Southern Community Laboratories

OS Operational Update MAR 16

TEST RELATED PSA reporting ANA ENA & dsDNA testing HARMONY PRE NATAL TESTING	**REQUEST RELATED** **SAMPLE RELATED** - Urine chlamydia - Transfusion Medicine **HOME VISITS**

TEST RELATED

Changes in reporting of Prostate Specific Antigen (PSA)

The Ministry of Health (MOH) has published a guidance on prostate cancer testing and management in primary care, including defined pathways for referral to specialist care. These can be found at: http://www.health.govt.nz/publication/prostate-cancer-management-and-referral-guidance

The guidance has been endorsed by RNZCGP, The Prostate Cancer Foundation, The Urological Society of Australia and New Zealand, The New Zealand Urological Nurses Society and The New Zealand Society of Pathologists.

From autumn this year, we will be incorporating the recommendations of the guideline in PSA reports - as requested by MOH. This will be through a standard comment, indicating abnormal levels of PSA, as they are defined in the guideline (see below).

The new guideline defines the level of PSA above which referral to a urologist should be considered. Confirmation of these abnormal levels indicates that referral for specialist assessment is required. The levels have been chosen according to the likelihood of prostate cancer being present, but also take into account that the benefits of early diagnosis of prostate cancer decrease with age. At each age interval the definition of abnormal PSA is determined solely by total PSA, as shown below. ***Free PSA is not used to refine the predictive value of the total PSA.***

PSA level by age at which routine referral should occur (if confirmed) according to the guideline

Age	Abnormal PSA level (µg/L)
≤ 70 years	≥ 4.0
71 – 75 years	≥ 10.0
≥ 76 years	≥ 20.0

Patients should have repeat PSA after 6 – 12 weeks to confirm the abnormal levels. Confirmation indicates a routine referral to a urology service is required. When a repeat PSA is less than the threshold for abnormal, the patient should be followed up according to the algorithm on page 3 of the guideline. The algorithm also defines other situations where more urgent referral is indicated, in men with abnormal PSA and red flag clinical signs and symptoms consistent with prostate cancer.

PSA levels may increase in non-malignant conditions including benign prostatic hypertrophy and prostatitis. In addition, digital rectal examination (DRE), ejaculation or cycling may cause a transient increase in PSA. It recommended that PSA should not be checked within 2 days of a DRE or within 3 days of ejaculation or cycling.

Geoff Smith 0275545262 and Guy Mulligan 0275701749 – Chemical Pathologists

Changing testing approach to ANA screening and subsequent ENA and dsDNA antibody testing.

The anti-nuclear antibody (ANA) remains the quintessential test for assessing the presence of systemic autoimmune diseases such as systemic lupus erythematosus (SLE), systemic sclerosis or Sjogren's syndrome. The ANA is a screening test with a strong negative predictive value, and is therefore helpful in ruling out systemic autoimmune disease, particularly SLE.

The ANA is useful for triaging patients for further testing for extractable nuclear antibodies (ENA) or anti-dsDNA antibodies. Indeed in our laboratory >99.5% of ANA negative cases, the ENA and anti-dsDNA will also be negative.

In 2012 to June 2013 we reviewed the results of 6543 patients where the ANA and ENA had both been performed. We also reviewed the results of 9379 patients where the ANA and anti-dsDNA antibodies had been performed at Southern Community Laboratories.

Only 32/9739 (0.33%) had negative or low positive (1:80) ANA and a positive anti-dsDNA antibody result. There were 24 patients with 8 duplicate results. Reviewing the clinical data on those 24 patients, three had SLE while one had Juvenile Idiopathic arthritis. The rest were deemed false positive results.

Only 5/6543 (0.08%) had negative or low positive (1:80) ANA and a positive ENA. There were 4 patients with 1 duplicate result. Three patients had anti-Jo-1 antibodies and one patient had anti-SSa antibodies. Reviewing the clinical data on those 4 patients; of the three patients with anti-Jo-1 antibodies, one had definite inflammatory myositis (dermatomyositis). The patient with anti-SSa antibodies had ANA negative SLE.

From the beginning of April, to reduce the likelihood of false positive results and to assist you with appropriate test selection, the following system will be implemented:

- Where a patient is ANA negative or 1:80 the accompanying requests for ENA or anti dsDNA antibody tests will be declined
- Patient serum will be stored for one month in these cases, so that where there is strong clinical suspicion for performing the testing (such as ANA negative SLE or inflammatory myositis), this may be requested via discussion with the Immunology department.

Note that we will continue to reflex ENA and anti-dsDNA antibodies on new patients with significant ANA titres ≥1:160.

