

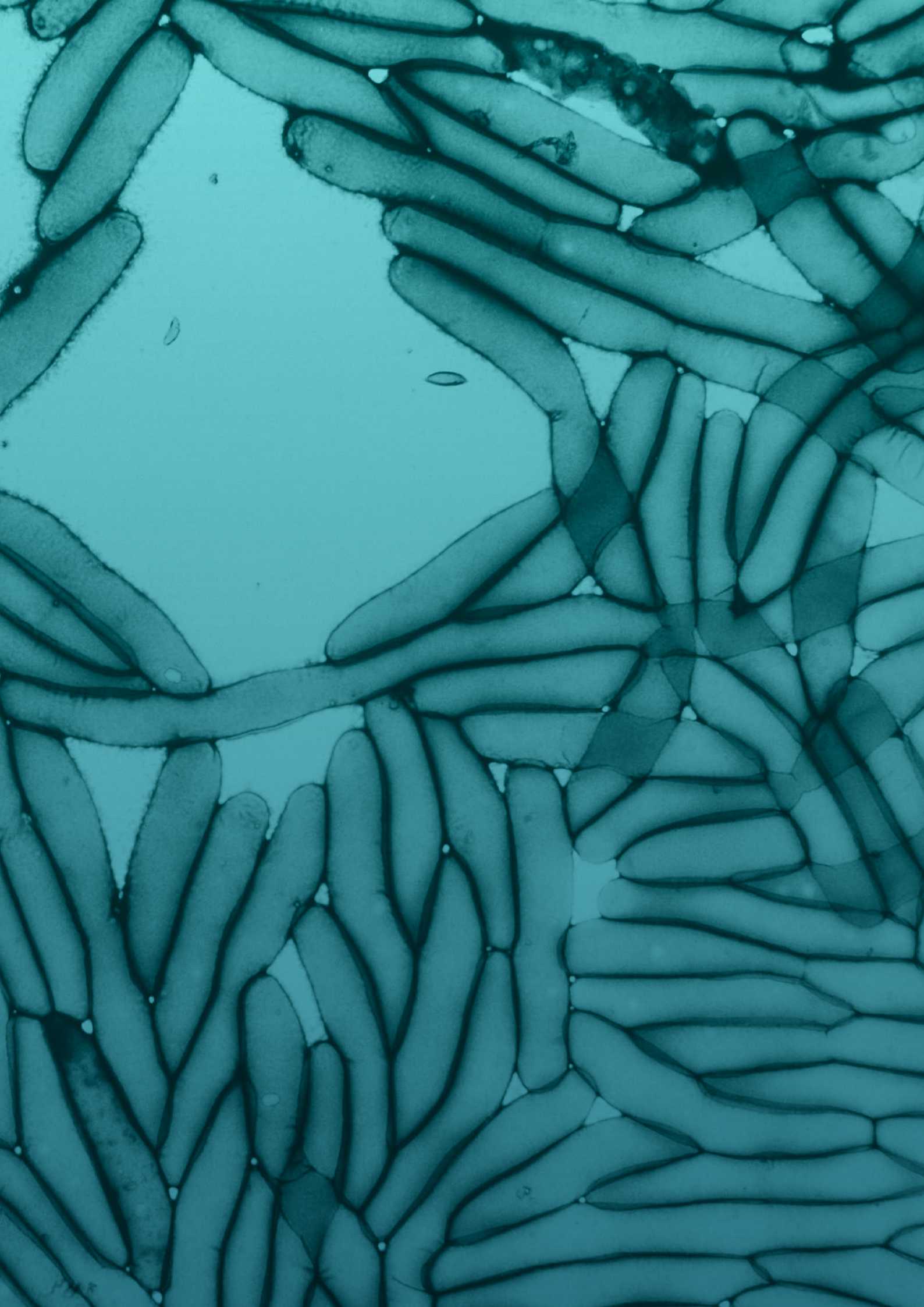


WHITEPAPER

## ALERE™ READER

Take the subjectivity out of your results for accurate diagnosis and effective clinical management.





