OS Operational Update SEPT 16

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TEST RELATED

Serum Folate (HBL only)

From the beginning of October 2016, Southern Community Laboratories in Hawkes Bay will use a new calibration for the serum folate assay. This will have the effect of reducing measured serum folate concentrations for some patients. At low (important) concentrations of serum folate, the change is likely to result in better agreement with those results produced by the DHB laboratory. For this reason it has been decided for the moment not to change the lower reference limit (>8 nmol/L). The appropriateness of the lower reference limit will be reviewed over the following months. Once the change in calibration is in place a comment to that effect will be placed on reports. Note also that Southern Community Laboratories and the DHB laboratory regularly perform cross-site comparison studies for serum folate and a range of other analytes to ensure agreement where possible. The new calibration has been put in place by the kit manufacturer to counter assay drift upwards that has occurred over the last few years.

Serum Folate (SDHB)

From 1st September 2016, the laboratories in Dunedin and Invercargill have been using an updated calibration for the serum folate assay. This has resulted in a reduction in measured serum folate concentration – particularly at lower concentrations. After discussing the issue with local haematologists, we have adjusted the lower reference limit to take account of this. Since 1.9.16 this new lower reference limit has been on reports – along with an explanatory comment. The new calibration has been put in place by the kit manufacturer to counter assay drift upwards that has occurred over the last few years.

Serum Folate (Taupo)

From 1st September 2016, the laboratory providing serum folate assays to Taupo Pathology has been using an updated calibration for this assay. This has resulted in a reduction in measured serum folate concentration – particularly at lower concentrations. After discussing the issue with haematologists, we have adjusted the lower reference limit to take account of this. Since 1.9.16, this new lower reference limit has been on reports – along with an explanatory comment. The new calibration has been put in place by the kit manufacturer to counter assay drift upwards that has occurred over the last few years.

Molecular Diagnostics

Following a review of our molecular methods we have decided to switch all our assays from the AusDiagnostics EasyPlex to the AusDiagnostics HiPlex. This allows greater throughput and a much improved laboratory workflow, especially during the influenza season. As a result we have had to change the panels that we are using. A summary of the changes is as follows:

Respiratory virus PCR panel – contains all of our current targets but also includes Parainfluenza virus 4, and the bacterial targets *Bordetella pertussis* and *Mycoplasma pneumoniae*.

Pneumonia PCR panel (replaces the atypical pneumonia PCR panel) – no longer targets *B. parapertussis*, pan-*Chlamydia*, or pan–*Legionella*. It now includes *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenza, Chlamydophila psittaci*, *Cryptococcus neoformans*, *Aspergillus fumigatus*, and *Coxiella burnetii*,. We are not be routinely reporting *C. neoformans, A. fumigatus, C. burnetii*, or *M. tuberculosis*. As *S. aureus, S. pneumoniae,* and *H. influenzae* can be part of the normal oropharnygeal flora, reporting will depend upon the amount detected and the specimen type. The preferred method to diagnose infection by *S. aureus, S. pneumoniae,* and *H. influenza* is by culture, which allows assessment of the relative amount of the organism present.

CSF PCR panel – contains all of our current targets but also includes Parechovirus and *Leptospira* spp. Parechovirus will be reported routinely on under 1 year olds or if positive. *Leptospira* will not be routinely reported unless positive. We will also no longer routinely report EBV.

For further information or comments on this change, please contact

Dr James Ussher (Microbiologist Ph (03) 4702924, email: james.ussher@sclabs.co.nz)

Dr Antje van der Linden (Microbiologist Ph (03) 470 2920, email: antje.vanderlinden@sclabs.co.nz)

Dr Jenny Grant (Head of Department, Molecular Pathology Ph (03) 470 2949, email: jenny.grant@sclabs.co.nz)

Fertility Assessment, Seminal Fluid Assessment:

In order to ensure the quality of Fertility assessments, SCL are introducing a booking system for acceptance of seminal fluid specimens for fertility at our Dunstan and Queenstown laboratories, effective immediately. This change is to ensure we have competent staff on-site to assess motility, which needs to be assessed within 1 hour of specimen collection. In Invercargill, Dunedin, and Oamaru a booking will not be required, however specimens can only be accepted at the laboratory between 8:30AM and 4:30 PM Monday to Friday.

Heterophile antibody testing for Glandular Fever

From October 1st Heterophile antibody testing (also known as Paul-Bunnell or Monospot test) will no longer be available for investigating Glandular Fever due to the poor sensitivity and specificity of this test.

CDC guidelines http://www.cdc.gov/epstein-barr/laboratory-testing.html indicate the Monospot test is not recommended for general use. The antibodies detected by Monospot can be caused by conditions other than infectious mononucleosis. Moreover, studies have shown that the Monospot produces both false positive and false negative results. For example, the heterophile antibodies detected by Monospot are often not present in children with infectious mononucleosis. At best, the Monospot test may indicate that a person has a typical case of infectious mononucleosis, but does not confirm the presence of EBV infection.

