

A refreshed approach to positive and negative culture controls

Executive summary

Establishing proper quality assurance (QA) and quality control (QC) practices is a core responsibility of any environmental laboratory team. While some laboratories hesitate to change established QA/QC practices, IDEXX has found that many water testing laboratories may be able to capture low-risk cost savings and efficiencies by refreshing their approach to one specific QA/QC practice: how they perform positive and negative culture controls. These benefits may be significant and will vary based on the laboratory’s current approach (figure 1).

Benefits of switching to IDEXX-QC						
		Cost savings	Time savings	Reduced risk	Reduced waste	Simplified ordering
Current approach	In-house cultures		●	○	○	○
	Built-in swab controls	○	○	○	●	○
	Controls from proficiency testing (PT) providers	●		○	○	○
	Controls from food or pharma provider			○	●	○

Figure 1. Assessing different control practices and the primary benefits (●) and benefits (○) they offer. Based on a review of the most popular on-market materials.

Any water testing laboratory interested in the benefits above should consider utilizing IDEXX-QC for positive and negative culture controls. IDEXX-QC kits contain traceable ATCC^{®*} and NCTC⁺ strains and are purpose-built to meet certification and accreditation requirements.[‡] Read on to learn how these fit-for-purpose kits can benefit your laboratory.

“Many labs could benefit from the professional perspectives shared in this document. The content will make lab managers think twice about doing things the way they always have. I anticipate a lot of labs will want to review their standard practices and consider changing to an all-around cleaner way of performing quality control.”

—Laboratory manager, large drinking water utility

Introduction

Quality assurance (QA) and quality control (QC) are critical to ensuring defensible data at an environmental laboratory. The validity and reproducibility of your results are the foundation of your organization; all other functions and systems serve that goal. A well-maintained quality management system developed according to recognized standards and guidelines is universally acknowledged as best practice for ensuring accurate results.

It is no wonder that quality management systems, once functional, are only seldom changed. Quality systems are often subject to a “if it’s not broken, don’t fix it” mentality. We spoke with an auditor who suggested many microbiologists have followed certain practices “since the dawn of time,” a nod to the field’s resistance to change practices that are tried and true.

However, there are several aspects of quality assurance and quality control where efficiency gains could make meaningful contributions to how a laboratory functions overall and where best practices have been well-established, meaning the risk of change is very low. One of these areas is how laboratories manage and perform positive and negative culture controls.

Most environmental laboratories are very familiar with these controls. They are used to ensure the media shipped to their laboratories reacts appropriately to target and non-target organisms, and as routine checks on method or analyst performance. While media manufacturers, including IDEXX, perform rigorous quality control on all media shipped to customers, manufacturers have less control over what happens during product shipping. Checking each lot once it arrives in the lab (or more often) is suggested or required in several different standards and guidance documents.[§]

Performing positive and negative culture controls requires obtaining or maintaining specific strains of bacteria. A positive control demonstrates that the media detects the target organism. Therefore, a positive control must

be known to contain the target organism. Conversely, a negative control demonstrates the media does not detect a non-target organism. A method blank (i.e., a media-only control sample), therefore, is not a negative control. A negative control must contain a known non-target organism.

Approaches to maintaining the required strains for positive and negative controls vary from laboratory to laboratory. Some environmental laboratories purchase strains directly from a culture type collection, such as ATCC or NCTC, and maintain the strain in or on a growth media in their laboratory. Others repurpose materials originally intended for other fields, such as food microbiology or pharmaceutical testing. Still others purchase positive and negative culture controls from their proficiency testing (PT) providers so that each use of the materials becomes a “practice run” for an official PT.



Laboratories may not have considered their positive and negative controls as an area for potential improvements or efficiencies. In many cases, however, “the way it’s always been done” is not the most efficient or effective way to perform these controls. Furthermore, positive and negative culture controls that are purpose-built for environmental water testing laboratories are available, are used by laboratories around the world, have been proven to be effective, and can be implemented with minimal risk. We hope that taking a deep dive into this often-overlooked subject will unlock significant efficiencies for laboratories and allow you and your team to focus on higher-value tasks.