# Table of contents

4	<b>The Alere™ Reader and its key benefits</b>
4	Accurate diagnosis is central to effective clinical management
5	Why use the Alere Reader?
6	<b>The benefits of the Alere Reader are scientifically proven</b>
6	The Alere Reader increases the clinical and analytical sensitivity of the Alere BinaxNOW™ <i>Legionella</i> urinary antigen card
7	The Alere Reader also increases the clinical sensitivity of the Alere BinaxNOW™ <i>Streptococcus pneumoniae</i> urinary antigen card
8	<b>Data connectivity for point-of-care data management</b>
10	<b>The Alere Reader improves laboratory quality standards</b>
12	<b>References</b>





## The Alere™ Reader and its key benefits

### ACCURATE DIAGNOSIS IS CENTRAL TO EFFECTIVE CLINICAL MANAGEMENT.

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Over recent decades, dramatic advances in diagnostic testing have led to improved patient management with associated clinical, operational, and economic advantages.<sup>1-3</sup> Rapid diagnosis benefits both patients (by allowing timely therapy) and public health (by collecting data for epidemiological studies to help prevent outbreaks and spread of disease).<sup>2</sup> As every physician knows, correct diagnosis is central to effective clinical management, and rapid diagnostic testing can play a central role in optimising management of patients and diseases, allowing patients to be diagnosed faster and more precisely than ever before.<sup>2,3</sup>

Accurate interpretation of laboratory results in infectious disease is one particular area in which early and accurate screening of pathogens is intimately linked to effective prevention and clinical management.<sup>2</sup> Traditional diagnostic testing involves multiple steps that include analysis and pre- and post-analysis stages, each of which is associated with risk of error.<sup>4</sup> An important factor contributing to potential failure of diagnostic testing is incorrect interpretation of the test result, and manual or visual interpretation is associated with significant risk of error.<sup>3</sup> Retrospective reviews of malpractice claims showed incorrect interpretation of diagnostic testing to be the causative factor in 37% of delayed or missed diagnosis cases.<sup>5,6</sup>

## WHY USE THE ALERE READER?

The use of technology in diagnostic testing can substantially reduce the number of errors, and therefore offers the potential to improve patient management.<sup>3,7</sup> Abbott offers a range of rapid point-of-care (POC) diagnostic tests to help healthcare professionals to make faster, better decisions, leading to improved medical outcomes. The Alere Reader enhances the accuracy and sensitivity of Alere diagnostic tests, adding even more support to optimise healthcare diagnosis (Figure 1).

The Alere Reader is a camera-based instrument designed for use by physicians, laboratory technicians, and other healthcare personnel and delivers automated objective results in seconds.<sup>8</sup> The Alere Reader accurately detects and identifies completed lateral flow assays and offers seven key benefits (Figure 2).<sup>9</sup>

**Figure 1.** Manual versus Alere Reader interpretation of a diagnostic test card.<sup>4</sup>

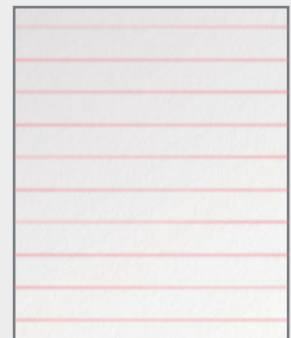


How many test lines can you identify on this calibration card?



The Alere Reader can detect 10 lines.

*Enhanced image to depict the Alere Reader "view."*



**Figure 2.** Key benefits of the Alere Reader



**ENHANCED QC**  
QC module and lockout feature



**RAPID RESULTS**  
Maximises accuracy and minimises human error



**OBJECTIVE RESULTS**  
Eliminates operator subjectivity and provides consistency in reading



**FLEXIBLE ACCESS**  
Save, share, and print results directly from the Alere Reader



**EASY TO USE**  
Scan the barcode, enter the patient ID and place the test into the Alere Reader



**BARCODE TECHNOLOGY**  
The control of a connected instrument and the speed of a rapid lateral flow assay



**WORKFLOW FLEXIBILITY**  
Flexible implementation into existing workflow

# The benefits of the Alere™ Reader are scientifically proven.

## THE ALERE READER INCREASES THE CLINICAL AND ANALYTICAL SENSITIVITY OF THE ALERE BINAXNOW® LEGIONELLA URINARY ANTIGEN CARD.

Detection of *Legionella pneumophila* serogroup 1 antigen in urine samples is widely used for the diagnosis of Legionnaires' disease (LD).<sup>10</sup> The Alere BinaxNOW *Legionella* urinary antigen card (UAC) is a rapid assay designed for the qualitative detection of *L. pneumophila* serogroup 1 antigen in urine samples from patients with symptoms of pneumonia.<sup>11</sup> The Alere BinaxNOW *Legionella* UAC has been used in a study designed to scientifically evaluate the performance of the Alere Reader.<sup>10</sup> In this study, 49 positive samples and a selection of negative urine samples (surcharged with lipopolysaccharide [LPS] from 10 *L. pneumophila* strains) were evaluated using human visual interpretation and the Alere Reader.<sup>10</sup>

## THE ALERE READER DEMONSTRATED AN OVERALL SENSITIVITY OF 100%

Of the 49 positive samples, the Alere Reader correctly identified all 49 samples as positive, while visual interpretation only identified 41 samples as positive (Table 1).