Laboratory investigation may not be necessary where the clinical features suggest a diagnosis. If the clinical picture is unclear a Full Blood Count is recommended where a lymphocytosis will be noted of which a high percentage of the lymphocytes will be reactive. If the blood film is not diagnostic then specific EBV serology should be requested. Other causes of a reactive lymphocytosis include; cytomegalovirus, HIV, viral hepatitis, toxoplasmosis and human herpes virus-6. http://www.bpac.org.nz/BT/2012/October/glandular.aspx

Haematologists, Southern Community Laboratories.

Choosing Wisely and change to processing of female genital culture specimens OS only

Choosing Wisely is an international campaign endorsed by the Royal College of Pathologists of Australasia and the Royal New Zealand College of General Practitioners that is aiming to eliminate unnecessary and sometimes harmful tests, treatments, and procedures.

Southern Community Laboratories is committed to promoting appropriate test ordering and antibiotic prescribing.

Inappropriate specimens for culture often grow organisms that are colonisers and not the cause of the patient's symptoms. In the absence of relevant clinical details it can be difficult for the laboratory to determine which organisms are significant. Research shows that laboratory reporting promotes prescription of antibiotics, with the accompanying risk of adverse effects for the patient and the wider community.

We are continually reviewing our laboratory procedures to improve the quality of our service. As part of this we are seeking to reduce inappropriate testing. For example, we receive an average of 220 urine samples and 100 genital swabs a day, many of these are part of "screens" with little in the way of clinical details. Laboratory audit data suggests that over 40% of the genital culture swabs are being referred together with a cervical smear and less than half of request forms give adequate clinical details. Therefore, we will be introducing the following changes:

From 10th October 2016 vaginal swabs will not be processed unless appropriate clinical details are provided on the request form.

Vaginal swabs are primarily recommended for:

- diagnosis of bacterial vaginosis (BV), *Trichomonas vaginalis* (see separate comments below) or candidiasis in *symptomatic* women
- investigation of vaginal discharge and STI
- investigation of vaginal thrush which is recurrent or non-responsive to treatment

Treatment of BV is not recommended unless symptoms are present, and *Candida* spp. can be normal commensals of the genital tract.
Genital swabs should not be performed as part of a "routine screen" taken concurrently with a cervical smear in asymptomatic women.

This policy will include pregnant women since **screening of asymptomatic pregnant women for BV and TV infection is not recommended,** in line with Australian Clinical Practice[1], UK NICE[2] and US CDC[3] guidelines.

Clinical details can include vaginal discharge, recurrent thrush, STI screen, dyspareunia

Genital swabs which have not been processed will be stored for seven days before being discarded. During this time, referrers can contact the laboratory to discuss specimen processing.

For further information or comments on this proposed change, please contact
Dr James Ussher (Microbiologist Ph (03) 4702924, email: james.ussher@sclabs.co.nz) or
Dr Antje van der Linden (Microbiologist Ph (03) 470 2920, email: antje.vanderlinden@sclabs.co.nz)
prior to the 1st October 2016.

References:

1. Australian Health Ministers' Advisory Council 2012, *Clinical Practice Guidelines: Antenatal Care – Module 1*. Australian Government Department of Health and Ageing, Canberra. http://www.health.gov.au/antenatal
2. National Institute for Health and Care Excellence 2008, Clinical Guideline 62: Antenatal care for uncomplicated pregnancies. http://www.nice.org.uk/guidance/cg62
3. Centers for Disease Control and Prevention, 2015 Sexually Transmitted Diseases Treatment Guidelines. http://www.cdc.gov/std/tg2015/specialpops.htm

Testing for Trichomonas vaginalis

Testing for *Trichomonas vaginalis* (TV) is indicated in the following situations:

- Female with vaginal discharge or vulval irritation
- Female requesting full sexual health check

Specimens for TV MUST be collected with the Aptima NAAT vaginal swab *Chalmydia*/*N. gonorrhoeae* collection kit (pink swab and orange tube). Both vulvovaginal (self- or physician-collected) and high vaginal swabs, can be tested. Testing for TV can be performed on samples submitted for *N. gonorrohoeae*/*Chalmydia* testing.

REQUEST RELATED

Request Forms – with the advent of Health Connect South (Testsafe) in the Southern region it has become even more essential that request forms are correctly completed:

- There must be a referring medical consultant (this can be a Registrar if they have been setup to acknowledge results on HCS).
    - The referrer's name should be clearly printed in full (we receive requests with nothing but the first name, or completely illegible)
    - Forms completed by nursing staff require the GP/Consultant's name on them
- All referrers have a laboratory code – or several codes if working in different locations – which can be used in place of a full name; please contact douglas.fraser@sclabs.co.nz to find your code
- If a copy of the results is to be sent to the GP please name the GP

Urine Samples

1) "MSU" means "mid-stream urine." This is a specimen type, not a test. We periodically have issues with urine samples, e.g. "MSU, cytology" where the referrer intended the sample to go to cytology *and* microbiology departments.

   To avoid confusion please clearly state the specimen type **and** the test required e.g. MSU – culture or MSU cytology or catheter urine for culture etc..

2) "Urine PCR" – usually this refers to urine protein/creatinine ratio. However it is ambiguous because PCR is also a method of testing used for *Chlamydia*/*Neisseria gonorrhoeae*.