Approaches to positive and negative culture controls

The benefits to be gained from refreshing your laboratory's approach to positive and negative culture controls are highly dependent on your current practices. The following pages are organized by the different approaches that laboratories use today and the benefits that updating each approach will offer.

A. Maintaining cultures in-house

Many laboratories maintain cultures in-house, either due to a high frequency of use (daily or weekly positive and negative culture controls) or because it has simply always been done that way. Maintaining cultures requires purchasing an input strain. This is often a reference culture from a culture type collection such as ATCC or NCTC, which can be aliquoted and stored frozen for future use. Other sources of cultures can be used; any material that creates a viable isolate will work. For example, culture control materials with a built-in swab can be used to easily create working cultures on growth media. Several laboratories utilize IDEXX-QC or Quanti-Cult® to start working cultures.

To maintain the strain, laboratories have developed standard operating procedures (SOPs) that involve culturing the strain in a growth medium: on an agar plate, agar slant, or in a broth, for example. This creates a working culture, which can then be used to inoculate 100 mL of sterile water to perform a media check or quality control with IDEXX reagents. These materials may also be used for quality control of other methods.

C. Purchasing controls from a PT provider

Many PT providers also offer the materials they provide as blinded PTs as culture control materials with identified strains, sometimes referred to as "certified reference materials." Many laboratories use these certified reference materials for media checks or quality control. They see each use as a practice run for their PT, which allows them to surface any issues when the stakes are lower.

Materials from PT providers are delivered in different forms: In some cases, positive and negative culture controls come as lyophilized pellets in glass vials, which are dropped directly into sterile water. In other cases, controls are delivered in a ready-to-use liquid.

B. Purchasing a control with a built-in swab

While the prescribed use of products with built-in swabs is to inoculate a growth media, in practice, many environmental water testing laboratories utilize these materials to directly inoculate sterile water for a one-time media check or method quality control. While different built-in swab solutions vary, laboratories will generally:

- Crack the included ampule to release the hydrating fluid
- Resuspend the bacterial pellet in the hydrating fluid
- Saturate the included swab
- Inoculate a positive culture control by swirling the swab in 100 mL of sterile water

D. Purchasing controls from a food or pharmaceutical microbiology provider

Known strains of bacteria are used in several branches of microbiology beyond water testing, including food and beverage and pharmaceutical microbiology. Providers of culture controls to those industries often also offer those same controls to environmental water testing laboratories. In many cases, these cultures are delivered in bulk formats: packs of 10 or even 20. These materials can be delivered in many formats, such as lyophilized pellets or discs that are rehydrated prior to use.

Benefits of refreshing your approach to positive and negative culture controls

The following paragraphs detail the benefits of refreshing your approach to positive and negative culture controls. You may skip forward to the section most relevant to your laboratory, depending on your needs and interest.

A. For laboratories that maintain cultures in-house

Laboratories that maintain cultures in-house are likely to find significant benefits from adjusting their approach. There are a wide variety of techniques and procedures for maintaining cultures, and some require significantly more time and expertise than others.

Is it necessary for your laboratory to maintain cultures?

The first step for these laboratories is to consider whether it is necessary to maintain cultures at all. If a laboratory is using these cultures daily or weekly, it may be cost prohibitive to pay for each culture control performed, and maintaining cultures may be the most cost-effective path forward. However, official guidance in many states only requires the use of positive and negative culture controls for each new lot of media received, or in some cases quarterly. Laboratory or QA managers should check with their local regulations and/or accreditors or certification officers to identify their specific requirements.

If a laboratory is maintaining cultures for use on a quarterly or even monthly basis, switching to a lyophilized pellet for one-time use can result in significant time and labor savings, as well as reduced risk of errors. Maintaining cultures generally requires lab staff to create working cultures every week; performing these tasks with proper technique is important. This generally means a significant time investment from laboratory staff. If your laboratory has a trained microbiologist maintaining cultures, consider the other, more important tasks that individual could be performing instead of a weekly culture transfer. It is highly likely that the value of those tasks would offset the cost of a “one-shot” culture control, which are generally around \$30 (approximately \$40 CAN) per strain.