## UP TO 10-FOLD INCREASE IN SENSITIVITY

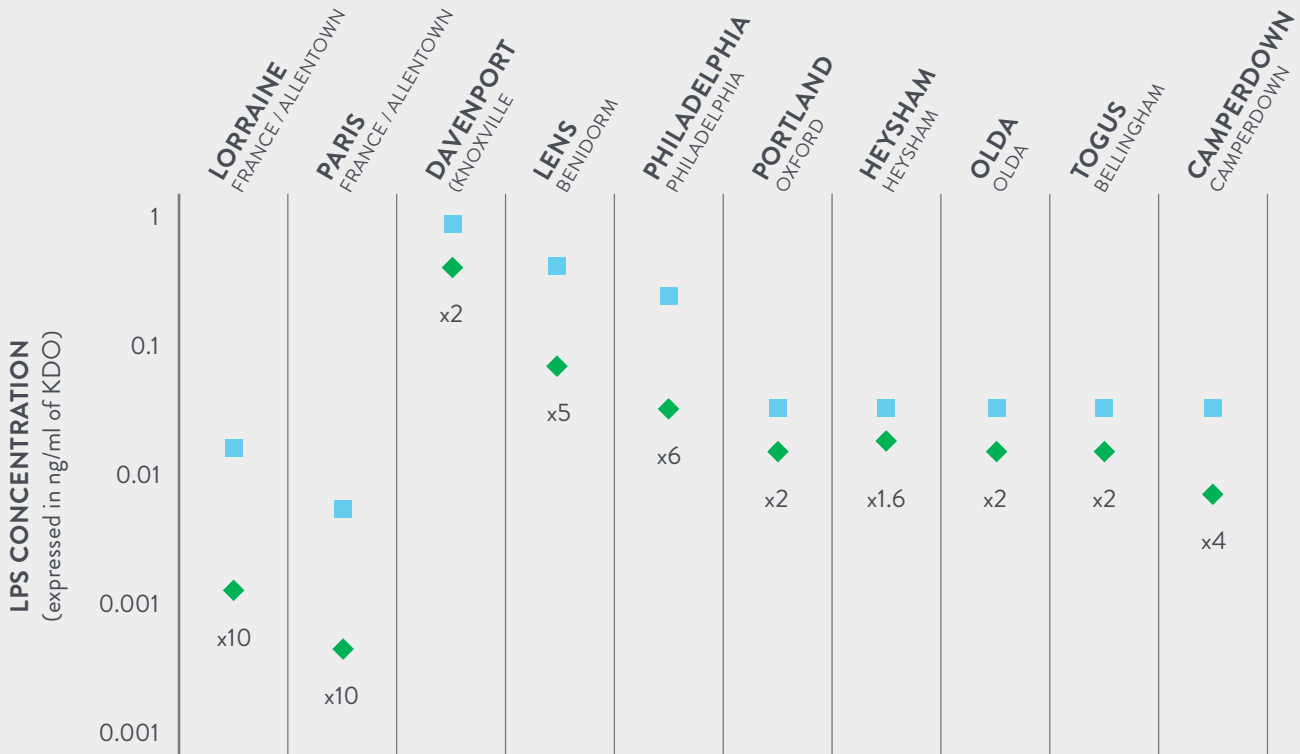
**Table 1.** Correct identification of *L. pneumophila*-positive frozen urine samples (n=49).<sup>10</sup>

SAMPLE IDENTIFICATION	VISUAL INTERPRETATION	ALERE READER
NEGATIVE	8	0
POSITIVE	41	49

## WITH THE ALERE READER VERSUS VISUAL INTERPRETATION.

The second part of this study evaluated the sensitivity of the Alere Reader when used with different strains of *L. pneumophila*. Results showed that the greatest increase in analytical sensitivity was with monoclonal antibody (mAb) 3/1+ strains (Figure 3).<sup>10</sup> The greatest improvement in sensitivity (10-fold) was observed with the France/Allentown strains that are frequently isolated in urine samples from patients with LD (Figure 3).<sup>10</sup>

**Figure 3.** Sensitivity of the Alere Reader versus visual interpretation of *L. pneumophila* urine samples.<sup>10</sup>



Lower detection limits of BinaxNOW® Legionella UAC analysed visually (■) and by the reader (◆). KDO, keto-deoxy-d-manno-8-octanoic acid; lipopolysaccharide; mAb, monoclonal antibody; UAC, urinary antigen card.

