The New Zealand Laboratory Schedule and Test Guidelines: **Microbiological and Serological Tests**

In October, 2013, the New Zealand Laboratory Test Schedule was published to provide consistent guidance and ensure uniform availability of tests across all District Health Boards (DHBs). The new Schedule divides tests into Tier 1 and Tier 2 to indicate whether all referrers can order the test, i.e. Tier 1, or whether a test must be ordered in conjunction with another health professional with a particular area of expertise, i.e. Tier 2. In this third article of an ongoing series we focus on the new Laboratory Schedule and Guidelines in relation to microbiological and serological tests for infectious diseases.

General Practitioners have access to more than 500 different laboratory tests in New Zealand. From this range the average General Practitioner requests over 4000 tests each year.[1] With this number of tests available, and this volume of testing, selecting the right test, for the right patient, at the right time can be challenging. Emerging evidence, changing guidelines, new testing methods and the ability of infectious organisms to evolve relatively quickly means that best practice inevitably changes with time.

The Laboratory Test Schedule and Laboratory Test Guidelines are available from: **www.dhbsharedservices.health.nz/Site/Laboratory/Laboratory-Schedule-Review-Project.aspx**

How was the infectious diseases section created?

A microbiological and serological Subgroup was formed to review tests for infectious diseases. This was made up of clinical microbiologists (both hospital and community) and public health specialists who examined the currently available tests and made recommendations as to which health professionals required access to each test. The Subgroup will continue to review the infectious diseases section of the Schedule regularly.

For further information see: "The New Zealand Laboratory Schedule and Test Guidelines: What does it mean for general practice?", BT (Nov, 2013).

Important points to note for microbiological and serological tests

The microbiological and serological test section of the Laboratory Schedule includes the following features:

- Alerts have been added to tests for notifiable infections to remind clinicians when notification to the Medical Officer of Health is required
- Tests for organisms causing infectious diarrhoea are now labeled by the suspected organism, rather than by the test that is used to identify them
- The practice of "sentinel testing" has been introduced
- Situations where "screening" tests will not be funded have been specified
- Outdated or unnecessary tests have been removed from the Schedule, where appropriate

Guidance has been provided for some tests in the microbiological and serological Laboratory Schedule to help clinicians request the most appropriate test. These recommendations are based on New Zealand and/or international best practice. Further guidance is likely to be added to the Schedule in future reviews.

Clinicians are invited to provide feedback by suggesting areas where additional information would be helpful. To provide feedback on the Schedule email: **ALLDHBs@dhbsharedservices.health.nz**

Tier 1 and Tier 2 tests for infectious diseases

The Tier 1 category makes the following tests more accessible:

Faecal antigen testing for *Helicobacter pylori* is now considered the most appropriate test for *H. pylori* infection. Previously, faecal antigen testing for *H. pylori* was only funded for hospital laboratories despite most of the requests for this test being made by General Practitioners.

For further information see: "The changing face of *Helicobacter pylori* testing", (Page 20).

The interferon gamma release assay (IGRA, Quantiferon gold test) for tuberculosis exposure or latent tuberculosis infection is now recommended to identify patients who are at high risk of developing active tuberculosis, in preference to older tuberculin tests, e.g. the Mantoux test. The IGRA has greater specificity than tuberculin testing and requires only one patient visit to the clinic. IGRA testing for latent tuberculosis is particularly recommended in the following patients: BCG-vaccinated people, immunocompromised people, e.g. those taking corticosteroids or methotrexate, high risk people who may not attend a second consultation or where a second visit is impractical.[2] IGRA testing in children aged under seven years is not currently recommended.[2] The Mantoux test can still be used to diagnose latent tuberculosis infection and is the preferred test in children aged under seven years.[2] The guideline to the microbiological and serological Laboratory Schedule can provide further information to clinicians when requesting a test for tuberculosis.

Nucleic acid amplification tests (NAAT) to detect *Bordetella pertussis*, *Chlamydia trachomatis* and *Neisseria gonorrhoeae* are Tier 1 tests. Unlike culture tests that were previously used, NAAT tests only need a sample of DNA, and do not require viable bacteria to produce a positive result. Results are also available within hours, compared to cultures which may take three to 12 days.[3] NAAT testing also has the advantages over serology testing of not requiring the patient to have mounted an immune response in order to produce a positive result and of not being complicated by immunisation or past infection.

Influenza virus testing has been included as a Tier 1 test when assisting public health authorities in defining the epidemiology of large scale outbreaks. Previously this was possible but was not recognised in testing guidelines. Under normal circumstances this test may only be requested in primary care after consultation with a public health specialist. The Schedule also has the flexibility to allow other tests to be changed from Tier 2 to 1 as required.

The Tier 2 category will have little effect on general practice

The creation of a Tier 2 category for microbiological and serological testing will not have a significant impact on clinicians in the community as many of the tests in this category were already restricted to specific situations.

