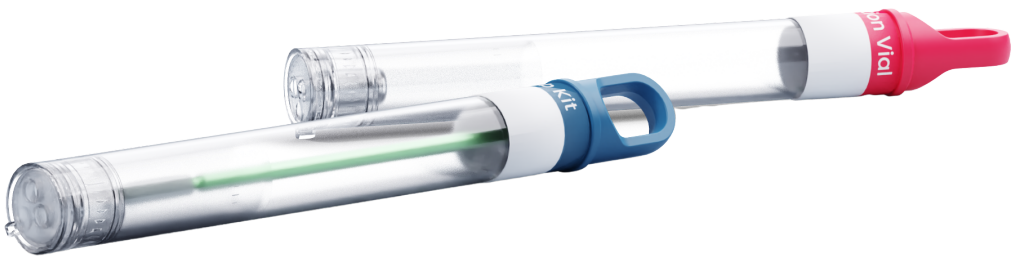
Direct quantification of bacteria and residue particles enables proper verification of both cleaning and disinfection procedures (IFS 7.1).

Results in 30 seconds allow for preventive control and pre-operational actions.

Measurements are not influenced by disinfectants or temperature, reducing result variability.

Simple test procedure does not require a lab or special training.

Simple connectivity allows you to save, export and document test results with ease.

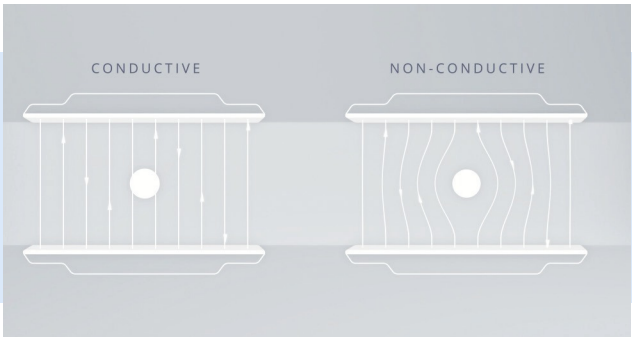


How does CytoQuant® work?

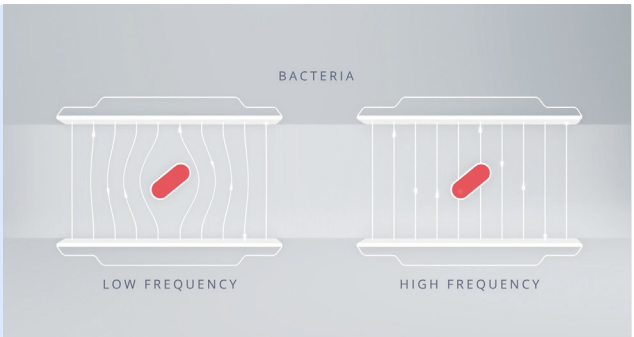
By using impedance flow cytometry, the CytoQuant® device takes advantage of the unique electromagnetic properties of the structure of bacteria (cell membrane and cytoplasm) to distinguish them from other particles.

Microelectrodes in the microfluidic flow cell generate electrical fields at both low and high frequencies, enabling the device to detect changes in conductivity and resistance induced by the sample passing through the flow channel. These changes can then be attributed in precise numbers to either particles or intact bacteria cells.

Regardless of the frequency of the electric field, the conductivity of metallic particles, for example, will permit the electrical field to pass through mostly unimpeded. Contrariwise, non-conductive particles such as polystyrene will resist the electrical field; the current will only move in the liquid medium, which leads to measurable impedance in the flow cell.



Intact bacteria cells, however, are unique in that they simultaneously resemble both non-conductive and conductive particles, depending on the frequency of the electric field. At low frequencies, the isolating quality of a cell's membrane prevents the electric field from penetrating it, leading to the same degree of displacement as with non-conductive particles. Higher frequencies, however, can partially penetrate the membrane. In this way, cells are more similar to conductive particles.



The detector identifies the target as a bacterium based on the varying degree of impedance or conductivity at the applied frequencies. The device then displays separate counts of intact cells and particles.