If your laboratory has anyone other than a trained microbiologist maintaining cultures, consider the potential risks introduced by this approach. Proper technique is required to ensure that bacteria are transferred and grow correctly, and a failed media check can create significant issues in laboratory workflow. Conversely, culture controls delivered as lyophilized pellets require no advanced techniques; a pellet is simply transferred into 100 mL of sterile water, swirled to dissolve, and mixed. It is therefore significantly easier to train new staff on this procedure.

For laboratories that cannot switch to a one-shot culture control

Some laboratories are performing culture controls daily or weekly. In these cases, using a “one-shot” culture control may indeed be cost prohibitive, and it may be necessary for these laboratories to maintain cultures in-house. That said, there are several different methods for maintaining cultures, and some are more labor intensive than others. IDEXX has developed a procedure for using IDEXX-QC to start and maintain working stock cultures which is both robust and easy to perform. We encourage you to reach out to our technical support team for this procedure to evaluate whether it can benefit your laboratory.

B. For laboratories that purchase a control with a built-in swab

We at IDEXX appreciate the appeal of culture controls with built-in swabs. It's an innovative design and they are very robust. However, while laboratories may be accustomed to using these solutions, there are several benefits of using a lyophilized pellet over using a built-in swab solution.

The first is the amount of waste associated with controls with built-in swabs. The most popular products are delivered in packs of 2 or 6, and each of these are packaged in a foil packet and placed inside a plastic tube. Each shipment is delivered with a large paper insert. Beyond the packaging, there is significant waste associated with the product itself: essentially a plastic tube with an ampule and swab, which cannot be recycled.

Compare this amount of waste to a lyophilized pellet. These solutions, including IDEXX-QC, are packaged with recyclable materials and have electronic inserts. The pellets are delivered in glass vials, which can be recycled after use.

In addition to the waste benefits, there are procedural benefits to using a lyophilized pellet instead of a built-in swab. Overall, there are fewer steps associated with a lyophilized pellet than the built-in swab: Just open the vial and transfer the pellet into 100 mL of sterile water, swirl to dissolve, and then mix. Built-in swab solutions require rehydrating the pellet in the built-in tube, which requires several added steps.

There is also risk associated with the built-in swab procedure. After the swab has been heavily saturated with the bacterial slurry, the analyst does not have a free hand to open a 100 mL vessel, so must carefully place the bottom half of the plastic tube containing the slurry somewhere where it will not fall over. There is significant risk of spillage and contamination associated with this step, especially for a new analyst. The lyophilized pellet approach is significantly easier to introduce to new staff.

C. For laboratories that purchase controls from a PT provider

The logic around using the same format of culture controls for your laboratory's media checks and/or quality control as your official PT is very sound. Analysts get additional practice with that format, and any issues or challenges can be surfaced before a laboratory's accreditation is on the line. For this reason, many labs purchase positive and negative culture controls from their PT providers.

Laboratories can access these same benefits using IDEXX-QC. While IDEXX does not administer PTs, laboratories can coordinate their PTs through IDEXX, which are then provided by NSI Lab Solutions. Importantly, NSI PTs are delivered in the same format as IDEXX-QC, so laboratories get the benefit of a PT "practice run."

While aligning your PT and culture controls has tangible benefits, different PT vendors provide culture controls in different formats and at different prices. Perhaps most importantly, we found that two of the most popular U.S. PT vendors' prices for positive and negative controls were about 30% higher than the prices for IDEXX-QC. We encourage laboratories to compare prices to ensure they are accessing these benefits at the lowest cost.

Additionally, different vendors provide positive and negative culture controls in different formats. For example, one popular provider provides 5 different bacteria strains, in a lyophilized pellet format, as a total coliform and *Escherichia coli* (*E. coli*) quality control, in the exact same format as their PT. As laboratories well know, only 3 strains are required for media checks or QC for coliform/*E. coli*: a positive *E. coli* control, a positive total coliform control, and a negative control (often *Pseudomonas aeruginosa*). Unfortunately, the two additional pellets and associated packaging provided by this vendor will be wasted.

Another popular vendor delivers their controls in liquid format. While these solutions are very easy to use and remove a process step, they have limited shelf life and higher shipping costs. Laboratories need to carefully plan ahead to make sure they have the necessary controls to perform a media check. If the required controls are not available, this may interfere with the laboratory's ability to continue testing.