The following are examples of Tier 2 tests:

Reflex testing, which occurs automatically when the need for a second test is identified by the laboratory after an initial positive result. For example, when a test for *Toxoplasma gondii* is performed, if the initial test for IgG is positive, and clinical information suggests that this may be an acute infection, the sample is sent for avidity testing to determine if the IgG is a response to a past or recent infection. Screening Gram-negative bacilli that are resistant to cephalosporins for extended β-lactamase production is another example of reflex testing.

Some tests that require invasive sampling by a specialist clinician are classified as Tier 2, e.g. biopsies for *H. pylori* culture and susceptibility testing.

Tests for uncommon pathogens, e.g. arboviruses, are now classified as Tier 2. When considering requesting tests for uncommon pathogens a discussion with an Infectious Diseases Specialist or Clinical Microbiologist may be helpful in assessing the likelihood of a pathogen being present or in interpreting the results of the test. The Tier 2 category promotes consultation in less common situations and improves the quality of requests and the interpretation of test results.

Alerts for notifiable infections

The microbiological and serological Laboratory Schedule now includes an alert column to remind clinicians when notification to a Medical Officer of Health is required, e.g. a positive *Salmonella*, *Shigella*, *Yersinia*, or *Campylobacter* faecal culture. This feature was introduced to increase notifications and to improve understanding of when notification is required.

The Schedule also contains some footnotes relating to case definitions of notifiable diseases, e.g. defining a probable case of pertussis as opposed to a confirmed case.

Tests for faecal pathogens are now specified by pathogen

Test for organisms causing infectious diarrhoea are now labeled in the Schedule by the suspected organism, rather than by the test that is used to identify them. This change was made to encourage clinicians to include clinical information when requesting tests and to allow laboratories to choose the most appropriate test. Listing the patient's risk factors, e.g. recent overseas travel, helps laboratories to optimise testing.

For example, previously, when investigating infectious diarrhoea, if a request for enteric pathogens was made the laboratory performed microscopy and culture, however, different laboratories might culture for different organisms as there was no standardisation in which cultures would be performed. Now clinicians may request the "*Salmonella, Shigella, Yersinia, Campylobacter culture*" test for these common pathogens and additional testing can be added by the laboratory on the basis of clinical information provided.

Sentinel testing may be appropriate in some DHBs

The microbiological and serological Laboratory Schedule allows for DHBs to request health professionals to participate in the reporting of local antimicrobial susceptibility profiles, i.e. sentinel testing, to assist prescribers in the use of empiric antimicrobial treatment. This practice enables laboratory validation of local antibiotic guidelines for the treatment of common conditions. Examples where sentinel testing may

provide useful information in local susceptibility include:

- Females with uncomplicated cystitis, who are generally treated empirically, may have urine samples tested to determine local patterns of antibiotic susceptibility. This was suggested by the Subgroup in response to the introduction of increasingly resistant urinary pathogens, and because the susceptibility of *Escherichia coli* isolates varies geographically.
- *Neisseria gonorrhoeae* is now generally detected by NAAT and therefore susceptibility data is not available in every case
- *Streptococcus pneumoniae* is a common respiratory pathogen with a susceptibility profile that is hard to predict

It is anticipated that sentinel testing will improve the use of tests to diagnose and test for infections and promote the rational use of antimicrobials. Local sentinel testing is not recommended unless initiated by a DHB. Participation in the ESR national surveillance programme of antimicrobial resistance remains important to monitor changes at a national level.

When are "screening" tests not funded?

The microbiological and serological Laboratory Schedule now outlines situations when tests are not funded. This will make it clear for laboratories and DHBs under which situations tests will not be funded, when they are negotiating contracts. Tests are not funded in the following situations:

- Occupational testing, e.g. pre-employment drug testing
- To provide evidence of immunity for travel purposes
- Providing information for insurance or for visa applications
- Tests required by sports groups, e.g. testing for prohibited substances in athletes or proof of HIV status to obtain a professional boxing license
- Testing pre- or post-vaccination, e.g. hepatitis A testing to determine a patient's immunity before or after vaccination

Tests that are no longer necessary have been removed

Microbiological and serological tests which were not considered necessary have been removed from the schedule include:

- Chlamydia IgG tests have not been found to be useful for the routine diagnosis of Chlamydia infections. NAAT is considered a better test for patients suspected of having a Chlamydia infection.
- *H. pylori* serum antibody tests were routinely used to test for *H. pylori*. This test has been superseded by the use of *H. pylori* faecal antigen tests using monoclonal antibodies. A guideline will be released to assist clinicians in the use of this test.
- Hepatitis C antibody immunoblot and hepatitis C confirmatory immunoblot have been replaced by hepatitis C NAAT tests for viral detection and confirmation of patients with active infection
- TORCH screening for perinatal infections in newborn infants is no longer recommended and is not funded. Individual tests should be ordered when a congenital infection is suspected.
- Typhoid serology is not funded because culture for *Salmonella typhi* is considered to be a better test

ACKNOWLEDGMENT Thank you to **Dr Rosemary Ikram**, Clinical Microbiologist, Christchurch, Chair of the Microbiology Subgroup, New Zealand Laboratory Schedule and Guidelines for contributing this article.

References

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