### THE ALERE READER ALSO INCREASES THE CLINICAL SENSITIVITY OF THE ALERE BINAXNOW® STREPTOCOCCUS PNEUMONIAE URINARY ANTIGEN CARD.

Detection of *Streptococcus pneumoniae* antigens in urine samples is used for the diagnosis of pneumococcal disease, an infection spread through coughing, sneezing and close contact with the infected person. The Alere BinaxNOW® *Streptococcus pneumoniae* UAC is a rapid assay designed for the detection of *S. pneumoniae* in urine samples.

The Alere BinaxNOW *S. pneumoniae* UAC has been used in a study to scientifically evaluate the performance of the Alere Reader (Table 2).<sup>12</sup> In this study, 499 urine samples from 472 patients were evaluated. The observer identified negative results in 19 patients but the Alere Reader detected all of these as positive; 15/19 patients were found to have a diagnosis of pneumonia, showing the Alere Reader to be more sensitive compared with visual interpretation.

**Table 2.** Identification of *S. pneumoniae* urine samples using two different methods (n=499).<sup>12</sup>

		VISUAL INTERPRETATION		
		SAMPLE IDENTIFICATION	POSITIVE	NEGATIVE
READER INTERPRETATION	POSITIVE		62	19
	NEGATIVE		0	418

Out of 19 patients who had discrepant results between the two methods, 15 were diagnosed with pneumonia, indicating the Alere Reader was accurate in these cases.

# Data connectivity for point-of-care data management

## INFORMATION TECHNOLOGY OFFERS THE MOST EFFECTIVE DATA MANAGEMENT SOLUTION

Breakdown in information flow and communication is one of the most common factors identified for diagnostic error.<sup>7</sup> Timely, efficient, and accurate exchange of information among healthcare professionals is therefore critical to optimise diagnosis and healthcare decisions. Original, manual documentation methods for recording POC test results are still used in many healthcare facilities, but these older methods possess inherent opportunity for error, are time-consuming, and work-intensive.<sup>13</sup>

Technology has significantly advanced over recent years, and now, the optimal connectivity solution to manage POC test results involves the use of online management platforms. Online POC management platforms allow multiple devices to interface with information systems from laboratories, hospitals, and healthcare centres, and offer multiple advantages over manual documentation methods (Figure 4). POC devices with networking can integrate QC measurements into a central data management system, reducing the burden of paperwork, which is otherwise placed on operators.<sup>13</sup> From a clinical perspective, near-immediate test results allow physicians to review results, evaluate progress, and establish treatment regimens in a single visit. This simple change can result in improved disease management, treatment adherence, and patient satisfaction.<sup>13</sup>

Figure 4. Key benefits of the AegisPOC™ Point-of-Care Management Solutions platform.



