OS Operational Update DEC 16

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TEST RELATED

New Testosterone Assay

From 20.12.16, tests for testosterone in females and children will be carried out in Dunedin instead of Christchurch. Southern Community Laboratories in Dunedin has established a highly specific and sensitive assay for low levels of testosterone that is suitable for the values typically seen in women and children. This change means that Sex Hormone Binding Globulin (SHBG) and Free Testosterone will also be reported from the Dunedin laboratory. Because it adds no useful information to the Free Testosterone, Free Androgen Index will no longer be reported.

The provisional reference intervals reported with test results will be slightly different to those currently used.

The 'standard' testosterone test used in adult males will continue unchanged.

Note: Testosterone must be collected in a red-top tube only now

An Update on Thrombophilia testing

Screening for hereditary thrombophilia remains complex. Southern Community Laboratories follows the British Society of Haematology (previously known as the British Committee for Standards in Haematology) guidelines published in 2010 (available at http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2141.2009.08022.x/full) in order to produce meaningful results for appropriate clinical management. All requests (including those for individual tests such as Factor V Leiden) require haematologist approval and an Application Form is available on the SCL website (http://www.sclabs.co.nz/images/docs/thrombophilia.pdf). This also lists appropriate indications for testing, timing of sample collection and situations when testing is not indicated.

Gene testing for Hereditary Haemochromatosis

Hereditary haemochromatosis due to homozygosity for the C282Y mutation in the HFE gene is one of the commonest autosomal recessive conditions recognised. The prevalence of the disease-causing genotype is approximately 0.5% in Caucasians. It is extremely uncommon in non-Caucasians.

Not all who are homozygous for the C282Y mutation will develop disease. When they occur, characteristic findings include fatigue, arthralgia, cirrhosis and, rarely, diabetes mellitus, skin pigmentation, impotence and ECG abnormalities (due to cardiomyopathy). Clinical presentation is unusual before age 40 in males and before the menopause in females. However, now that assessment of iron status is readily undertaken, most patients are detected on the basis of abnormal iron studies in the absence of relevant clinical findings.

The characteristic abnormality when testing markers of iron metabolism is an elevated transferrin saturation otherwise unexplained by iron therapy, transfusion or ethanol use. Elevated transferrin saturation is a measure of circulating iron and a marker of ongoing iron accumulation. On the other hand, elevated ferritin may signify increased iron storage but may also be due to unrelated liver disease, inflammation or some anaemias. Since the majority of people with elevated serum ferritin do not have haemochromatosis, raised serum ferritin should not be used as the sole basis for requesting haemochromatosis genotyping.

Where clinical suspicion exists the best initial tests are to measure iron, transferrin and ferritin. Transferrin saturation will be calculated.

If the transferrin saturation is consistently >45% (and other causes of increased iron absorption have been excluded) HFE genotyping may be carried out. The mutations tested for are C282Y and H63D. Homozygosity for C282Y (and occasionally compound heterozygosity – C282Y / H63D) may be associated with biochemical and clinical features of iron overload. Iron overload is not likely to occur when an individual is a heterozygote for C282Y or H63D or when homozygous for H63D.

There is usually no clinical requirement to genotype those under the age of 16 years. Iron utilisation associated with growth (and in girls, onset of menarche) usually protects against iron overload. Testing, in affected families, should be considered once an individual reaches late teenager years or young adulthood.

In summary

- The most specific marker for iron overload is **transferrin saturation**.
- **Do not** use raised ferritin as a sole determinant of the need to perform genetic testing – it is too non-specific.
- Most patients with hereditary haemochromatosis are identified on the basis of abnormal iron studies.
- There is **no** clinical requirement to genotype young people as iron overload is **extremely uncommon** in this group.

For further information or comments on this change, please contact

Dr Geoff Smith Chemical Pathologist 0275545262 Email Geoff.Smith@sclabs.co.nz
Prof Ian Morison Haematologist 0212797170 Email Ian.Morison@sclabs.co.nz

Referral for Therapeutic Venesection

As venesection is a therapeutic procedure with a small risk of complications, Southern Community Laboratories requires that all new referrals have a formal letter addressed to the local laboratory who will forward this onto a haematologist for approval. Please list the indication for venesection, any supportive data (e.g. haemochromatosis gene status) and any co-morbidities that may influence the procedure. A laboratory request form is inadequate for referral.

Choosing Wisely and change to processing of female genital culture specimens

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 encourages 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. Therefore, since the 10th October 2016, we have no longer been processing vaginal swabs 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
- screening for bacterial vaginosis, regardless of symptomatology, prior to termination of pregnancy (TOP) or hysterectomy
- investigation of vaginal discharge
- investigation of vaginal thrush which is *recurrent* or non-responsive to treatment

Treatment of BV is not recommended unless symptoms are present. Treatment of asymptomatic BV is only recommended pre-TOP or hysterectomy.

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 or as part of an asymptomatic STI screen.

This policy includes 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, dyspareunia, pre-TOP, pre-hysterectomy etc.

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, please contact either:

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)

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
4. New Zealand Sexual Health Society Best Practice Guidelines http://www.nzshs.org/guidelines

Faecal bacterial culture and parasite PCR is to be replaced with a multiplex PCR for enteric pathogens

From the 23rd of January, a new multiplex PCR assay to detect enteric pathogens will replace faecal bacterial culture and the current parasite PCR.

