TEST RELATED	**REQUEST RELATED**
ANCA Testing	Venesection services
Brucella & Hydatid CFT	Informed consent for Genetic requests
Pertussis Serology	Hospital Requests
Serum Protein Electrophoresis	Electronic requesting
New creatinine assay (OS)	Non-funded tests
Ingestion of Biotin	STI checks on non-residents
Mycobacterium chimaera	**SAMPLE COLLECTIONS**
Mycoplasma genitalium	

TEST RELATED

Changes in testing for anti-neutrophil cytoplasmic antibodies (ANCA)

In keeping with the recently updated international consensus guidelines, from Tue 1st May ANCA immunofluorescence will no longer be performed routinely when ANCA testing is ordered. Instead anti-MPO and anti-PR3 antibodies will be performed only. ANCA immunofluorescence can still be specifically requested if felt clinically useful. Newly positive anti-PR3 and anti-MPO results will still be evaluated for the corresponding immunofluorescence patterns and reported to requesting clinicians.

ANCA testing is warranted ONLY for the diagnosis of vasculitis where specific clinical situations are present. The scientific literature suggests results can be misleading when ordered outside these clinical situations and is highly unlikely to yield a diagnosis of a small vessel vasculitis.

These clinical situations are:

1. GN (rapidly progressive)
2. Pulmonary haemorrhage especially pulmonary renal syndrome
3. Cutaneous vasculitis with systemic features
4. Multiple lung nodules (that is not cancer)
5. Chronic destructive disease of the upper airways-epistaxis or erosive changes seen on clinical examination or imaging studies not due to previous surgery
6. Longstanding sinusitis or otitis
7. Subglottic tracheal stenosis
8. Mononeuritis multiplex or other peripheral neuropathy sensory or motor changes including cranial nerve palsies
9. Retro-orbital mass
10. Scleritis

The numerical level anti-PR3 and anti-MPO antibodies may also be used to monitor disease activity. For further information contact either:

Helen van der Loo (Helen.Vanderloo@sclabs.co.nz) or Terry Taylor (Terry.Taylor@sclabs.co.nz)
Dr Richard Steele, Immunopathologist, Southern Community Laboratories

Source: Bossuyt et al Revised 2017 international consensus on testing of ANCAs in granulomatosis with polyangiitis and microscopic polyangiitis Nature Rev Rheumatology 2017; 13: 683-692

Brucella and Hydatid Complement Fixation Testing

Canterbury Health Laboratories (CHL) wish to advise you that from Monday 26th March 2018 Brucella and Hydatid complement fixation testing will no longer be available, as these tests have been surpassed by more advanced procedures.

Brucella serology is available at CHL: standard agglutination and AHG, please provide travel history and onset dates.

Hydatid serology is available at CHL: Haemagglutination method.

Pertussis Serology

PCR is the test of choice during the acute stages of the pertussis infection, up to 4 weeks after the onset of symptoms. Serology is often utilised in patients who have a longer duration of symptoms, however *Bordetella pertussis* serology suffers from sub-optimal sensitivity and specificity. In addition, the presence of *B pertussis* IgG is not a reliable indicator for a patient's immune status. As of Tuesday May 1st, we will no longer be offering B pertussis serology

Serum protein electrophoresis

EPP is a labour intensive, manual test that involves some variability in interpretation. This is performed in context of the clinical background and results of other investigations such as renal function, serum calcium, haemoglobin, serum free light chains, and previous EPP findings. Whereas an automated test can be resulted within hours, EPP resulting can take up to a week.