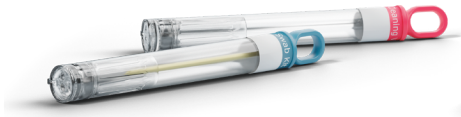
For more information on how the CytoQuant® mobile flow cytometer works, scan this QR code:

What are we really measuring?

How do intact cells and particles relate to common, known parameters?

CytoQuant® provides precise counts of intact cells and particles. Intact cells are defined as cells with an intact cell wall, irrespective of their state (such as stressed, or viable but not culturable) or required growth conditions (aerobic or anaerobic, pH, nutrition, salt concentration, temperature, lag-time, incubation time, etc.). Because no solid or liquid media can cover this full range, and because only about 1% of existing bacteria are culturable (Staley & Konopka, 1985; Amann et al., 1995; Hugenholtz et al., 1998), intact cell counts and plate counts are two very different parameters.

CytoQuant® additionally classifies any objects that are not bacteria and pass through the microfluidic flow cell as residue particles. Particle counts are a direct indication of cleanliness.



How reliable are CytoQuant® intact cell count results?

The accuracy of CytoQuant® measurements has been the subject of a large number of studies. In the latest, described below, Romer Labs partnered with a university and compared the intact cell counts of the CytoQuant® mobile flow cytometer with counts from a fluorescence microscope, a fluorescence flow cytometer and those from aerobic plates (TSA: tryptic soy agar).
Overnight cultures were prepared from pure cell cultures with a known cell count. Dilutions were made to cover the whole quantification range of both flow cytometers (10^4-10^7 cells/mL).

Measurements were done in triplicate. Microscope and plate counts were conducted at about 10^6 cells/mL and about 100 cfu/plate, respectively.
Not only were counts from CytoQuant® closest to those of the reference microscope method *(figure 1)*, CytoQuant® also had the lowest relative average standard deviations of all methods *(table 1)*. As expected, TSA plates returned the lowest bacteria counts as not all colonies emerge from a single cell and not all cells eventually multiply and form colonies. The fluorescence flow cytometer had significantly lower bacteria counts than CytoQuant® and the reference microscope method.

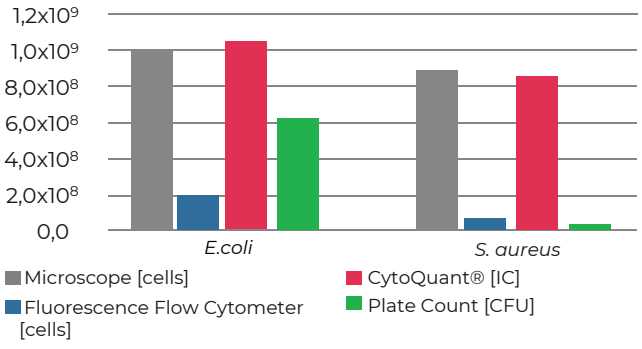


Figure 1: Method comparison – average bacteria counts

Table 1: Method comparison - relative standard deviation

	Bacteria	SD [%]
Microscope	*E. coli* (ATCC 25922)	20%
Fluorescence FC		20%
CytoQuant®		9%
Plate Count		10%
Microscope	*S. aureus* (ATCC 25923)	4%
Fluorescence FC		19%
CytoQuant®		6%
Plate Count		21%

Implementing CytoQuant®

The implementation of CytoQuant® is not essentially different from that of other, better-known environmental monitoring methods, such as culturing or ATP testing. What makes CytoQuant® different is that it empowers you to verify your cleaning and disinfection procedure on the spot by allowing you to create preventive control strategies. Implementation tactics usually involve a three-step plan *(figure 2)* and depend on whether a validated cleaning and disinfection procedure is already in place.

STEP 1	STEP 2	STEP 3
Devise risk-based monitoring program This could entail a full validation/revalidation of the cleaning & disinfection procedure	**Perform verification** Analysis of routine monitoring data in corroboration with product hygiene & safety data	**Optimise monitoring program** Grouping & randomising sampling areas of equal status, reducing sampling frequency

Figure 2: Implementation scheme for environmental monitoring programs in food processing facilities

If a validated cleaning and disinfection procedure is in place...

continue to use your current analytical monitoring methods while running separate trials with CytoQuant®. If a typical control chart is to be employed to control the cleaning and disinfection process, at least 20 data points per sampling area would suffice for the appropriate statistical analysis to be performed and for the monitoring program to be devised (see example in case study). Once the CytoQuant® method is in place, you can discard your old quantitative monitoring method.