This PCR assay is able to detect *Salmonella*, *Shigella*, *Campylobacter, E.coli* O157, Shiga toxin-producing *E.coli* (STEC), *Clostridium difficle, Giardia*, *Cryptosporidium*, and *Entamoeba histolytica*. This PCR assay will provide better or equal sensitivity to our current culture methods for all targets except *Salmonella*, where there is a slight reduction in comparison with enrichment culture. Detection of Shiga toxin-producing *E. coli* (especially strains other than *E. coli* O157), and community-acquired *C. difficle* infection will both be improved.

Culture methods will continue to be used to detect *Yersinia*, *Vibrio* and *Aeromonas* where clinically indicated. Please ensure you include clinical details with all requests so that the laboratory can determine which samples require investigation for these pathogens.

PCR testing is still available for *Blastocystis hominis* and *Dientamoeba fragilis* when specifically requested with relevant clinical details.

Requests on patients where clinical details indicate recent travel will continue to be examined microscopically for other parasites.

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 *Chlamydia*/*N. gonorrhoeae* collection kit (pink swab and orange labelled 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. gonorrhoeae*/*Chlamydia* testing.

Clinical Details: To assist the laboratory in conducting an optimal microbiological investigation, please ensure relevant clinical details are always provided with ALL specimens.

REQUEST RELATED

Antenatal Requests

A number of errors have recently come to light in the reporting of reference ranges for Antenatal screening, and for Glucose testing in particular.

Normal ranges of a number of assays alter quite significantly in pregnancy, and our systems are designed to reflect this. However, a large number of request forms do not provide the necessary information, and patients are being registered as non-pregnant. This may mean a result being flagged as abnormal when in fact it is not, potentially resulting in unnecessary treatment.

To assist us in providing the best possible outcome for your patients, please ensure that **gestation is clearly stated on all request forms for pregnant patients.**

Non-eligible Patients - If you know your patient is not an NZ citizen, or not eligible for public funding, please ensure this is clearly indicated on the form. We have had a several cases recently where the information has been volunteered by the patient in the absence of any indication from the referrer.

Allergy Testing - Please indicate on request forms for allergy testing whether it is the Inhalant or Food panel that is being requested.

Repeat Cards - There are a significant number of repeat cards in the system that have been completed by practices but which nominate a hospital consultant or department as the primary referrer. This is inappropriate and results in the hospital consultant getting results on HCS for signoff for a patient they may not have seen for many years. The problem is particularly obvious in Rheumatology where the department, as a matter of policy, do not use the repeat cards.

Responsibility for follow-up of results lies very clearly with the requester who must be clearly identified.

- Such cards are being reissued by the laboratory in the name of the GP concerned
- Cards, with the exception of INR and Renal Transplant patients, may not be issued for longer than one year and will be cancelled on expiry. It is a reasonable expectation that if a patient is being monitored at regular intervals their requirement for blood tests will also be reviewed at least annually
- Hospital consultants, unless particularly requested, should not be copied in. They are able to access the results on HCS if required.

Anonymous Testing - The laboratory allows for anonymous testing, by identifying the patient with a special code instead of the patient's usual personal details.

Unfortunately we have recently seen a number of <u>improperly performed anonymous requests</u> eg: an 'anonymous' sample which includes patient's initials and NHI. Not only will this fail to properly 'anonymise' the specimen, it actually brings it to the attention of lab staff who then need to troubleshoot the labelling. This is particularly awkward for us when a member of laboratory staff is the 'anonymous' patient involved.

The process to follow is as follows:

- Do NOT label the form or specimen with ANY details that can identify the patient. No address, no NHI, no initials.
- Select a suitable code to identify the patient. This should be unique and distinctive. Label the form and specimens with this code only. Don't lose this code!
- One option for a code is the 'universal' system: first two letters of the surname, first letter of first name, sex (M or F) then date of birth as six numbers.

  For example, Jamie Evans, Male, born 25/11/1981 would be coded as EVJM251181

- However, any other coding system, including completely random letters, is acceptable
  - Include 'anonymous coded specimen' in the clinical details on the lab form
  - When the results come back, they will NOT be filed automatically under the patient's results in your computer system; you will need to manually review and file them
  - Bear in mind that these results will NOT be filed in any regional repositories, such as Health Connect South or SCL Éclair.

Note: some samples cannot be tested anonymously. In particular, there is a legal requirement that all cervical smears are fully labelled with the patient's details including NHI.

SAMPLE RELATED

Test Adds – A reminder that specimens are only kept 7 days from receipt in the laboratory. We are getting a number of requests for test additions after the seven day cut-off.

Note: some tests can't be added on up to the seven days as the analysis is time limited

Histology Samples (Hospital) – on occasion we receive unannounced samples, either frozen sections or fresh tissue for sentinel node, muscle or DIF studies. If we are not looking out for them there may be delays – please inform the Histology team when such samples are being sent

Sample Delivery – Please ask patients who are dropping laboratory samples off at the Dunedin Laboratory to bring them *directly* to the laboratory on the third floor of the Clinical Services Building. They should not be left at ED reception, the hospital main reception (in one recent instance, some were literally dropped on the floor at the front entrance) or at Plunket House.

All the best for a peaceful and blessed Christmas

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