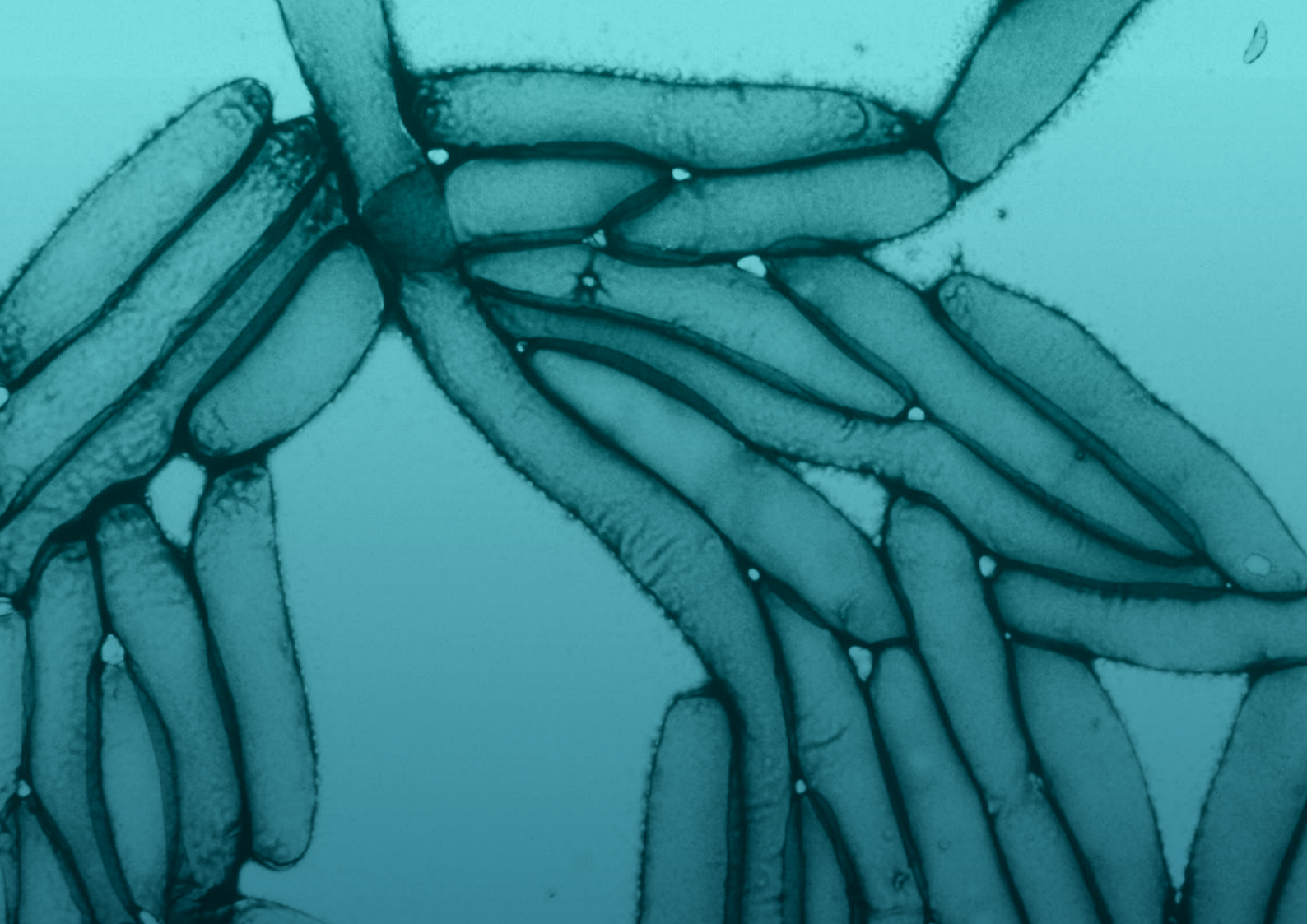


## AEGISPOC™ POINT OF CARE MANAGEMENT SOLUTIONS – A POC MANAGEMENT SOLUTION.

AegisPOC Point of Care Management Solutions is a web-based, open platform that connects POC devices located in the hospital or in the community to the laboratory. The AegisPOC Point of Care system allows the laboratory to effectively and efficiently manage and share data from POC devices, using a flexible, scalable middleware. Workload to manage the POC device is reduced, as user certification and re-certification, training and QC can be automatically and remotely managed.

The AegisPOC system integrates POC devices with laboratory and hospital information systems as well as emergency room, quality management, user management, and other systems, making it easy to manage patient test results from any location. The AegisPOC system also contains an extensive library of reports that helps meet compliance requirements while streamlining data management, POC usage reporting, and reimbursement claims.





