Southern Community Laboratories

OS Operational Update SEPT 15

TEST RELATED	REPEAT CARDS
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TEST RELATED

Infectious Diseases

Please note that if requests are received for any of the following tests without the required travel and clinical history they will not be accepted for testing by the referral laboratory

Test	Travel history required	Clinical history required
Arbo Virus (Dengue, Ross River , Barmah Forest, Chikungunya, Zika)	Yes	Yes
Chlamydia pneumonia (paired samples)	Yes	Yes
Chlamydia psittaci	No	Yes
Coccidiomycosis	Yes	Yes
Hepatitis E	No	Yes
Histoplasmosis	Yes	Yes
HHV6	No	Yes
Lyme	Yes	Yes
Q fever diagnostic	Yes	Yes
Rickettsia	No	Yes
T. cruzi	Yes	Yes

Cortisol results

There will be a major change in the serum cortisol assay used by Southern Community Laboratories on 15.9.15. This will result in values that are 30% lower than the old assay. However, the new test results are more closely aligned to accurate, state-of-the-art mass spectrometry methods and are less susceptible to interference from exogenous glucocorticoids. Reference intervals and interpretive comments for serum cortisol, synacthen tests and dexamethasone suppression tests have been updated to reflect this change.

Change to Conjugated Bilirubin results

The calibration of the biochemistry laboratory method for conjugated bilirubin has been changed resulting in values that are approximately 20% lower than previously reported. It was clear that the previous method appeared to 'read high' when compared to similar assays from other manufacturers. We believe that the new test provides a more accurate measure of conjugated bilirubin.

Warfarin and INR testing

When changing the dose of warfarin the full effect on the INR can take 4-7 days. If the INR is checked too frequently, there is a risk of over-responding, leading to see-sawing of therapeutic control.

Occasionally it is necessary to monitor the INR more frequently. For example, some algorithms use daily monitoring during the first few days of initiation of warfarin for acute thrombosis. In addition, in patients with very high INRs , or in patients who have overdosed on warfarin, close monitoring is recommended to follow the effects of treatment. However, in patients with moderately high INRs (e.g., 4-7), in whom warfarin is stopped, daily monitoring is not usually needed.

Troponin results

When the current troponin T assay was introduced in 2015 the 99th centile reported was 13 ng/L. Since then, as more data has become available, the kit manufacturer has re-established the 99th centile value at 14 ng/L. SDHB laboratory reports will be changed to reflect this from 7th September 2015.

HbA1c to screen for diabetes in pregnancy.

The Ministry of Health has directed DHBs to offer screening for diabetes mellitus to women in the early stages of pregnancy. To this end, Southern Community Laboratories will add HbA1c to the first antenatal blood test panel from 1.10.15. From this date it will no longer be necessary to request HbA1c separately for these women – so long as the first antenatal screening tests have been requested.

Vitamin D Requests

The main source of vitamin D is the action of sunlight on the skin. Low plasma vitamin D is common, especially among darker skinned people of all age groups, and those who are not exposed to sunlight for any reason. Vitamin D concentrations are lowest during winter, and low vitamin D tends to recur each winter in susceptible individuals. The half-life of 25-hydroxy vitamin D in plasma is 3 months.

Most people with low vitamin D are asymptomatic. If prolonged and severe, vitamin D deficiency may lead to rickets in children and osteomalacia in adults; these are uncommon conditions. The role of low vitamin D as a contributing factor to osteoporosis is still a matter of debate. Overall evidence from RCT's suggests that supplementation with vitamin D does not have consistent benefits for fracture prevention[1,2].

Individuals who are at risk of symptomatic vitamin D deficiency are those of Indian or African descent, frail institutionalized elderly, and those who avoid sunlight for cultural or medical reasons. In such individuals, vitamin D supplementation is reasonable without blood testing. There is insufficient evidence to support routine vitamin D supplementation or testing vitamin D levels in healthy community-dwelling individuals.

Pregnancy: Available evidence does not suggest that pregnant women are at increased risk of vitamin D deficiency compared with the non-pregnant population[3]. Current guidelines do not support routine testing of vitamin D levels in pregnancy[4].

Treatment of Vitamin D Deficiency

Adults: Cholecalciferol 1.25 mg (50,000 units) per month. Annual bolus dosing of vitamin D might be harmful[5].

Children (<15 years): The formulation and dosage of Vitamin D supplements for children depends on the indication and should be discussed with a paediatrician.

Calcitriol (Rocaltrol) or Alfacalcidol (One Alpha) should NOT be used to treat vitamin D deficiency, except in specific disorders (e.g. chronic renal disease).

SDHB Policy on vitamin D testing

Vitamin D tests were originally developed for investigation of rickets, osteomalacia and other metabolic bone disorders. In recent years the number of requests for vitamin D tests has increased dramatically. Most of these requests are unrelated to metabolic bone disease, and have arisen because of reported associations between various disease states (cancers, cardiovascular disease, diabetes, autoimmune disorders and infectious diseases) and lower vitamin D concentrations.

However, a causal link has yet to be demonstrated for any of these conditions[1,6-8]. The Institute of Medicine, following a comprehensive review of the evidence, concluded that "For extraskeletal outcomes, including cancer, cardiovascular disease, diabetes, and autoimmune disorders, the evidence was inconsistent, inconclusive as to causality, and insufficient to inform nutritional requirements. Randomized clinical trial evidence for extraskeletal outcomes was limited and generally uninformative."[7]

A recent review for the Ontario Ministry of Health has concluded that there is little evidence that it is useful to measure vitamin D concentrations in patients without symptoms of metabolic bone disease.[9]

From 1st October 2015, the following criteria will be applied to vitamin D tests in SDHB.

