

A Guide to Implementing
Diagnostic
Stewardship in Asian Hospitals





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This document is intended to provide a practical step-by-step guide to the implementation of microbiological diagnostic stewardship (DS) in Asian hospitals. The information contained in this guide is consistent with recommendations from international organizations.¹⁻³ DS is an essential partner to antimicrobial stewardship (AMS),⁴ and as such this guide can be used in conjunction with our **Guide to Implementing Antimicrobial Stewardship Programs in Asian Hospitals**.

A glossary of DS-related terms commonly used throughout this guide is provided in the Appendix.

Defining diagnostic stewardship

In relation to infectious diseases, DS focuses on methods to arrive at a correct diagnosis while AMS focuses on optimizing antimicrobial treatment (Figure 1).^{4,5} The diagnostic process consists of three phases⁶:

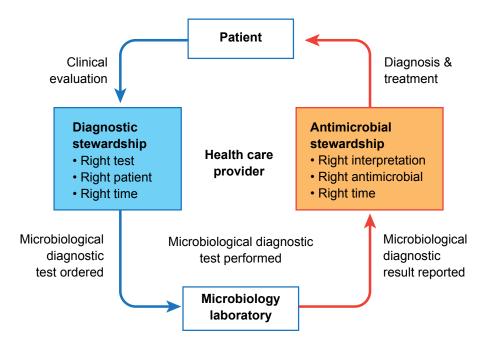
- · Preanalytical:
 - Test ordering
 - Specimen collection, transportation, and preparation
- Analytical:
 - Performance of the test itself and any associated laboratory practices
- Postanalytical:
 - Reporting, evaluation and interpretation of test results
 - Intervention

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Figure 1

Roles of diagnostic stewardship and antimicrobial stewardship in patient care⁵



Adapted from Messacar K, et al. 2017.

Diagnostic error, which can lead to patient harm, occurs when a patient has a nonindicated test, delayed diagnosis, or incorrect application or interpretation of a test result. DS is an approach to reduce diagnostic error.⁶

DS has been defined as "coordinated guidance and interventions to improve appropriate use of microbiological diagnostics to guide therapeutic decisions". DS is commonly described as "right test, right patient, right time" (Figure 1 and Table 1). DS also extends to assisting clinicians to correctly interpret complex text results and apply them to treatment decisions. The ultimate goal of DS is to optimize patient care by improving the diagnostic process. As such, DS should

promote appropriate, timely diagnostic testing, including specimen collection and pathogen identification, and accurate, timely reporting of results to inform optimal clinical care.¹ By maximizing the probability that clinicians will arrive at a correct diagnosis in a timely manner, DS supports AMS efforts to ensure optimal pathogen-targeted treatment of infections while avoiding inappropriate use of antibiotics empirically, thereby limiting the spread of antimicrobial resistance.⁴,7



Table 1
Diagnostic stewardship goals and key questions⁴⁻⁶

Goal	Key questions
Right test	Is the test appropriate for the clinical setting?
	- What is the test's sensitivity?
	- What is the test's specificity?
	- What is the positive predictive value of the test?
	- What is the negative predictive value of the test?
	- What does the test cost?
Right patient	Will clinical care of the patients be affected by the test result?
	- Is the pretest probability appropriately high?*
Right time	Will the test result be available in time to optimally inform clinical care?
	- What is the test's turnaround time?
Right	Will the clinician understand the test result?
interpretation	- Are the results reported clearly?
	- Should selective reporting be applied?

^{*}The lower the pretest probability, the less likely a diagnostic test will further the diagnostic process.

Table 2
Key steps and requirements for the implementation of diagnostic stewardship^{1,6}

Key steps	Requirements
Step 1: Planning	Situation analysis, resources and needs assessment
Step 2: Resources	 Required Approval and funding for DS activities DS leader and/or multidisciplinary DS team Reliable microbiological laboratory facilities and appropriately trained staff Desired Access to rapid diagnostic testing IT support systems
Step 3: Interventions	Design and implement interventions to improve the appropriate use of microbiological diagnostic tests and assist in the interpretation of results
Step 4: Monitoring and reporting	 Monitor and report appropriateness of microbiological diagnostic ordering, sample collection and processing, and reporting and interpretation of test results Monitor and report the impact of DS on patient care, and the economic impact of DS

DS, diagnostic stewardship; IT, information technology.