The primary reason for requesting an EPP is to identify a monoclonal gammopathy for the diagnosis (or exclusion) of myeloma or a lymphoproliferative disorder. It can also occasionally be requested for other reasons, e.g. for identifying the type of proteinuria in a patient, although other tests such as urine albumin, and specific tubular proteins can provide more specific information. The most common clinical and laboratory findings leading to suspicion of a lymphoproliferative process are listed in the table below:

Indications based on clinical findings:	Indications based on laboratory findings
· Suspected multiple myeloma, Waldenström's macroglobulinemia, primary amyloidosis or other related disorders · Unexplained bone pain or fracture · Recurrent infections · Unexplained peripheral neuropathy (not able to be attributed to another condition, e.g. type 2 diabetes, chemotherapy)	· High (or low) total serum globulin or immunoglobulin · Extremely high percentage of lymphocytes · Incidental finding of an increased total protein level · Unexplained anaemia (multiple myeloma is a recognised cause of non-iron deficiency anaemia) or other persisting cytopaenias for which there is no other explanation · Unexplained high ESR (>50) with a normal CRP · Unexplained hypercalcaemia or renal impairment · Red cell rouleaux formations noted on the peripheral blood smear · Unexplained high urine protein with relatively low or normal urine albumin · Presence of urine free light chains (Bence-Jones proteinuria)
Indications based on radiological findings: · Lytic lesions in bone · Unexplained osteopaenia (as not all patients with multiple myeloma will have osteolytic lesions)	

Note that the diagnosis of myeloma and other lymphoproliferative processes rests not only on the electrophoresis findings but on other evidence of tissue damage, and on the haematology and bone marrow findings. While they can occur in younger patients, myeloma and other

lymphoproliferative disorders are much more common in patients over age 40 years. We recive many requests for children and young adults, the vast majority of which show normal patterns. We encourage you to use the above table as a guide to requesting EPP in all patients, but particularly in young patients in whom lymphoproliferative disease is rare.

New creatinine assay

From 17th April, Southern Community Laboratories will replace the current creatinine assay with a new enzymatic assay. Extensive laboratory validation has shown that results in the new test are approximately 5-10% lower than the current test. However, extensive modelling of estimated glomerular filtration rate (eGFR) with the new test has shown that there is no significant change. The new test is much more precise and is not susceptible to interference from non-creatinine substances. Comments will be placed on renal function test reports to alert you to the change when it happens.

Ingestion of biotin may lead to invalid laboratory results.

The use of dietary and vitamin supplements is increasing. It is important to recognise that some of these may lead to erroneous laboratory results. Biotin is a water-soluble vitamin that is widely distributed in food sources and it is an essential co-factor in key carbohydrate and lipid metabolism. The daily intake on average is 0.03 – 0.1 mg and the dose present in daily multivitamins is typically 0.03 – 0.04 mg but certain supplements may contain 5 – 20 mg of biotin. Ingestion of high dose biotin significantly increase blood biotin levels.

Biotin is used in some biochemical laboratory tests as part of the system for generating the 'signal' that allows determination of the test result. High plasma concentrations of biotin can therefore cause interference immunoassay tests where biotin is used as part of the assay system. Depending on the specific test, the presence of high doses of plasma biotin can result in falsely low or falsely high results. Incorrect test results could lead to misdiagnosis and have resulted in inappropriate management. For example high plasma levels of biotin can lead to a pattern of results mimicking severe hyperthyroidism in a patient who is clearly clinically euthyroid.

When spurious results are thought likely, they can be checked in a system that is not dependent on the use of biotin in which case normal results will be seen. The only way to pick up these spurious results is the inconsistency between the clinical picture and the laboratory findings. Test results are generally only affected by high doses of biotin. Multivitamin supplements with biotin 0.03 – 0.04 mg would not affect the assays. It is recommended that patients taking biotin > 5 mg per day should stop biotin at least 8 hours before the blood tests. Higher doses of biotin > 10 mg per day would need to be withheld for a longer time. The FDA has issued an alert regarding biotin interference in laboratory tests. A diagnostics manufacturer has set up an educational website providing details on biotin assay interference.

It is important to recognise that pre-analytical factors have a sizeable impact on the accuracy of laboratory results. A detailed drug history including health supplements and awareness of the interference issue are indispensable in identifying patients who may have laboratory test results affected by biotin.