# The Alere Reader improves laboratory quality standards.

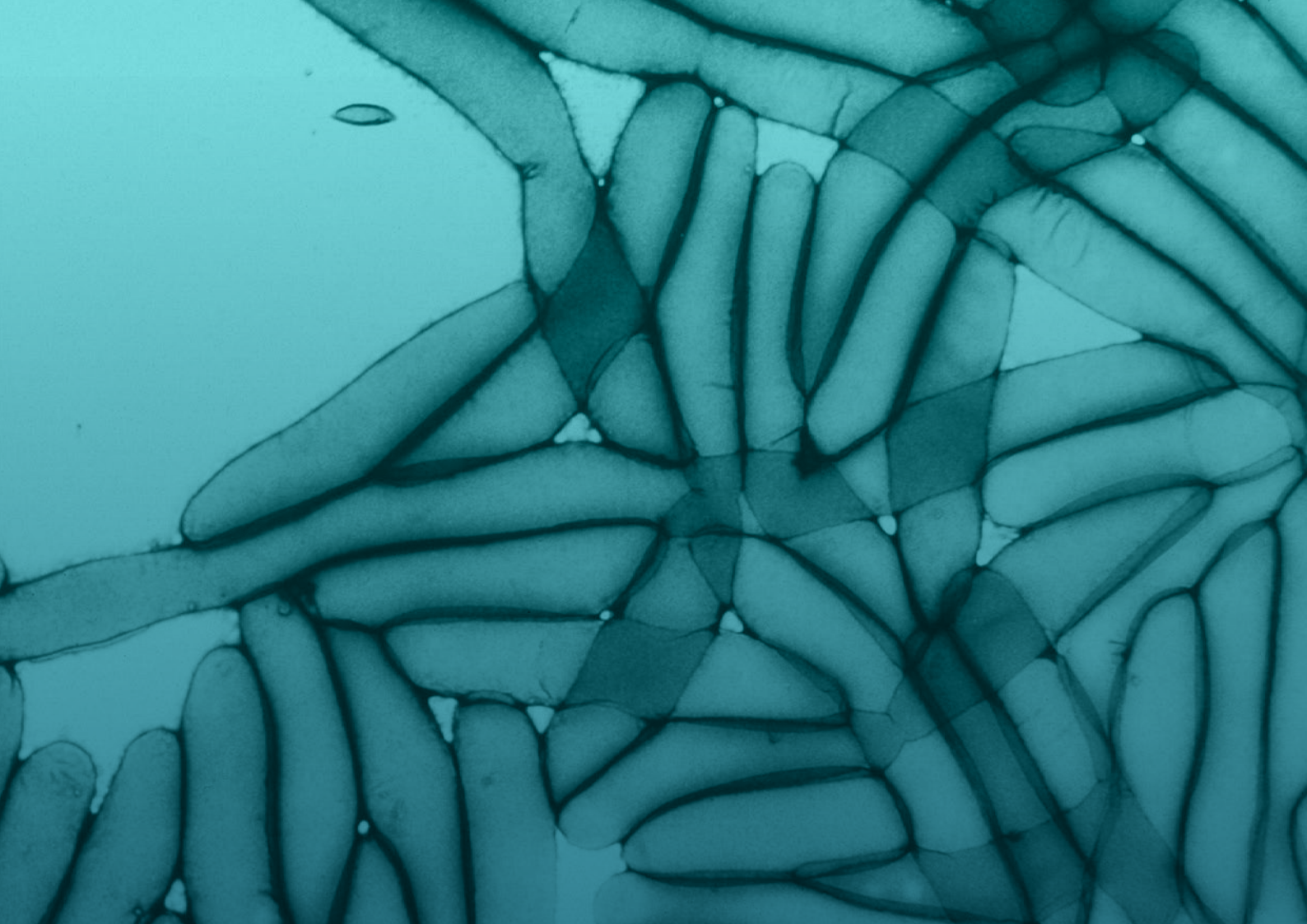
## QC FEATURES OF THE ALERE READER

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Good standards of QC and confidence in the reliability of diagnostic test results are essential aspects of accurate clinical diagnosis.<sup>14</sup> A POC testing tool can only be as accurate as the competency of its operator.<sup>13</sup> Guidelines on Good Laboratory Practice (GLP) outline standards that include training of laboratory personnel, assay controls and validation, and QC logs, compliance to which are expected to improve data integrity, and provide results that are repeatable, reliable and auditable.<sup>15</sup>

In line with the importance of adhering to GLP and QC, the Alere Reader has been designed with a 'Quality Control Lockout' feature that ensures that QC tests are run every time the laboratory receives a new batch of product. In addition, the Reader has a 'Quality Control Test Module' that allows the laboratory to record and objectively evaluate whether a technician is capable of properly performing an assay and provides audit trails for training compliance. The Alere Reader therefore contains three key features designed to minimise human error (Figure 5).





**Figure 5.** Features of the Alere Reader that minimise human error.

Bar code scanner reduces transcribing errors



Connectivity solutions remove error from test results reporting



QC features allow high-quality laboratory standards & training compliance



## CONCLUSIONS

As healthcare continues to evolve towards the demand for ever faster and more accurate diagnosis, POC testing is expected to play an increasingly important role in patient management.

Easy-to-use, high-technology, quality-controlled devices are important tools for achieving this goal, offering multiple benefits as well as reassurance for improved diagnostic quality for physicians, and medical care for patients.

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