What is needed for diagnostic stewardship?

Working through the four main steps and requirements outlined in Table 2 will help to ensure implementation of effective DS in your hospital.

Step 1: Situation analysis

The first step towards the implementation of DS involves the comprehensive assessment of the situation, resources and needs of the hospital.¹ A review of policies, resources and systems that are already in place to optimize test ordering, specimen collection, laboratory processing and test result reporting should be conducted. Any potential challenges should be identified.1 These might include costs of microbiological diagnostic testing, lack of reliable microbiological laboratory services and expertise, lack of understanding and training among clinical and/or laboratory staff, and lack of information technology (IT) systems to support DS activities. Based on the findings of the review, a realistic plan for the implementation of DS should be developed.

Collect data to answer the following key questions:

- Are certain microbiological tests overused or underused at your hospital?
- Does your hospital have access to microbiological laboratory facilities that are able to deliver timely, reliable diagnostic testing services?
- Do clinicians have a full appreciation of available tests and their correct use?
- Do the tests available at your hospital provide all the required information?
- What potentially beneficial tests are unavailable at your hospital laboratory?

- Do microbiologists and laboratory staff provide guidance and input to clinicians ordering the tests?
- What changes could be made to ensure that appropriate tests are ordered, the tests are carried out correctly, and the results interpreted correctly?

Examples of tests that may be overused include urine culture and *Clostridium difficile* testing in patients with low pretest probability of urinary tract infection (UTI) and true *C. difficile infection* (CDI), respectively. 4,8,9 Such tests are frequently ordered in response to non-specific symptoms and often lack a valid clinical indication. 8,10 When test results are positive, unnecessary antimicrobial agents are often prescribed although these can be false-positive results or colonization rather than true infection. 10

Step 2: Resources

Approval and funding

Based on findings from the situation analysis, a budget for the implementation of DS activities should be developed and will need to be approved by hospital administration. Cost estimations should consider requirements at all phases of the diagnostic process, including the costs of developing and implementing guidelines, standard operating procedures (SOPs) and training material. As is also the case for AMS, funding for DS activities may be difficult to obtain because of competition for resources, so it is important to provide hospital administrators with a credible business case to persuade them that funding is beneficial to the hospital. 1.2

Some ideas for developing the business case:

- Explain that inappropriate use of diagnostic tests can lead to unnecessary interventions leading to potentially harmful consequences and increased costs and resource utilization.^{6,9}
- Emphasize that accurate diagnosis is closely associated with more appropriate antimicrobial use, potentially resulting in fewer adverse effects, shorter hospital stays and less antimicrobial resistance.^{6,10}
- Highlight DS as an essential partner to AMS, enhancing the ability of AMS programs to implement interventions such as deescalation to pathogen-targeted therapy, and realization of AMS goals and cost-saving benefits.⁴
- According to hospital priorities, capacities and resources, propose gradual implementation of DS (eg, initially only for blood cultures or rapid diagnostic tests [RDTs] for detecting bloodstream infection, and/or tests that have high testing volumes such as those for UTI).¹⁶

Diagnostic stewardship team

Laboratory staff, physicians, pharmacists and nurses all play a role in DS.¹¹ It is important to work within the hospital's budget and personnel constraints to create the most effective multidisciplinary team available.¹⁶ This team should be mandated by senior management to implement DS activities.¹ Clinical microbiologists and infectious disease specialists are best suited to working collaboratively on DS interventions to optimize the use of microbiological diagnostic tests and communicate test results (see Step 3).²⁷

Nurses can play an especially important role in²:

- Selecting the right patients for diagnostic testing (ie, informing decisions about whether a patient has symptoms that might justify a urine culture).
- Assuring that cultures are performed correctly before starting antibiotics (ie, knowing proper techniques to reduce contamination).

Ideally, a subcommittee of the **AMS team**, including clinical microbiology, IT, medical and pharmacy staff, should be delegated the task of DS. ¹²⁻¹⁴ DS/AMS Responsibilities of clinical microbiologists include¹⁵:

- Guiding appropriate specimen collection, cultures and tests.
- Ensuring accurate pathogen identification and susceptibility testing.
- Ensuring timely reporting and clear interpretation of patient-specific culture results (including probable contamination or colonization).
- Regular provision of **antibiograms**.
- Keeping abreast of new developments in the field of diagnostics.