   To avoid confusion clearly state "urine prot/creat ratio" or "urine Chlamydia/N.gono."

Note: the specimen container for urine *Chlamydia*/*N. gonorrhoeae* testing is not the same as that for urine biochemistry.

Home Visits

Please ensure the laboratory is supplied with full information. On several occasions recently hospital staff have faxed through forms with no patient address (on discharge they may not be returning to their own home) and with instructions to send the report to an un-named GP who has no idea the tests are being ordered

Chain of evidence:

When specimens are collected for medicolegal purposes (eg rape, sexual assault, sexual abuse), they must be accompanied by a Laboratory Chain of Evidence Form. The Laboratory Chain of Evidence Form contains information about all persons handling the specimen, noting time, date, place and signature. It is critical that the form is completed by the person collecting the specimens and that it is completed at all handovers of the specimen, including transport. The laboratory has a procedure in place for processing these specimens. Laboratory Chain of Evidence Forms are available upon request from the Laboratory. For further information, please contact Roger Barton, Quality Coordinator (roger.barton@sclabs.co.nz, phone (03) 470 2950).

REPEAT CARDS

Repeat Cards

With the exception of patients for INR testing and transplant patients all cards expire at one year (or sooner if indicated). Renewal requires review of the patient's requirements and completion of a new card. The following are general guidelines:

- Tests required 6 monthly or annually should not be put on a repeat card, a normal request form should be used
- Repeat cards, or request forms, must not be written out in another requester's name. The referrer making the request has the clinical responsibility for follow-up of the results and this cannot be abrogated. When hospital consultants refer a patient back to the care of their GP a copy of the result is not required unless specifically requested.

A reminder re 'usual' frequencies:

- **CEA** – As a general rule, CEA (like most other tumour markers) is a poor screening test and is not recommended to be used in this way. Testing is usually reserved for those with a diagnosis of colorectal cancer who are being monitored after therapy to detect recurrence or progression. However, even then the optimal frequency of testing is not clear and it will be dictated by the nature and intent of the original therapy and what the likely response to any recurrence might be. A number of US and European guidelines recommend testing at 3 monthly intervals for the first 3 years after therapy if the patient is a candidate for surgery or systemic therapy after tumour recurrence. (http://www.aacc.org/members/nacb/LMPG/OnlineGuide/PublishedGuidelines/major/Documents/TumorMarkersMajor10.pdf)
- **PSA** - Men who have undergone radical prostatectomy or radiotherapy should have their PSA level checked regularly (bpac Best Tests; Oct 2012). Testing should begin 6 weeks after treatment (unless adjuvant hormonal treatment is being given) and then at least every six months for the first two years. Thereafter annual testing should be carried out. Where watchful waiting is being used to follow disease, PSA should be checked at least once a year. For those being followed by active surveillance, general guidance is that PSA should be checked 3-6 monthly but actual frequency is guided by how quickly the PSA value is changing.
- **HbA1c** – For those with established diabetes, guidelines in the NZ Primary Care Handbook recommend review of HbA1c every 3 to 6 months depending on an individual's risk of diabetes-related complications. When assessing cardiovascular risk in the non-diabetic individual, HbA1c should be assayed as part of that risk assessment. The frequency of this testing depends on the current level of risk and ranges from annually for those at high risk (5y risk $\geq$ 15%) to every 10 years in those with a 5y risk of <5%).
- **Uric Acid** – In the treatment of gout, monthly assay of serum urate is recommended until the target serum urate of <0.36 mmol/L is achieved. Thereafter 3 monthly monitoring is recommended to ensure that this target value is maintained (source: Canterbury Health Pathways). N.B. a normal serum urate in an acute attack of joint pain does not exclude gout.
- **Clozapine** patients on clozapine have a blood level done when they get to the target dose, when doses are increased and thereafter annually. Clozapine levels might also be considered when there are issues of compliance or there are reasons to be concerned about toxicity. Clozapine should not be requested using a repeat card.
- **IMMUNOLOGY –** patients should not be put on a repeat card until their initial status has been determined.
- **ANA, ENA antibodies –** twice to confirm positive or negative then annually (these tests should not be requested on a repeat card)
- **ANCA** – negatives annually, positive **MPO or PR3** not more often than 6 weekly
- **RF, Thyroid antibodies, CCP antibodies** known positives 6-12 monthly

- **dsDNA** known positives 6 weekly, negatives annually (should not be put on a repeat card until initial status has been ascertained)

PATIENT CHARGING

The Health and Disability Services Eligibility Direction 2011 states a person is eligible for publicly funded health and disability services in New Zealand if they hold a **work** visa allowing them to stay in New Zealand for a minimum of two years or longer. **If the work visa is for less than two years**, we count the time spent lawfully in New Zealand **immediately prior to its issue**, on a student, visitor, or other work visa, toward the two year required minimum, provided the visas are consecutive.

People who hold visitor visas are not usually eligible for publicly funded healthcare, regardless of length of visa

THE LABORATORY COLLECTION GUIDE

The latest update is now available at

http://www.sclabs.co.nz/index.php/clinicians/information

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