Vitamin D will be performed only when:

1. Ordered by the following specialists: Endocrinologist, Gastroenterologist, Bariatric Surgeon, Rheumatologists, Paediatricians and Nephrologists.
2. Ordered for those in specific high risk groups for rickets/osteomalacia (e.g. cystic fibrosis, proven malabsorption, bariatric surgery, refugees, those with deeply pigmented skin and those who wear clothing that covers the head and face)
3. Ordered for the investigation of rickets or osteomalacia, disorders of calcium and phosphate metabolism or osteoporosis
4. Children under 16 years of age
5. Ordered for other patients after discussion with, and approval by, a Chemical Pathologist
6. Patient on Retuximab

The reason for testing must be stated on the request form**.**

For testing outside these criteria there is the option for the patient to pay

HBV Viral Loads

There have been a number of instances lately of over-requesting for HBV viral loads (eg weekly). The indications for HBV DNA testing in chronic HBV infection are:

1) As part of the initial evaluation
2) In untreated patients at 12 monthly intervals or earlier if there is an increase in ALT
3) In patients treated with nucleoside analogues, at baseline, 1 month, and then 3 monthly while on treatment. HBV DNA testing should be performed at the cessation of treatment and at 3, 6 and 12 months post-treatment.

4) In patients treated with pegylated interferon, at baseline and then 3 monthly while on treatment. After the cessation of treatment, HBV DNA testing should be performed every 3- 6 months for 12-18 months post-treatment.

We will be restricting testing for non-specialist referrers to not more than 3 monthly intervals. Please see the Australian and New Zealand Chronic Hepatitis B (CHB) Recommendations or contact the clinical microbiologist for further information.

HLA B27 - Testing brought in house from the beginning of September

Reducing Substances

The test for reducing substances in neonatal stools was first published in 1964, and involved using Clinitest® tablets (Benedict's reagent) to detect reducing sugars, such as glucose and galactose, produced by bacterial lysis of di- and oligosaccharides by colonic bacteria. It is thus an indirect indicator of lack of hydrolysis of di- and oligosaccharides in the small intestine. For milk-fed infants, this most commonly indicates lactose intolerance.

The test is fairly crude, with its sensitivity dependent on the infant's diet, the intestinal transit time, and the delay between passage of the stool and testing. Test specificity is poor, and there is no realistic method of quality control. While the test may continue to have some usefulness if performed by the clinician on freshly passed stool at the cotside, and interpreted in the context of the stool's appearance and the history and physical examination of the infant, it is a test which does not meet the standards for reliability and quality assurance required of a modern medical laboratory. The test will no longer be provided by Southern Community Laboratories. In most cases the diagnosis of lactose intolerance can be made clinically, using withdrawal and challenge with lactose.

Testing for reducing substances in urine has been long since been superseded by the test for urine sugar and will also no longer be offered

REPEAT TESTING

Information re the use of repeat cards

- Cards will normally expire after one year (or sooner if indicated), the expiry date must be entered. Patients who present after the expiry date will have the card marked as expired and be asked to return to their referrer for review and if necessary re-issue
- A separate card is available for INR testing only and is open ended – please ensure the testing regime is established before issuing, we have had instances of patients still on very frequent testing months later
- The card will be returned to the patient after use and they will need to bring it with them on each occasion
- Different tests can be specified at different frequencies
- Supplies of the new cards can be obtained by ringing or emailing the Stores on XXXX

Please be specific when making requests, the following are not helpful
'weekly until normal' 'as required' '2-3 monthly'

Usual minimum ordering frequencies for some of the more common repeat tests:

Frequency	Test
Not suitable	Cloazapine and other annual checks
3 monthly	dsDNA, HbA1C, HBV viral load

6 monthly	ANA, ENA, ANCA, MPO, PR3, RF, anti-CCP antibodies

Clozapine Testing

On several occasions lately patients on clozapine have presented with a repeat card for monthly clozapine testing and no CBC. Advice from Novartis is that 'Clozapine testing is indicated in special circumstances only, and is not indicated on a regular weekly or monthly basis'.

The local recommendation is that 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.

Requesting of ANA

When not to request ANA

- For monitoring a connective tissue disease
- Screening for CTD when someone already has an autoimmune condition
- "Tiredness"
- Other forms of arthritis (Gout, OA_
- Other symptoms/signs that remain unexplained

Suggested indications for ANA Testing

- Systemic inflammatory signs that are not related to infection
- Mouth ulcers, hair loss
- Chronic suggestive rashes or erythema (photosensitive, urticarial)
- Inflammatory Arthritis
- Sicca Symptoms (Xerostomia, Xerophthalmia)
- Unexplained serositis (pleuritis/pericarditis)
- Possible autoimmune liver disease
- Glomerular disease (haematuria/casts, proteinuria)
- Myositis (raised CK and weakness)
- Skin thickening
- Raynaud's phenomenon
- Interstitial lung disease
- Leukopenia, lymphopenia or haemolytic anaemia

HbA1C Repeat Testing

Under normal circumstances HBA1C should not be repeated > 3 mthly. An audit of the 1415 HBA1C requests for Otago Southland showed

- 15pts repeated 9 times, 5pts 10 times, 2pts each 12 and 13 times
- 15, 16, 19 times – 1 patient each, the two largest number ordered by a registered nurse

Causes of the excessive testing:

1. Repeat cards being written out for monthly testing
2. Patients with a repeat card being given random forms when they present to the GP (who may sometimes be unaware the patient has a repeat card issued by a hospital clinic)
3. Referrers in both the primary and secondary sector being unaware of testing being carried out in the other sector
4. Patients presenting at greater than the requested frequency

Where staff become aware of excessive testing the repeat card will be altered accordingly

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