If staffing constraints mean that it is impossible to assemble a DS subcommittee, part of each AMS meeting agenda should be reserved for discussions on DS.¹⁴



Obtaining support for access to reliable microbiology laboratory services and expertise should be prioritized.^{15,16}

Microbiological laboratory facilities for conventional and rapid diagnostic testing

Affordable access to a laboratory with good quality management, and the capacity and capability to perform timely and reliable microbiological diagnostics are essential to implement DS activities. Hospitals where microbiology services are contracted to an external organization should ensure that adequate information is available to inform DS efforts. Lack of understanding and training can hinder successful implementation of DS.

Delayed (72 hours) conventional bacterial culture and antimicrobial susceptibility testing results, necessitating initial empiric therapy, are barriers to optimizing antibiotic therapy. Few hospitals in Asia use RDTs, and many are not even in a position to deliver accurate and reliable conventional pathogen-defining testing.¹⁵ It is essential to strive toward strengthening laboratory capacity that can deliver such services.

Transportation of specimens and communication between the hospital and the laboratory (on-site or off-site) must be organized to ensure that specimens can be processed without delay and that results can be reported in a timely manner.¹ A courier system to transport the specimens from the surveillance site to the laboratory under carefully controlled conditions may be needed, particularly if the laboratory is off-site.¹ For example, urine specimens need to be refrigerated at 2-8°C.⁸

IT systems to support DS

As hospitals move toward adopting electronic medical records (EMRs), there are increasing opportunities to integrate DS and decision support into IT systems.^{7,15} If a hospital does not have the infrastructure to set up IT systems to support DS, paper-based systems and guidelines will suffice.

Step 3: Interventions

Any number of DS interventions can be chosen to improve diagnostic processes in your hospital. Examples are listed in Table 3.4

Table 3

Examples of DS interventions grouped according to DS goals^{4-8,10}

Diagnostic stewardship goals						
Limit testing to patients with high pretest probability	Ensure correct specimen technique; maximize test sensitivity and specificity	Communicate suboptimal posttest probability and help clinicians interpret test results				
 Provide training, reminders and learning resources regarding appropriate testing Guidelines, clinical pathways, or policies Formal training (in-person, online) Visual reminders (screensavers, posters, pocket cards) Computerized order entry decision support (ie, prompts/best practice advisories/smart ordering systems built into the EMR) Customized laboratory test ordering menus featuring appropriate evidence-based options for a specific clinical pathway Block inappropriate orders from being placed Hard stop in EMR Preauthorization by laboratory, pharmacy, or another gate keeper Cancel inappropriate orders Test cancellation by laboratory or another gatekeeper 	 Choose a testing strategy with high sensitivity and specificity for the condition of interest (may involve RDTs) Educate clinicians on the correct use of diagnostic tests, eg, via online learning, continuing medical education, continuing professional development Develop training programs on diagnostic test implementation and reporting Implement policies and training promoting correct microbiological specimen collection technique and transport practices Produce guidelines and SOPs for sample collection and processing 	 Add comments to the test report/EMR to provide contextualized reporting of results tailored to the needs and unique epidemiology of individual institutions Clinical decision support systems Introduce selective antimicrobial susceptibility reporting to encourage use of the least toxic and most narrow-spectrum agent available 				

DS, diagnostic stewardship; EMR, electronic medical record; RDT, rapid diagnostic test; SOP, standard operating procedure.



Table 4

Stages of the diagnostic process at which interventions improve the use of common infectious disease tests^{4,7-10}

