

## Novel automated microbiological analysis in meeting Philippine drinking water standards

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### Abstract

The Philippines water industry is highly regulated, with monthly water quality reports required. For microbiological failures, retesting is required immediately to ensure continuous supply of potable water. Report data are generated using classical standard analytical methods, with incubation periods of 18 to 24 hours for the presumptive phase and up to an additional 48 hours for confirmation of contamination. The methods used must be accepted by the Philippine regulating bodies. Recently, instrumented microbiological techniques have been approved by the Philippine Department of Health. However, they are not yet being used. This paper presents the challenges and triumphs encountered in registering a new analytical method in the Philippines, and difficulties in changing methods. The capabilities and opportunities presented by the new system – e.g., rapid failure detection, cost effectiveness, and applications to complement relief efforts in providing emergency water supplies – are also illustrated.

**Key words:** automated, microbiology, regulatory

### INTRODUCTION

The water industry in the Philippines is highly regulated. Water quality reports must be submitted monthly. For microbiological failures, retesting is required immediately to ensure continuous supply of potable water. Report data are generated using classical standard analytical methods requiring 18 to 24 hour incubation periods for the presumptive phase and up to an additional 48 hours for confirmation of contamination. The methods used must be acceptable to the Philippine regulating bodies.

Recently, instrumented microbiological techniques have been approved by the Philippine Department of Health for generating regulatory report data. However, they are not yet being used.

This paper presents the challenges and triumphs encountered in registering a new analytical method for water quality in the Philippines, and the difficulties in changing methods. It also illustrates the capabilities and opportunities presented by the system – e.g., rapid failure detection, cost effectiveness, and applications to complement relief efforts in providing emergency water supply.

### ENDETEC TECTA B-16

Tecta EC/TC is a microbiological method for the simultaneous detection of total coliforms and *E. coli* in drinking water. It is based on detecting two enzymes,  $\beta$ -glucuronidase and  $\beta$ -galactosidase, which are characteristic of *E. coli* and the coliform group, respectively. TECTA EC/TC detects the activity of the two enzymes as they hydrolyse the specific substrates present in the medium. The substrate cleavage products are hydrophobic and fluorescent at different wavelengths, and diffuse into a polymer structure embedded in the base of TECTA EC/TC cartridge where their presence is detected.

When the product concentration from the enzymatic reactions reaches a threshold, the instrument recognises that total coliforms and/or *E. coli* are present and promptly alerts the monitoring laboratory of the findings much earlier than traditional EST methods.

## THE PHILIPPINE STORY

### Challenge

The Philippines is typhoon prone. In Metro Manila, where cities and municipalities prepare evacuation centres, the government needs to ensure the safe drinking water supply of hundreds or thousands of evacuees. Thus, the challenges in water quality monitoring can be very demanding.

### A solution

Tecta B-16 (Pathogens Detection Systems, Canada) was created in response to contamination events, and demand for faster, automated microbial detection. It is fully automated, and provides *E. coli* and coliform bacteria test results much faster than traditional methods. It is also simple, sensitive and flexible, and enables testing at any time.

### Method acceptance

The Philippines Department of Health (DOH), through the National Reference Laboratory (NRL), validated TECTA-B16 with both environmental and spiked lab samples to challenge its accuracy in detecting high and low levels of *E. coli*. The lab results show that it can detect as little as 1 CFU/100 ml, as well as high concentrations, of the target organisms in two hours without the need for sample dilution (Department of Health – National Reference Laboratory 2016).

## LABORATORY VERIFICATION

Due to its acceptance in the Philippines, Tecta B-16 was chosen for the investigation of bacteriological complaints and to enhance the turn-around time for critical disinfection projects.

A Tecta B-16 unit was calibrated and set to quantitative determination of total coliform and *E. coli*, and subjected to verification studies. Testing media were sourced from Tecta (TectAlert CCA Media) and came in the analytical container with a special fluorescent detecting medium. Samples were placed in the container and analysed according to the manufacturer's directions – the results are summarized in Table 1:

**Table 1** | Verification results for tecta PDS 16 – from maynilad central laboratory

Sample type	<i>E. coli</i> detection time	<i>E. coli</i> count	Total coliform detection	Total coliform count	Interpretation
Intake (raw water)	8 h 14 m 44 s	4,377 CFU/100 mL	9 h 12 m 36 s	10 <sup>4</sup> CFU/100 ml	<i>E. coli</i> and total coliform present
Potable water	n/a	<1 CFU/100 mL	n/a	<1 CFU/100 mL	<i>E. coli</i> and total coliform absent
Wastewater influent	3 h 4 m 32 s	10 <sup>7</sup> CFU/100 mL	2 h 32 m 56 s	10 <sup>9</sup> CFU/100 mL	<i>E. coli</i> and total coliform present
Surface raw water	10 h 1 m 25 s	144 CFU/100 mL	11 h 59 m 45 s	144 CFU/100 mL	<i>E. coli</i> and total coliform present

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## REGULATORY COMPLIANCE

Regulatory compliance in the Philippines is generally similar to that elsewhere. The minimum requirement for any laboratory is ISO/IEC 17025:2005 accreditation, although this does not automatically mean that the results from such laboratories will be accepted in a court of law for cases such as arbitration, adjudication, or confirmation. This is because laboratories desiring to be regarded as 'regulatory compliance' laboratories in the Philippines, i.e., labs whose results are to be accepted by regulators as proof of compliance to specified parameters, must pass the agency's additional audits to have legal standing. In general, the specified analytical method must be followed precisely, too. Some agencies do not prescribe particular methods – e.g., the Dangerous Drugs Board for Confirmatory Drug Testing Laboratories (DDB 2003). Those that require strict adherence to specified methods are:

- (1) DOH – for accredited laboratories for parameters listed in the Philippine National Standards for Drinking Water (PNSDW) (Philippines Department of Health 2017).
- (2) Department of Environment and Natural Resources (DENR) – for recognized environmental testing laboratories for parameters listed in various regulations, notably DENR-AO 2016-08, or the Water Quality Guidelines and Revised Effluent Standards of 2016 (DENR 2016).
- (3) Food and Drug Administration (FDA) – for cosmetics, pharmaceuticals, food items, foods, supplements, and bottled water (Republic of the Philippines RA 9711, 2009).

Under the DOH Order 2017-0010 – also known as the PNSDW of 2017 (Philippines Department of Health 2017) – the approved methods of analysis for the microbiological quality of drinking water, based on the Standard Methods for the Examination of Water and Waste Water (2011) 22nd edition are the multiple tube fermentation technique (MTFT), membrane filter technique (MFT) and Enzyme Substrate Coliform Test (EST). In this respect, the method to be used in the country is strictly prescribed. Often, proof of equivalence requires that regulating agencies are the first to adopt new technologies, and to validate and verify them. This can then become a funding issue. If the agency concerned cannot afford a unit, verification cannot start.

In the case of Tecta, however, it was distributor-initiated, allowing the regulatory agency access to the technology to prove its equivalence to accepted methods. This venture is at cost to the distributor and a risk to them as they have no assurance to a return. Complications can also arise when two distributors compete with different systems – since these agencies have budgetary restrictions, the cheaper offer might win.

In the Philippines, government acquisition is governed by a General Appropriations Act – RA6670 (Republic of the Philippines 1988). In summary, it is a legislative list of things an agency would want to acquire and budgeted in advance (usually prepared the year before), therefore any technology that comes along the way cannot be purchased if it was not budgeted. And since it is essentially a legislative instrument it is subject to liquidation and audit. However, since Tecta was distributor-initiated, it was able to be validated and verified, resulting in it being recommended by the DOH-NRL. They concluded that the ENDETEC TECTA –B16 is effective for total coliforms detection and as sensitive as the MTFT for *E. coli* detection.

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## APPLICATIONS IN PHILIPPINE RELIEF EFFORTS

The PNSDW of 2017 (DOH A.O.2017-10) lists emergency parameters that must be monitored within 72 hours of a disaster, such as an earthquake with magnitude greater than 7.0, severe monsoon flooding, or severe drought, and up to seven days afterwards:

- (1) Residual chlorine
- (2) Thermotolerant coliform/*E. coli*

During relief efforts following monsoons or typhoons like Haiyan (Category 5, November 2013), one of the most critical supplies needing immediate security is potable water. Frequently, disaster relief drinking water is supplied in bottles, in the Philippines, and private entities like Maynilad help by deploying mobile treatment plants. In the Mayon volcano eruption in January 2018, Maynilad's mobile treatment plant (Figure 1) was sent to Leyte Province. The plant consists of a microfiltration reverse osmosis (MF-RO) unit capable of producing approximately 26.5 m<sup>3</sup>/d (7,000 US gallons).



**Figure 1** | Maynilad's mobile treatment plant, as deployed in disaster relief efforts after the Mayon volcano eruption, 2018.

While the efficacy of MF-RO with chlorination is well documented, critical parameter monitoring by PNSDW 2017 is not totally compliant, as the finished water is only monitored for residual chlorine and turbidity (Figure 2).



**Figure 2** | Test kits used in monitoring mobile MF-RO plant finished water.

If bacteriological analysis are needed in the field, sharing a laboratory with the Local Government Unit (LGU), setting up a field office, or deploying a mobile lab are the common practices. After typhoon Haiyan, which devastated several towns in Leyte, the first two options were effectively impractical as the province had no stable power supply. Using a portable generator to power mini-incubators was too expensive and transporting hazardous reagents like Kovac's solution for confirmatory testing of the presence of *E. coli* was impractical.

The self-contained nature of Tecta meant that it could be deployed alongside other 'kit' methods in the field – travelling in the same vehicle and powered by the same portable generator as the MF-RO plant. Further, because DOH accepted it as a valid analytical method for water potability, the results could be sent to the main laboratory for quality control and data validation, etc, thus complying with the requirements of PNSDW 2017.

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## CONCLUSION

Philippine regulatory agencies dictate the methods used to monitor drinking water parameters. Unlike other countries, where other methods can be used upon offering proof of equivalence, novel methods cannot be adopted easily as it is the regulatory agency that must prove equivalence through rigorous testing and validation. Unbudgeted new technologies cannot be validated if they are not included in that year's list of purchases. Suppliers can provide access to new technologies for testing at their own cost, but this represents a risk to the supplier as no return is guaranteed.

A new field kit, microbiological analytical system was recently approved for use in the Philippines to monitor compliance according to the PNSDW 2017. This was accomplished through a supplier initiative in cooperation with the DOH-NRL. The Tecta B-16 was shown capable of detecting microbiological contamination relatively quickly.

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