Mycobacterium chimaera

Several District Health Boards have recently contacted patients who have had open heart surgery in the last five years in which foreign material was implanted. Due to contamination at the point of manufacture of a single brand of heater cooler unit, these patients may be at risk of infection with *Mycobacterium chimaera*. It is important to note that the implicated brand of heater cooler unit has NOT been used at Dunedin Hospital or Mercy Hospital, so patients who had their surgery in Dunedin are NOT at risk.

Patients have been advised to present to their GP if they have the following symptoms:

- Unexplained fevers or night sweats
- Unexplained weight loss
- Extreme tiredness (fatigue)
- Pain in the chest, and/or swelling, redness or pus around the site of surgery
- Increased shortness of breath
- Joint or muscle pain
- Nausea, vomiting or abdominal pain

If a patient presents with these symptoms, the general practitioner should perform an initial assessment. Asymptomatic patients do not require further investigation. For symptomatic patients, more common causes for their symptoms are much more likely. Where patients present with symptoms suggestive of sub-acute bacterial endocarditis, (e.g. fevers, weight loss, change in/new heart murmur) conventional blood cultures should be performed (3 sets, each collected by a separate venepuncture). Testing for disseminated mycobacterial infection (e.g. blood cultures that will isolate non-tuberculous mycobacteria) is available following discussions with the Clinical Microbiologist. If, following initial assessment, there is concern that the patient may require further investigation then specialist referral to Cardiology or Infectious Diseases is warranted.

Mycoplasma genitalium

Mycoplasma genitalium (MG) is considered to be an 'emerging pathogen' and is increasingly being recognised as a cause of genital tract infection similar in nature to *Chlamydia trachomatis* (CT). Previously testing for this pathogen was performed at Labtests, Auckland. Labtests have now discontinued this test and all requests will be sent to Canterbury Health Laboratories (CHL). While urethral. Vaginal and cervical Aptima swabs can be tested (the same swabs currently in use for CT and gonorrhoea), urines in Aptima transport media cannot; instead, a fresh first void urine should be submitted for testing. CHL will perform reflex genotypic resistance testing on positive samples.

The following patients will be considered for MG testing after discussion with the Clinical Microbiologist:

1. Patients aged 15-65 years
2. Persistent symptoms consistent with vaginitis where testing for BV, candida, trichomonas, CT and gonorrhoea are all negative
3. Persistent symptoms consistent with urethritis where testing for CT and gonorrhoea is negative
4. Persistent symptoms consistent with vaginitis or urethritis non-responsive to conventional treatment (over 50% of isolates may be resistant to azithromycin)
5. Direct requests from sexual health clinicians
6. Persistent unexplained dysuria or sterile pyuria

If you would like to discuss this further please contact one of our clinical microbiologists.

REQUEST RELATED

Venesection Services

Management of the Dunedin service has been devolved to SCL under Dr Mustafa Saydoon. New patients should be referred to him in the first instance; actual venesection will continue to be performed by the NZBS staff in their premises.

Informed consent required for all molecular tests to Wellington Regional Genetics Laboratories (WRGL).

From the 1st May 2018 WRGL will require evidence of informed consent for any requested molecular test (eg microarray, Cystic Fibrosis, Prader Willi Syndrome, Angelman Syndrome, Fragile X, Spinal Muscular Dystrophy, DMD, BMD). This does not apply to karyotype requests.

The link for consent forms for Microarray, and Molecular Genetic testing is http://www.wellingtongenetics.co.nz/Sample+Requirements++Forms/Consent+Forms.html.

This link is also on our SCL website. Please complete the relevant consent form and send in with the patient sample.

If the consent form is not received, WRGL will extract DNA but will notify you that testing will not proceed until the consent form is received.