	Preanalytic		Analytic	Postanalytic
	Ordering	Collection	(processing)	(reporting)
Urine cultures	Test only when symptoms suggest UTI or, if asymptomatic, only if there is an evidence-based indication (eg, before urologic surgery, pregnancy, clearly defined neutropenia)	Use aseptic technique (midstream clean catch after periurethral cleansing) Obtain catheter sample from collection port (not bag), prefer newly inserted catheter	Only perform urine culture if pyuria present Rejection of contaminated urine specimens as indicated by elevated squamous cells	Example text: "multiple organisms indicating likely contamination"; "no pyuria, culture not performed" Selective reporting of antibiotic susceptibilities (display preferred antibiotics only) Electronic prompt to consider asymptomatic bacteriuria and necessity for treatment in patients with low posttest probability
Blood cultures	Test only when there is concern for sepsis or endovascular infection or symptoms of infections associated with a high or intermediate risk of bacteremia Avoid repeat cultures unless concern for persistent or endovascular infection	Use aseptic technique (prefer peripheral samples obtained by trained phlebotomists) Avoid catheter draws	Consider rapid testing on initial positive results, eg, PCR, PNA-FISH, MALDI-TOF	Example text: "likely skin contaminant"; "Staphylococcus aureus likely pathogen, consider infectious diseases consultation
C. difficile testing	Test only when disease likely (eg, recent antibiotic exposure, >3 loose stools/day, duration >24 hours, and no recent laxative use) Avoid repeat testing in patients who have recently tested positive Avoid tests of cure	Only collect and send loose stool (ie, that conforms to the container)	Consider use of a testing algorithm that includes toxin immunoassay	Example text: "toxin / PCR+ indicating possible colonization rather than disease"

PCR, polymerase chain reaction; PNA-FISH, peptide nucleic acid-fluorescence in situ hybridization; MALDI-TOF, matrix-assisted laser desorption/ionization time-of-flight.



To date, most DS literature describe interventions that have promoted accurate diagnosis of UTI and CDI, both of which are prone to over-diagnosis, and bloodstream infections, for which testing criteria are ambiguous and blood culturing is challenging. 4,10,17 Interventions can be implemented at any phase of the diagnostic process to optimize test ordering, specimen collection, laboratory processing, and test result reporting (Tables 3 and 4).4,10 DS interventions can be as simple as introducing laboratory policies and systems to refuse to process specimens that are collected or handled inappropriately, or including a reminder in the urine culture report about the possibility of asymptomatic bacteriuria in patients with low suspicion of a UTI.^{4,8,10} Such interventions represent cost-effective strategies that can be implemented in most settings, including resource-limited settings.

Rapid diagnostic testing

RDT has the potential to lead to earlier administration of effective, targeted antimicrobial agents and reduce the use of unnecessary empirical therapies.^{5,6} However, although they expedite organism identification, many RDTs do not provide synchronous information regarding antimicrobial susceptibility, so **antibiograms** are required to guide selection of therapy pending the availability of susceptibility results.^{5,18} The use of RDTs without active AMS intervention may not improve antimicrobial therapy or patient outcomes⁶ – both DS and AMS are essential for successful implementation of RDTs in the clinical setting to optimize patient care.^{5,7}

A range of technologies can be classified as RDTs, including procalcitonin (PCT), matrixassisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS), peptide nucleic acid fluorescence in situ hybridization (PNA-FISH), and polymerase chain reaction (PCR).^{12,13} Use of certain types of RDTs is increasingly becoming part of standard practice in high-income countries within the Asian region.¹² Realistically, however, cost is likely to remain prohibitive in many hospitals, particularly in low- and middleincome countries, and a selective approach is required.¹² For RDTs to be approved by hospital administration, DS teams may need to carefully communicate their cost-saving potential. For example, several studies have proven overall cost-savings of PCT-guided AMS at the hospital level when considering expenses in the laboratory and reduced antibiotic expenses at the pharmacy.19

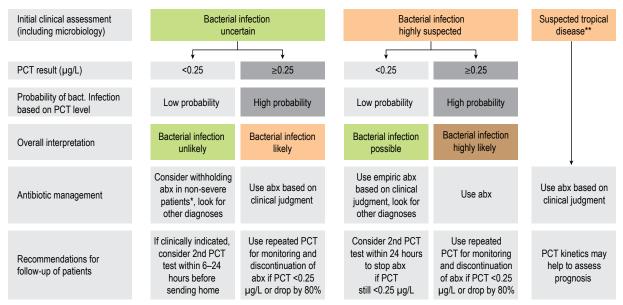
PCT, a blood biomarker of bacterial infection, is an increasingly accepted concept in Asia, particularly in the setting of respiratory infections and sepsis.¹⁹ However, as is the case for other diagnostic tests for infectious diseases, most PCT test result interpretations are done by clinicians who are not infection specialists, and misinterpretation with resulting inappropriate antibiotic use can occur.¹⁹ Education on the correct use of RDTs is essential, with guidelines, algorithms and/ or clinical decision support systems provided to minimize the risk of misinterpretation. Algorithms on optimal use of PCT in Asia-Pacific countries have already been developed (Figure 2).19

