

# Response to OIA request regarding changes to Policy and Procedure for Thyroid testing

Pathology Associates is responsible for Community testing in the Waikato region and hospital and community testing, for the BOP and Lakes regions. We perform testing for diagnostic and monitoring purposes and wherever possible adhere to what we consider is good laboratory practice. Where best practice guidelines (bpac) exist, we adopt these.

There have been a number of changes to Thyroid Function Testing over the years and the changes have always been communicated to our users via Clinical Updates. Additionally, changes that might impact clinical care are submitted to the Waikato DHB Community Laboratory Services Clinical Governance Group

**Reverse T3** was available prior to July 2012 and performed at the laboratory in Christchurch. This service was withdrawn in 2012. No other laboratory provider offers this test.

**TSH, FT4 and FT3** Changes to policy and procedure as follows:

**October 2012** – In conjunction with the Chemical Pathologist from Waikato hospital we prepared and sent out a Clinical Update relating to the bpac guidelines issued in December 2010 – enclosed with link to the NZ bpac site.

**March 2013** – In conjunction with the Chemical Pathologist from Waikato hospital we prepared and sent out a Clinical Update relating to falsely elevated FT3 results observed by us which would sometimes trigger further unnecessary investigations. We strongly advised following bpac guidelines and assured our requestors that FT4 and FT3 would be automatically added by the laboratory according to bpac guidelines. Clinical Update enclosed

**June 2014** – In conjunction with the Chemical Pathologist from Waikato hospital we prepared and sent out a Clinical Update relating specifically to FT3 requesting. The update included the rationale behind our decision to delete FT3 requests at source and to reflex them back on if the TSH was abnormal, according to bpac guidelines. Requests from endocrinologists were exempt from this action and all requests from this group were accepted. Any follow up contact from GPs asking for the FT3 to be added was actioned without exception. Clinical Update enclosed

**August 2015** - In conjunction with the Chemical Pathologist from Waikato hospital we prepared and sent out a Clinical Update clarifying that the first line test will be TSH and that if FT4 is required, then it should be specified on the request form. It also included some indications for requesting FT4 which again are in line with best practice guidelines. Clinical Update enclosed

**April 2016** – Pathlab thyroid function testing procedures were discussed at the Community Laboratory Services Clinical Governance Group (CLCGG) with representation from Pathlab, Hauraki PHO, Health Waikato laboratory and a number of Waikato DHB senior managers. Pathlab practice was endorsed by the group

**August 2016** – In conjunction with the Clinical Immunologist a clinical update was prepared and sent out relating to testing for Thyroid Antibodies. The clinical update is self-explanatory, and the changes have been adopted in most laboratories in New Zealand – see enclosed

I reiterate that the only test that we have discontinued is reverse T3 which is no longer available. FT3 and thyroglobulin antibodies are available to specialists, and also where clinically justified. These changes are all in line with best practice guidelines.

John Woodford Lead of Specialty Biochemistry

Pathlab Waikato Laboratory



## FOB TESTING AND THYROID FUNCTION TESTS

### Faecal Occult Blood testing

Following a review by the Community Laboratory Clinical Governance Group, Guaiac faecal occult blood testing (FOBT) is to be discontinued. Faecal immunochemical testing (FIT) will be performed on all samples (FIT is currently performed when FOBT is positive) but is not recommended other than as part of a public screening programme. A feasibility study of FIT screening in New Zealand is currently being performed in Waitemata.

- FIT should not be performed more frequently than 2-yearly or in those under 50 years of age (consistent with the feasibility study)
- Patients with iron deficiency, anaemia, rectal bleeding or other symptoms of gastrointestinal disease should not have FIT, but should be investigated according to the Waikato Hospital Primary Care Management Guidelines. (<http://www.waikatodhb.govt.nz/file/fileid/18567>).
- FIT does not require dietary adjustment and a single specimen is required (not three).
- FIT testing is only indicated in asymptomatic individuals as part of a public screening programme for colorectal cancer.
- A negative result does not exclude colon cancer.
- A positive FIT requires follow-up since approximately 1 in 10 appropriately tested patients with a positive result will have a colon neoplasm.

### Diagnosis of Thyroid dysfunction

The relationship between TSH and FT4 makes TSH a very sensitive marker of thyroid function; if FT4 is decreased by 50%, TSH will increase about 100 times. In most patients TSH is the preferred initial test when checking for thyroid disease. If TSH falls outside the reference interval, additional testing will be triggered:

TSH > 5 FT4 is added  
TSH < 0.3 FT4 and FT3 is added.

#### When to request both FT4 and TSH?

- During pregnancy.
- Suspected pituitary disease.
- Suspected non-compliance with supplementation.