If further information is required please contact Jenny Grant, Molecular Pathology department, 034702949

Hospital Requests

On a daily basis the laboratory receives request forms with no referring consultant, and often not even a location. These cause us huge problems because we are unable to get the results into anyone's queue for signoff and have no contact details in the case of grossly abnormal results. Further investigation has identified the following issues:

- Staff ordering tests on family members using hospital request forms when the patient has never been either an OP or an IP
- Ward staff giving patients request forms to be used after discharge and reporting to an unknown GP

Staff are reminded that it is not permitted to order tests in another referrer's name without consultation with that referrer. The person writing out the request is responsible for follow-up of the results, that responsibility cannot be abrogated by putting someone else's name on the form

Southern Community Laboratories strongly endorses Cole's Medical Practice in New Zealand (2013) as a framework for the follow-up of patient test results. We expect all our referrers to understand and observe the key principles:

- *If you request a clinical investigation, you should tell your patient why the clinical investigation is recommended and when and how they will learn the results*
- *All the relevant parties should understand their responsibilities clearly*
- *If you are responsible for conducting a clinical investigation you are also responsible for ensuring that the results are appropriately communicated to those in charge of conducting follow up, and for keeping the patient informed*
- *Identifying and following up overdue results is an essential, but [sometimes] difficult, office management task. Your system should ensure that test results are tracked successfully.*
- *If you order investigations it is your responsibility to review, interpret and act on the results.*

Note: Cole's entire text is available for free download from the Medical Council of New Zealand (including Kindle and iPad versions).

Requirement for Clinical Details on Microbiology Requests
Attached please find a consultation process regarding restricting microbiological testing where there are no relevant clinical details provided. We would be delighted to hear your thoughts on this so - details for responding are on the document

Electronic Requesting

We are in the process of expanding our network for electronic requests. The system we have developed is mostly our own work based on our main Laboratory Information System (LIS) and Sysmex Éclair. We have taken great care to ensure that it user friendly and does not impact the time for the consultation between the doctor and patient. The benefits of such a system are both for the practice and the laboratory including, but not limited to, accuracy of patient identification, avoiding duplication, better managing copy to results and reduction of paper.

Non-funded tests - CLAG Update

With the departure of Greg Sheffield to take up a position in Taranaki, administration of the system for managing new test applications has been devolved to SCL. Sign off of new applications is now the responsibility of David Murray, the Primary Care Manager with the Southern DHB. The transition has not been totally smooth but is now back on track.

Hospital applications should be made in the usual way via "Pulse > Applications > Clinical – District" –

- Care Coordination Centre ENS
- Central Line Associated Bacteraemia (CLAB)
- Clinical Laboratory Advisory Group (CLAG)
- CNC Referral Whiteboard

Community requests contact Jan.parker@sclabs.co.nz

STI screening of non-residents

Diagnosis and follow-up of patients with STIs is covered under the law regardless of the country of origin. This does not however include screening of asymptomatic individuals; non-residents from any country (including the UK and Australia) will be charged. Please clearly identify non-New Zealanders having screening. A recent example was two young asymptomatic women wanting to be checked before they went home.

SAMPLE COLLECTIONS

Collection Centres

A reminder that the Dunedin new collection centre at 18 Filleul Street is now open and the old collection centre at 95 Hanover Street has closed permanently. Please be sure to update any references you have that may refer to the old address. This may include checking your practise web sites and also reviewing any information being printed on your request forms.
The Filleul Street hours are M-F 7.00am – 5.15pm and Saturday XXXX

The Dunedin Hospital Collection Centre has re-opened after a short closure for renovations. It is open to all patients M-F 7.30am – 4.15pm

Please Note: All our Collection Centres close for admitting patients 15 minutes before staff finish. This is to allow to for sample preparation and packing in readiness for the courier pickup.

Samples for Dispatch

All laboratory samples for pick up by the courier must be bagged and in the marked collection areas within the medical practice. Our couriers must not be asked to complete the labelling and packing of the samples and forms. Please ensure that all specimens for pick up are ready prior to the courier arriving so that they are not missed. Any unpacked requests will not be taken by the courier which may result in a delay in turnaround time of the results. Please also ensure that specimens are always stored appropriately. Never leave specimens sitting on a bench where the sun hits it. Temperatures above 24 degrees can result in incorrect results.

