



Consultation Document: Clinical Details as a Pre-Requisite for Infectious Serology Testing

This is a consultation document designed to obtain feedback on the proposed policy as above. The quality of any laboratory result produced is dependent on multiple steps/processes from when the sample is taken and the request form is completed, until the result is released to the clinicians. It is often the pre-analytical phases of laboratory testing that are amongst the most difficult to control and standardise.

How Often Are Clinical Details Currently Provided On Forms?

This is dependent on many factors including requesting location, type of test, severity of illness etc. Anecdotal data suggests that the Midlands Region is relatively good at providing clinical details compared with other areas of the country. Recent audit data covering a range of different sample types showed that clinical details were provided on between 50 and 80% of requests dependant on the factors above. As an example we audited clinical details on 200 Hepatitis serology requests. Clinical details were provided on 127/200 samples, 63.5%.

Why Are Clinical Details For Infectious Serology Important?

We believe it is important for the laboratory to know **why** the serological test is being performed for the following reasons:

- **To ensure that the correct tests are being performed.** This is particularly important where the patient is immunocompromised, pregnant or has had overseas travel etc. Clinical details also allow the laboratory to decide whether it is evidence of immunity or current infection that is being sought by the clinician.
- **To allow interpretation of borderline results.** The clinical microbiologists phone clinicians on a regular basis for more clinical details to assist with interpreting serological results, particularly borderline results. Some of these consultations could be avoided by having more clinical details on the request form.
- **To allow suggestion of further tests.** When certain clinical details are provided on the request form, it can assist the laboratory in suggesting further tests in order to clarify the diagnosis. For example the duration of symptoms can dictate whether convalescent serology is required. Pregnancy, overseas travel, and immunocompromise are examples of clinical details where the laboratory may be able to suggest optimal testing for the patient.
- **To ensure that the test is performed for diagnostic reasons.**

Which Tests Would Be Covered By This Policy?

Initially this would involve Infectious serology tests that are performed in-house at Pathlab, namely serological testing for **EBV, CMV, toxoplasmosis, leptospirosis, streptococcal titres (ASOT & anti-DNAaseB), HIV, syphilis, brucellosis, Hepatitis A, B and C.**

Serological tests that are sent away to reference labs would not initially be involved in such a policy, for logistical reasons.

This policy will also have no effect on ante-natal screening serology.

Are There Any Potential Downsides To Having Clinical Details As A Pre-Requisite For Testing?

- **Delay in results:** If clinical details are not provided initially, then the time taken for the laboratory to receive appropriate clinical details may cause a delay in the test result being produced. It should be noted however, that if clinical details are not provided, a comment requesting these will go immediately back to the requestor from registration. The serum can be safely stored, without risk of sample degradation, until further details are provided by the requestor.
- **Extra work for requestors/clinicians:** It is appreciated how tight the time frames are that clinicians need to work to, particularly for patient consultations in the clinic setting. However we believe that the 20-30 seconds needed to provide useful clinical context to the laboratory is well worth it.

Would Such A Policy Involve Infectious Serology Requests From Both The Hospital And The Community Setting?

Yes, it is envisaged that such a policy would apply to Infectious Serology samples from both the hospital and community setting.

How Appropriate/Detailed Do Clinical Details Need To Be?

It is accepted that the appropriateness and extent of clinical details is a very subjective area. Therefore such a policy would be implemented with a strong degree of leniency as to what is acceptable with regards to clinical details. As the policy becomes more established then we would consider looking for more appropriate clinical details, particularly for tests where the clinical indications are very limited (e.g. history of glomerulonephritis/acute renal impairment/rheumatic fever for ASOT testing).

Would Such A Policy Be Extended To Other Areas Of Laboratory Testing?

We believe Infectious Serology is a good area to initiate such a policy. Clinical details are very important in this area of laboratory testing. In addition to this, serum can be safely stored for a prolonged period (without risk of sample degradation). However if this policy is implemented successfully, then we would consider extending to other testing disciplines within the laboratory.

Such a policy is unlikely ever to be appropriate for “difficult to obtain”, or “critical” specimens e.g. histopathology, CSF and other sterile site fluids. Ironically, these are samples for which clinical details are of the greatest importance.

How Would Such A Policy Be Implemented?

If a serum sample for one of the tests listed above is received without clinical details, it would be registered, stored, and a comment would be returned immediately to the requestor along the lines of *“This sample has been received by the laboratory for serological testing. However no clinical details have been provided. The serum has been stored. Please provide clinical details to the laboratory as soon as possible so that laboratory processing can proceed.”*

Conclusion

It is believed that this proposed move is an important step in optimising the provision of high quality Infectious Serology results from the laboratory. It would also improve the links and communication between clinicians and the laboratory, an area we are constantly working on.

It is very important that any laboratory result is interpreted in the clinical context that the request was made. When electronic requesting becomes established, it is our objective to present the provided clinical details as an integral part of the result report so that result interpretation can be expedited and optimised.

Such policies always take a bit of getting used to in the initiation period but we believe the end result will be beneficial to the laboratory, the clinician, and most importantly the patient.

All your feedback is welcome, positive or negative. Please direct such feedback to MichaelA@pathlab.co.nz by the 31st October 2015.

A further document will be produced with the accrued results of any clinical feedback received, along with a decision as to whether to proceed.

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