#### Monitoring of thyroid hormone supplementation in men and non-pregnant woman

Wait 6 weeks after a dose adjustment to allow TSH to stabilise.  
FT3 is not informative when taking T4 and should not be routinely requested.  
When on a stable dose, check TSH annually.  
For other thyroid conditions or settings consult the BPAC guidelines or an endocrinologist.  
(BPAC :<http://www.bpac.org.nz/magazine/2010/december/thyroid.asp>)

Stephen du Toit  
Chemical Pathologist  
Pathology Associates

John Woodford  
Charge Scientist  
Tel: 07 858 0795 ext. 7828

CLINICAL UPDATE



## Free T3 requesting and Oestradiol reporting

### Falsely elevated Free T3

We have noticed a number of isolated and elevated FT3 results. A mildly elevated FT3 is often seen in teenagers and adolescents and is probably "normal" in this age group. Isolated, elevated and unexplainable FT3 is sporadically seen in other patients. As best we can tell this doesn't seem to be related to the laboratory, assay used, or any interfering substance. Aside from very rare conditions, these results don't appear to be clinically relevant.

The conundrum of an isolated (and unexplainable) elevated FT3 is avoided by requesting FT3 only when indicated.

### **Pathlab strongly recommends following the BPAC guidelines:**

FT3 (and FT4) is automatically added by Pathlab when TSH is  $< 0.3$  mU/L.

FT4 is automatically added by Pathlab when TSH is  $> 4$  mU/L.

Do not request FT3 when monitoring T4 supplementation, request TSH only.

Do not request FT3 in asymptomatic patients.

FT3, FT4 and TSH is indicated when investigating suspected thyrotoxicosis, or during treatment of hyperthyroidism.

FT4 and TSH should be requested in patients with possible pituitary disease.

### Oestradiol reporting

After reviewing the performance of our Oestradiol method we have determined that the lower reportable limit should be raised to '200 pmol/L'. In future, we will report all results with a value less than 200 pmol/L as '<200 pmol/L'

Stephen du Toit  
Chemical Pathologist  
Pathology Associates

John Woodford  
Charge Scientist  
Tel: 07 858 0795 ext. 7828



## FT3 Requests and withdrawal of Red Cell Folate

### Free T3 (FT3) requests

While FT3 is the biologically active form of thyroid hormone, FT3 results are only informative in the setting of hyperthyroidism or thyrotoxicosis. Measuring FT3 in a euthyroid patient or when taking T4 is not helpful.

In fact we see patients with falsely high FT3 results, due to interference with the test method and this can lead to inappropriate, unnecessary and expensive further investigation.

**Therefore, from 1<sup>st</sup> July 2014** Pathlab will not be perform requests for FT3 but will re-add FT3 if TSH is low, as per BPAC guidelines. FT4 will also be added if TSH is either low or high. For the majority of patients, TSH is the most appropriate test to request.

The laboratory can be contacted if there is another indication for FT3 testing

### Withdrawal of Red Cell Folate

In theory, RBC-Folate is the ideal marker of folate status. Developing red blood cells take up folate via folate receptors but once red blood cells are released from the bone marrow there is no further uptake of folate. RBC-Folate is therefore not affected by recent folate intake.

Serum folate levels 'spike' for 1 – 3 hours after intake of folate supplementation but serum folate should not be measured in this setting. The increase in serum folate following food intake is thought to be less marked. Serum folate levels take 8 weeks to stabilise following modification of dietary intake, reflecting long term folate intake.

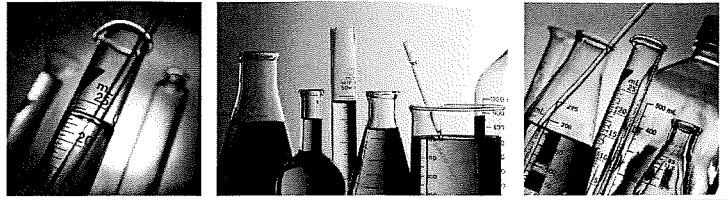
Measurement of red cell folate is complex, being affected by, for example Vitamin B12 status and polymorphisms in enzymes involved in folate metabolism. These and other factors limit the reliability of RBC-Folate results.

Available evidence suggests serum folate provides equivalent (perhaps better) information compared with RBC-Folate.

Following consultation with the local haematologist and with the approval from the CLCGG, it has been decided **to withdraw red cell folate measurement as from the 1st of July 2014.**

Stephen du Toit  
Chemical Pathologist

John Woodford  
Charge Scientist  
Tel: 07 858 0795 ext.7828



## Change to TFT Requesting

While TSH is the first line test in the majority of patients, there are settings when testing FT4 is indicated. In these settings (see below), it is best to request FT4 specifically and avoid any uncertainty associated with the term "TFT's".

Indications for requesting FT4:

- Central (pituitary disease) hypothyroidism
- Suspected non adherence with supplementation
- During first 2 months of treatment of hyper- or hypothyroidism
- Acutely unwell (only test if results are likely to alter management)
- Pregnancy

### From 10<sup>th</sup> August 2015

TSH and FT4 are performed when requested – this will not change.