Conversely, the IDEXX-QC Coliform and *E. coli* kits are delivered with three sets of the three strains necessary to perform media checks or method checks on the Colilert®, Colilert®-18, and Colisure® tests. The kits can be used until 12 months from the date of manufacture, meaning laboratories can be assured of having exactly the materials they need throughout the year.

D. For laboratories that purchase controls from a food or pharmaceutical microbiology provider

Laboratories may purchase positive and negative culture controls from a microbiology provider focused on the food or pharmaceutical industry. These organisms are generally delivered as lyophilized pellets or discs, which are very easy to rehydrate and use. Generally, these providers offer these materials by organism, so a laboratory will need to decide which organisms and which strains to purchase. Choosing an appropriate strain for environmental microbiology is critical; we have found that some clinical strains that are not usually found in water can impact results. When ordering from these vendors, each organism ordered will come in a package of between 6 and 20 pellets.

While some microbiology labs may have a need for that quantity of materials over the course of a year, many laboratories are using positive and negative culture controls only when they receive a new lot of media or potentially quarterly. This may create waste and added expense when unused materials expire.

The IDEXX-QC Coliform and *E. coli* kit comes with exactly the strains required to perform positive and negative culture controls on the Colilert, Colilert-18, and Colisure tests—no need to search an extensive catalog for the materials required. Additionally, it is delivered with 3 vials of each required organism, likely to cover the needs of most water testing laboratories for around a year.

Refresh your Approach to Positive and Negative Culture Controls with IDEXX-QC

Regardless of your current approach to positive and negative controls, switching to IDEXX-QC can streamline laboratory workflow and ordering, save money, and reduce waste. IDEXX-QC kits contain traceable ATCC and NCTC strains and are purpose-built to meet certification and accreditation requirements.† Kits are supported by IDEXX's best-in-class technical support and supply chain. If laboratories can use IDEXX-QC to eliminate the need to order from a separate vendor, this benefit should also be considered.

Benefits of using IDEXX-QC:

- Traceable to ATCC and NCTC strains
- Easy to use
- Comes with strains needed to QC IDEXX methods
- Supported by the IDEXX Water Technical Team
- May allow laboratories to consolidate vendors
- Quantified material for use in demonstrations of capability
- May be paired with PT services from NSI
- May be used as an input material for working stock cultures

IDEXX-QC kits are used by laboratories around the world and have been shown to be robust and consistent. Laboratories can switch to these materials and be confident that media checks and QC will be simplified, streamlined, and will deliver consistent results.

IDEXX-QC materials are also quantified, meaning they are ideal for use in demonstrations of capability. A laboratory or QA manager can have laboratory staff perform a quantified test without the staff knowing the required results. The target MPN values and acceptable ranges are listed on the product's certificate of analysis, which is only accessible with the lot number on the outer packaging of the IDEXX-QC kit. Analysts cannot use the lot number printed on the vial to access the certificate of analysis.

The kits are delivered with exactly the strains needed to perform media checks or quality control on all IDEXX methods and are easy to use. They are delivered as lyophilized pellets and are simply transferred to 100 mL of sterile water. They are cost-effective and can be paired with PT services from NSI. Laboratories that maintain working stock cultures can utilize IDEXX-QC as an input material; we encourage these laboratories to reach out to the IDEXX technical support team for a copy of our SOP.

While it's understandable that many laboratories are hesitant to change any of their QA/QC practices, labs that insist on maintaining their approach to positive and negative controls simply because "that's the way we've always done it" may be leaving both time and money on the table. Switching to IDEXX-QC is a low-risk change that can improve your laboratory's efficiency and effectiveness.



Visit [idexx.com/waterQC](https://www.idexx.com/waterQC) to learn more and order your kits today.

Acknowledgements

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*American Type Culture Collection; 1-800-638-6597, atcc.org.

†National Collection of Type Cultures; culturecollections.org.uk.

‡Always check with your regulators and/or certification or accreditation body to ensure local regulations and requirements are met.

§For example, the U.S. Environmental Protection Agency's Manual for the Certification of Laboratories Analyzing Drinking Water, section 9020 of the Standard Methods for the Examination of Water and Wastewater, and The NELAC Institute (TNI) standards.