If validation of the cleaning and disinfection procedure is required...

then follow these steps to generate a monitoring program:

- Use a risk-based approach **to select and rank sampling areas.**
- Use a risk-based approach to define **testing frequency**.
- **Test** these areas **before** and **after disinfection**. Also be sure to test the product against relevant hygiene and safety criteria.
- Analyze data and **set a baseline and thresholds for action**.
- **Define actions** to be carried out if thresholds are exceeded (for example, repeat cleaning and disinfection, deep cleaning, re-train cleaning personnel).

The common risk-based approach, typically used to select and rank sampling areas, is based on the hazard analysis step that is part of HACCP *(figure 3)*. This balances the likelihood that microbial contamination will make the product unsafe or faulty with the difficulty in cleaning a specific surface. Different sampling frequencies and action criteria are set for zones with low, medium and high degrees of risk. CytoQuant® is most useful in areas identified as high-risk zones, as the immediate quantification of bacteria and residue particles it provides allows you to carry out preventive control before beginning production.

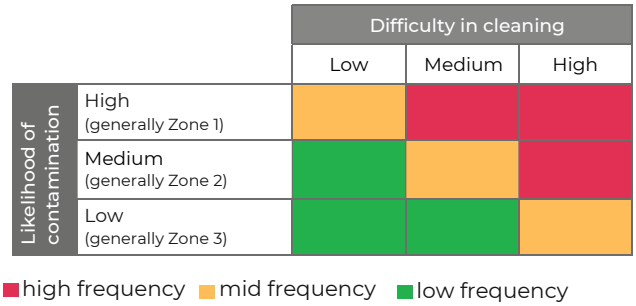


Figure 3: Risk assessment matrix to define high-risk zones in food production facilities

Once the monitoring program is in place...

perform verification of routine monitoring data and carry out continuous improvement (see steps 2 and 3 of the implementation scheme above) as they allow you to optimize the monitoring program by grouping and randomizing sampling areas of equal status and to reduce sampling frequency, thus eliminating needless testing.

Read on to learn how one meat producer, Hoppe Fleischwaren GmbH, implemented CytoQuant®.

Case Study: Hoppe Fleischwaren

Based in Eggebek in northern Germany, Hoppe Fleischwaren GmbH has been producing high-quality ready-to-eat meat products for over 70 years. The company maintains modern equipment and is IFS-certified. In line with its central values of safety and efficiency, Hoppe is looking to supplement its already robust quality control and food safety procedures and has implemented the CytoQuant® flow cytometer.

Important note: The data disclosed here is specific to Hoppe Fleischwaren GmbH. Each individual facility will need to generate its own data and evaluate it regularly as part of a risk-based monitoring plan.

The integrated monitoring process in Hoppe's food production facility is in line with active food safety system requirements. Cleaning and disinfection efficacy is a prerequisite to any HACCP program and is crucial to minimizing food safety and food quality risks.

Hoppe first focused on the following three sampling areas next to the slicer as these were deemed to pose the highest risk (zone 1): chopping board, slicer knives and conveyor belt. Hoppe carried out measurements with CytoQuant® while continuing to use their usual analytical monitoring methods, producing a set of data. Through statistical analysis, a control chart was produced to monitor and control cleaning and disinfection. In *table 2* you can find an excerpt of intact cell results documented after the cleaning and disinfection of the slicer knives along with the calculated mean value and the standard deviations used to define the control limit and the warning limit.

Slicer Knife Intact Cells

Table 2: Statistical analysis of results generated by CytoQuant®

Mean	STD	2 x STD	3 x STD
20,337.209	42,631.550	85,263.100	127,894.650

Date	Sample	Result [IC/mL]	Control Limit
31.01.22	A63	170,000	warning
31.01.22	A64	7,500	clear
01.02.22	A67	7,500	clear
02.02.22	A70	7,500	clear
03.02.22	A73	34,000	clear
04.02.22	A76	17,000	clear
07.02.22	A79	17,000	clear