The use of a biomarker-guided treatment protocol supports DS goals to provide the shortest possible duration of antibiotics only to patients truly in need of these drugs.¹⁹

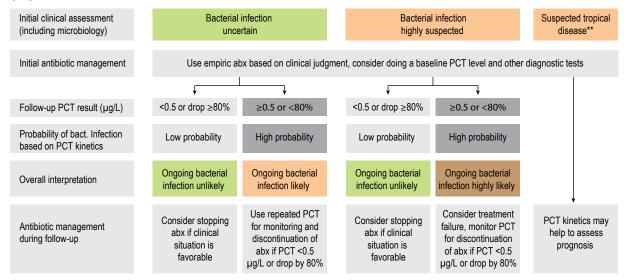
Figure 2

PCT use in (a) non-critically ill patients and (b) critically ill patients in Asia-Pacific countries¹⁹

(a)



(b)



^{*}Caution in patients with immune-suppression (including HIV), cystic fibrosis, pancreatitis, trauma, pregnancy, high volume transfusion, PCT-guided stewardship should not be applied to patients with chronic infections (eg, abscess, osteomyelitis, endocarditis)



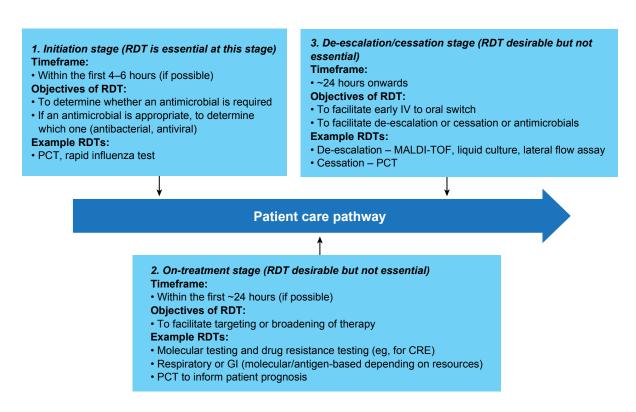
^{**}Tropical diseases include, but are not limited to, malaria, dengue fever, hemorrhagic fever, typhus Reproduced from Lee CC, et al. 2020.

As more RDTs become available, DS becomes ever-more important as it becomes more difficult for clinicians to choose an appropriate test, and for the laboratory to know which tests to add to their menu. Laboratories should routinely audit their test menus in consultation with DS and clinical teams to ensure manageability and clinical relevance.7,11 Multidisciplinary DS teams will need to make decisions about which RDTs to prioritize according to laboratory feasibility (ie, technologist training required), test sensitivity and specificity, positive and negative predictive values, turnaround time, ease-ofuse and cost-effectiveness.⁵ It is important to consider whether new tests would replace or be conducted in addition to existing tests.

For example, with multiplex PCR platform for cerebrospinal fluid testing, culture is still needed for detection of bacterial pathogens not detected by the panel, confirmation of positive results, and susceptibility testing.⁵

RDTs are generally most useful at the initiation of treatment; at other stages, more affordable conventional diagnostic tests may be more desirable, especially in resource-limited settings (Figure 3).¹² Preferred RDTs can yield results to guide treatment before the second dose of antimicrobial is administered. Ideally, results should be available to the clinician within 4–6 hours; in settings where this is not possible, delivery of results within 24 hours may be acceptable.^{12,13}

Figure 3
Usefulness of RDTs in relation to treatment initiation, duration and cessation¹²



CRE, carbapenem-resistant Enterobacterales; GI, gastrointestinal; IV, intravenous; MALDI-TOF, matrix-assisted laser desorption/ionization time-of-flight; PCT, procalcitonin; RDT, rapid diagnostic test. Figure reproduced from Apisarnthanarak A, et al. 2021.