Blood Counts

Our new analysers spin the tube to read the barcode and the process will not accept 'dog tags' etc. All labels must be firmly attached along the length of the tube with no wrinkles or protrusions.

MAIL SERVICES

While we are very happy to deliver mail between community GP clinics and to the hospital, we do not offer a general postal mail service; any mail that is not on our usual delivery routes will be returned to the sender. Any mail requiring franking or mail requiring to be put in the post will not be accepted. Please do not re-use SCL stamped envelopes for other purposes, they get returned to us with confidential contents that have nothing to do with us.

Jan Parker, COO SCL/MLS 0274 442 117 jan.parker@sclabs.co.nz

Southern Community Laboratories

Consultation document

REQUIREMENT FOR CLINICAL DETAILS ON HOSPITAL & COMMUNITY MICROBIOLOGY SPECIMENS / TEST REQUESTS

SCL DUNEDIN/SOUTHLAND

1. INTRODUCTION

'Choosing Wisely' is a global initiative that "aims to promote a culture where low value and inappropriate clinical interventions are avoided, and patients and health professionals have well-informed conversations around their treatment options, leading to better decisions and outcomes." New Zealand is participating (http://choosingwisely.org.nz/), and laboratories around NZ are actively engaging in the principles of 'choosing wisely'.

Over recent years, laboratories have seen the number of test requests increase significantly; and often they are not accompanied by relevant clinical details. While this may reflect the time and workload pressures that clinicians are under, we believe that patient outcomes can be improved with better communication between clinical and laboratory teams.

There is evidence that laboratory test requests are not always guided by pre-test probability (based on clinical assessment), and this can lead to excessive testing, misdirected testing, and patient harm.

We (Southern Community Laboratories) are consulting on a change that we believe would bring about improvements in this area.

2. CURRENT SERVICE

Currently, all tests are performed by the laboratory as requested, regardless of whether clinical details are provided. The only exceptions are the very few tests that require consultation with a pathologist prior to the test proceeding and vaginal swabs, where we have already introduced a requirement for the provision of relevant clinical details to ensure appropriate testing.

3. RATIONALE FOR CHANGE

The laboratory is an integral part of the healthcare system and providing clinical details on laboratory requests is good clinical practice. In fact, an argument can be made that the provision of clinical details is required under the Health and Disability Commission Right 4, part 5, which states:

"Every consumer has the right to co-operation among providers to ensure quality and continuity of services".

Recent audit has shown that over half of specimens received in the microbiology laboratory (from both the hospital and community) have no or inadequate clinical details on the request form. Unlike many automated blood analytical procedures, clinical microbiology is very much a labour-intensive and interpretive specialty.

For microbiology, clinical details are important for the following reasons:

- To ensure that the appropriate tests are performed when the specimen is received in the laboratory. Clinical details influence the pathogens we look for in the laboratory: these often need specialised culture plates and incubation conditions, or even molecular testing.
- To allow the scientist to interpret the initial results, and to aid them in deciding on further testing, including antimicrobial susceptibility testing when appropriate.
- To help the laboratory suggest whether further testing may be indicated. For instance, the specimen received may not be optimal for the diagnosis of that condition.

While this applies to all laboratory specialties, it is particularly important for microbiology.

The details which are important to specify on request forms include:

- Clinical history: why are you sending the specimen and what you are looking for? What is the timing of illness?
- Exposure history, including foreign travel, exposure to potential infection sources such as animals or sick contacts, recent antibiotic treatment or medical procedures, etc. Include timing of exposure relative to symptom onset
- Underlying conditions which may influence which tests are performed, such as immunocompromise, pregnancy, COPD, presence of foreign material such as indwelling urinary catheter
- The precise site of the specimen

In addition to the risk of under-diagnosis, where the laboratory is unaware of important clinical information, there is also risk of 'over-diagnosis' which can result from 'over-testing' where tests are requested in a reflex fashion without clinical assessment and evaluation. An example of this is urine culture. Studies and NZ laboratory experience have shown that where urine cultures are either not performed or the results are not released without supporting clinical information (either on the initial request form or upon receipt of a subsequent telephone call on the basis of a report stating requirement for clinical details), a significant proportion of specimens are discarded or not reported. This suggests that at least in a proportion of cases the initial urine culture request was not clinically indicated.