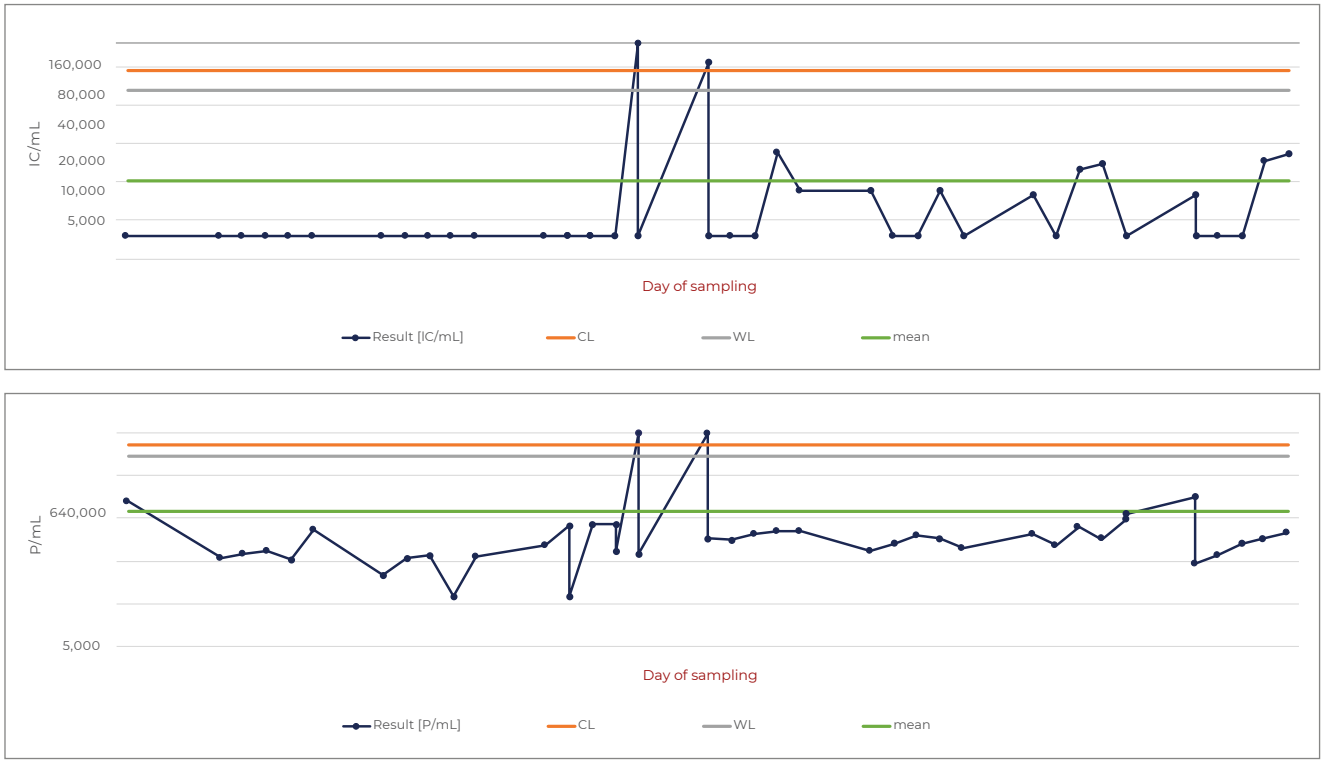


Figure 4: Control charts for intact cells and particles

Note: Measurements above the control limit were traced back to cleaning procedures performed by new cleaning personnel.

Ordering information

CytoQuant® Mobile Flow Cytometer System

CytoQuant® Mobile Flow Cytometer

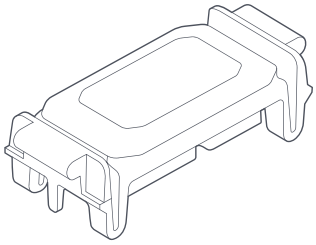
Order number:
10006469

Qty:
1 unit
(includes CountCell™)

CytoQuant® CountCell™

Order number:
10006471

Qty:
1 unit



CytoQuant® SwabKit

Order number: 10006468-10
Qty: 10/pk

CytoQuant® Cleaning Vial

Order number: 10006470-10
Qty: 10/pk

CytoQuant® Storage Vial

Order number: 10006624-10
Qty: 10/pk

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