Selective testing and reporting

Susceptibility testing should only be performed on clinically significant isolates, instead of all microorganisms covered in culture. When it comes to reporting, the laboratory does not need to report "everything that grows" to avoid irrelevant information that could lead to inaccurate diagnosis and inappropriate therapy. Only those that are accurate, significant and clinically relevant should be reported.²⁰

One approach is to selectively report antimicrobial susceptibility results to clinicians, whereby susceptibility results for second-line antimicrobial agents (eg, broader spectrum agents) are only automatically reported if isolates are resistant to narrow-spectrum agents, hence guiding appropriate antimicrobial selection.^{1,15,21,22} Although the practice of reporting susceptibility results for a limited number of antibiotics instead of all tested antibiotics may promote appropriate antibiotic use, it requires careful monitoring by a clinical microbiologist so that errors are not made and could be difficult to implement in many Asian hospitals.¹⁵

Guidelines, education and training

When developing SOPs, guidelines and educational materials for your hospital, make use of pre-existing guidelines and training courses such as those listed below:

- The Infectious Diseases Society of America/ American Society for Microbiology <u>Guide to</u> <u>Utilization of the Microbiology Laboratory</u> <u>for Diagnosis of Infectious Diseases</u> provides evidence-based, disease-specific information on the most reliable tests to order; samples (and volumes) to collect; specimen transport devices, procedures, times, and temperatures; and detailed notes on specific issues regarding the test methods, such as when tests are likely to have prolonged turnaround times.²⁰
- The WHO's guide to implementation of DS
 is also useful in this regard.¹
- A free online course (<u>Diagnostic</u>

 <u>Stewardship in Clinical Practice</u>) from
 the Open University also provides insight
 into microbiology laboratory workflow,
 proper methods of specimen collection and
 preparation, and the utilization of RDTs.

Make sure that clinicians, nurses, laboratory staff and other stakeholders are aware of new guidelines and SOPs, and that these resources are easily accessible. Consider using the intranet, printed pocket guides, ward posters and providing electronic summaries at workstations.

Step 4: Monitoring and reporting progress

The DS team should meet regularly to present progress reports regarding the implementation of DS interventions, and the effects of these interventions on diagnostic processes.¹
To confirm that DS is well implemented, collect data to determine whether problems identified during the situation analysis have improved after the implementation of DS interventions. For example, electronic alerts and clinical decision tools appear to be valuable in reducing CDI testing and overdiagnosis.⁹

In addition to diagnostic process measures, assess selected key performance indicators (KPIs) that that are likely to reveal health outcome and economic benefits to patients and hospitals from DS interventions over time. These KPIs, which overlap with **AMS KPIs**, may include 9,13:

- Appropriateness of antimicrobial use.
- Clinical outcomes, eg, length of hospital stay and infection-related mortality.
- Financial KPIs, eg, total admission costs, diagnostic test expenditure, and antibiotic expenditure.
- Antibiotic-resistant bacterial infection rates associated with overuse of tests (eg, vancomycin non-susceptible *C. difficile*).

Monitoring may show that even simple, costeffective DS interventions, such as a change in wording to improve the communication of microbiology results, are sometimes enough to have a beneficial impact on antibiotic prescribing and reduce antibiotic patient harm. This has been demonstrated by a study in which a respiratory culture comment change from "Commensal respiratory flora only" to "Commensal respiratory flora only: No S. aureus/methicillin-resistant Staphylococcus aureus (MRSA) or Pseudomonas aeruginosa" was associated with a reduction in the use of broad-spectrum antibiotics targeting MRSA and P. aeruginosa and reduced incidence of acute kidney injury.23

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Appendix

Glossary of DS-related terms^{6,13}

Diagnostic process: the ordering, collection, transportation, preparation, performance, reporting, evaluation, interpretation, and intervention associated with diagnostic tests.

Diagnostic test: device or modality performed to aid in the detection or clinical diagnosis of disease.

Negative predictive value: the probability that a person with a negative test truly does not have the disease.

Positive predictive value: the probability that a person with a positive test truly has the disease.

Posttest probability: estimated probability of a person having the disease after a diagnostic result is known.

Pretest probability: estimated probability of a person having the disease before a diagnostic is performed.

Rapid diagnostic test: a diagnostic test that offers faster identification of infectious organisms than conventional diagnostic testing.

Sensitivity: the ability of a test to correctly identify those with the disease.

Specificity: the ability of a test to correctly identify those without the disease.