Dr Richard Steele, Immunopathologist, SCL

Harmony Pre-natal Testing

We are pleased to say that the price for Harmony prenatal screening has dropped from $1000 to $675

Result Interpretation - Information to help with result interpretation is available on our website: http://sclabs.co.nz/index.php/clinicians/information which has a link to the RCPA Test Interpretation Manual

REQUEST RELATED

Referral Forms – under the terms of our contract nursing staff (with the exception of Nurse Practitioners and Midwives) are not permitted to request laboratory tests. All request forms are required to be signed by the requester

Urine requests – please inform the patient when a urine test has been requested and provide them with a collection device and instructions

Faxed forms – these are often faxed to the lab with no indication of why they have been sent. Additional instructions and/or contact details would be appreciated

Repeat Cards

- cards should not be completed by nursing staff, they do not have test ordering rights
- please provide complete clinical details, date of issue and date of expiry

Unfunded tests

- tests for immune status are unfunded under the contract with the exception of referrals from Haematologists testing immune compromised patients
- we have had referrers requesting testing for Health Science students on multiple forms and telling them to present on different days and requests annotated with 'diagnostic' – both are patently dishonest (and the students in all cases were charged)
- Samples with pending funding approval will be discarded if no approval has been received after one month
- Insurance requests should be accompanied by the Insurance company form or the policy or order number, as the companies will only pay our invoices if those are referenced. It is not sufficient to send a referral form from the practice with a comment that the request is "for insurance purposes"

Marinoto Clinic

- A drop box has been installed just inside the main Marinoto Clinic doors
- The box will be cleared at 1030 and 1800 Mon-Fri. It will not be cleared at weekends or on public holidays
- The box should not be used for URGENT samples - please take any urgent samples to the SCL Collection Rooms (Suite 2), or contact SCL on 080 101 444

SAMPLE RELATED

Blood gases – please check that the filter cap is secure, a number of leaking samples have been received recently

Urine Chlamydia/Gonorrhoea

All urines for Chlamydia/Gonorrhoea NAAT testing must be received in the Aptima Urine Collection tube. Urines not received in the Aptima tube will be rejected for NAAT testing. Transferring urine into the Aptima tube in the laboratory increases the risk of contamination of specimens, potentially leading to false positives, and of delays in transfer into the transport media, potentially leading to false negatives. Urines should be transferred to the collection tube either at the GP practice or in specimen collection/patient services rooms, where a single sample will be being handled at a time. While this may represent a minor inconvenience, it is essential for the provision of correct results. For further information, please contact Dr James Ussher, Clinical Microbiologist (Ph (03) 4702924, email: james.ussher@sclabs.co.nz).

Acceptance Criteria for Transfusion Medicine Specimens

Please note that the Acceptance Criteria for Transfusion samples is different to a standard diagnostic sample. The following information is required for transfusion specimens:

Request Form Requirements:

- Patient family name and given name/s (must be in full and not an abbreviated or nickname form)
- NHI number and/or date of birth (both preferred)
- Declaration must be signed by the sample collector confirming the patient was positively identified at the time of collection and the samples labelled by the collector before leaving the patient
- Gender Date and time of sample collection
- Clinical Diagnosis and indication for transfusion (include date of surgical procedure if applicable)
- Questions completed (previous transfusion in past 3 months etc)
- Name or signature or other identifier of the person completing the request form - must be legible. If the person completing the form is not the consultant please place the consultants name in the designated box on the top left hand corner of the request form
- Patient's location

Sample Requirements:

- Samples must be hand labelled
- Patient family name and one or more given names (not in abbreviated or nickname form)
- NHI number and/or date of birth (both preferred)
- Signature or initials of the collector Date and time of sample collection

NB: The declaration signature and the signature on the tube must clearly be the same person. If these signatures are not traceable to the same person then the sample will be rejected and a new sample required.

HOME VISITS

- Home visits are provided Monday to Friday, excluding Public Holidays, between 8am and 5pm
- Patients booked for a home visit must be:
    1. housebound or have such severely impaired mobility that it precludes access to routine medical services outside their residence without special arranged transportation ie: ambulance or taxi with assistance
    2. significantly mentally impaired and with no support person available to transport them
- Bookings will not be accepted for patients requiring restraint unless assistance is available
- Bookings must be made by the referring Medical Practitioner
- Patients may not self refer
- Bookings will be accepted to a maximum of four (4) weeks only unless the patient is defined as permanently housebound
- Bookings are limited to patients living within a 20km radius of the nearest Patient Services Centre. In exceptional circumstances, and by agreement, this requirement may be waived
- Patients who are not at home when the phlebotomist calls will be left a leaflet asking them to come in to the Patient Services Centre
- Patients who are considered to no longer require home visits will be discharged from the service after consultation with the referrer

Service Delivery

Notification – because the schedule is not completed until the morning of, and may be disrupted by urgent requirements, it is not possible to provide users of the service with the probable visit time. As patients are, by definition, housebound this should not be a cause of concern

Rest Homes – are allocated particular days of the week for routine testing. Urgent requests may be able to be accommodated but need to be discussed with the service. We require a Rest Home staff member to be available to assist with identification as many patients are unable to self-identify.

Cancellations – the service needs to be advised if a regular/booked patients is hospitalised or unavailable for some other reason

Information - to assist with scheduling the service needs to be informed of any special requirements eg: fasting, medications with-held

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