4. PROPOSED NEW SERVICE

We are consulting on a proposed new service whereby specimens received by the microbiology (routine microbiology and molecular) laboratories without accompanying relevant clinical details will not be processed.

The proposed change would not affect 'precious specimens' – specimens that cannot be re-collected without causing the patient harm, e.g. CSF. These specimens would be exempt from this rule. While precious specimens will be processed without clinical details, the laboratory will be requesting that additional details are provided.

List of precious specimens

CSF

BAL fluid / aspirates

Tissue biopsies

Joint aspirates

Bone marrow aspirates

Blood cultures, when antibiotic therapy has subsequently been initiated

The molecular tests included in the proposed new service are:

HSV, VZV, Enterovirus, and Adenovirus PCRs

Faecal pathogen PCR

HIV, HCV, and HBV viral loads

Respiratory multiplex panels

CSF multiplex panel

What happens to specimens without clinical details?

The request will be registered in Eclair and a comment will be sent out **as below.**

These requests will be held on site at the Laboratory for 48 hours. Within this time, provision of relevant clinical details by telephone call to clinical microbiologist or fax to (03) 4702992 will lead to processing of the specimen.

Where clinical details are provided but laboratory staff are unsure if they are sufficient or relevant, the proposed protocol would be that the on call clinical microbiologist reviews the request form and makes a decision regarding processing.

4.1 IMPLICATIONS OF PROPOSED NEW SERVICE

The proposed change is aimed at improving patient care and patient outcomes. The change may lead to irritation among referrers. However, it is our hope that overall it will lead to improved communication between the clinical and laboratory teams.

Is there risk to patients?

Minimising risk to patients and avoiding patient harm is paramount. For this reason, 'precious' specimens will not be included in the proposed change. For other specimens, risk will be mitigated by an automated comment that goes out to referrers stating:

"This specimen has not been processed as it has been received without accompanying relevant clinical details. The specimen will be stored for 48 hours and providing relevant clinical details in this time frame will lead to processing. Clinical details can be provided by faxing a request form to (03) 4702992 or by contacting the on-call clinical microbiologist."

5. CONSULTATION PROCESS

5.1 WHAT ARE WE CONSULTING ON

We are consulting on requiring relevant clinical details for processing of specimens for microbiological work up.

5.2 WHO IS BEING CONSULTED

We are consulting with the following groups:

1. DHB Chief Medical Officer
2. DHB Senior Medical Officers
3. Local PHO (Wellsouth)
4. Community referrers
5. MW representatives
6. Lead nurse
7. Local Public Health Physicians
8. Local Infectious Diseases Physicians
9. New Zealand Microbiology Network

5.3 CONSULTATION TIMELINE

Consultation document release:	Monday 16th April 2018
Feedback deadline:	Friday 11th May 2018
Decision announcement:	Friday 18th May 2018

5.4 HOW TO GIVE FEEDBACK

Please give feedback to: Dr Arlo Upton Arlo.upton@sclabs.co.nz

5.5 DECISION

A decision will be made by 5pm on Friday 18th May 2018 and communicated to stakeholders, and specifically to those who gave feedback.

6. REFERENCES

Clinical Laboratory Tests: Which, Why, and What Do The Results Mean? Frank H. Wians. *Laboratory Medicine*, Volume 40, Issue 2, 1 February 2009, Pages 105–113.

Reasons for ordering laboratory tests and relationship with frequency of abnormal results. Houben *et al*. Scand J Prim Health Care. 2010 Mar;28(1):18-23.

http://www.hdc.org.nz/your-rights/about-the-code/