FT3 testing – no change

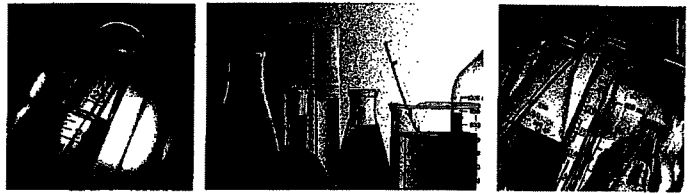
If "TFT's" are requested we will perform TSH only

If TSH is "abnormal" we will automatically add FT4 and FT3 as per BPAC guidelines.

If you have any queries or concerns to this change in our service please do not hesitate to contact me

Stephen du Toit  
Chemical Pathologist  
Pathology Associates

John Woodford  
Charge Scientist  
Tel: 07 858 0795 ext. 7828



# Changes In Thyroid Antibodies

The most common cause of thyroid dysfunction is autoimmune. Indeed, autoimmune thyroid disease is the most common autoimmune condition in our community. Thyroid related autoantibodies are useful in supporting autoimmune as the underlying mechanism, particularly where the cause of abnormal thyroid function tests is unclear.

In patients with hypothyroidism, in terms of specificity, anti-thyroid microsomal or peroxidase antibodies (anti- TPO) is the most helpful autoantibody to order when autoimmune (Hashimoto's) thyroiditis is suspected. However, like many autoantibodies, it can be detected in many patients' years before the onset of clinically overt hypothyroidism. Studies have shown that those with positive anti-TPO antibodies and normal thyroid function are at greater risk than the general population of developing hypothyroidism in the future.

Although commonly ordered, anti-thyroglobulin (Tg) antibodies are less specific for the diagnosis of autoimmune thyroid disease and can be found in a number of other conditions including thyroid carcinoma where its presence can be helpful in monitoring recurrence after thyroidectomy or radioactive thyroid ablation. Given the superior clinical utility of anti-thyroid microsomal (anti-TPO) antibodies, and bringing our testing in line with other local and national laboratories, when thyroid antibodies are ordered rather than performing both anti-TPO and anti-Tg antibodies, **Pathlab will perform anti-thyroid microsomal (anti-TPO) antibodies only. This will be introduced in early September 2016.**

The patient's sample will however be stored for a period of 1 month. If anti-Tg antibodies are thought to be clinically helpful for the diagnosis of a particular patient, this may be requested via the normal Test Add protocol – email [plw.testadd@pathlab.co.nz](mailto:plw.testadd@pathlab.co.nz) or fax 07 858 0879.

Anti-thyroglobulin antibodies will be routinely performed when thyroglobulin has been performed in patients with thyroid cancer as the antibody can interfere with the assay leading to falsely low results.

Tim Taylor  
Charge Scientist, Immunology  
Pathlab Waikato  
07 858 0795 ext. 6830

Dr Richard Steele  
Clinical Immunologist

CLINICAL UPDATE

# Variation to Agreement

between

# Waikato DHB

PO Box 934  
Waikato Mail Centre  
Hamilton 3240

Ph: 07-834 3646  
Fax: 07-839 4327

Contact: Ruth Rhodes

and

# Pathlab Waikato Limited

## Laboratory Agreement

PO Box 130  
Seventh Avenue  
Tauranga 3140  
Ph: 07-858 0799  
Fax:

Contact: Stephen May

RL  
*[Handwritten signature]*

## CONTENTS OF THIS AGREEMENT

<b>A:</b>	<b>SUMMARY</b>	<b>2</b>
<b>B:</b>	<b>PROVIDER SPECIFIC TERMS AND CONDITIONS</b>	<b>3</b>



# A: SUMMARY

**A1 Definitions**

- a. "we", "us", "our" means Waikato DHB
- b. "you", "your" means Pathlab Waikato Limited
- c. "either of us" means either we or you
- d. "both of us" means both we and you

**A2 The Agreement**

In 2008 both of us entered into a Health and Disability Services Agreement (the Agreement). The Agreement commenced on 1 July 2008 and ends on 30 June 2013 and is numbered (646463 / 325236/00).

**A3 Variation**

This is the 03 variation to the Agreement and modifies service details. This variation to the Agreement begins on 01 February 2012 and ends on 30 June 2015.

**A4 Section B**

The attached Section B includes all of the adjustments to this Agreement as a result of this variation.

**A5 Remainder of Agreement**

The remaining terms and conditions of the Agreement are confirmed in all respects except for the variations as set out in this document.


**A6 Signatures**

Please confirm your acceptance of the Agreement by signing where indicated below.

For **Waikato DHB:**

For **Pathlab Waikato Limited:**

 (signature)

 (signature)

Name Brett Paradine

Name Stephen John May

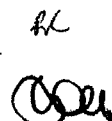
Position General Manager  
Planning & Funding

Position Director

Date Waikato DHB

Date 28.2.12

19/3/2012



# A: SUMMARY

## A1 Definitions

- a. "we", "us", "our" means Waikato DHB
- b. "you", "your" means Pathlab Waikato Limited
- c. "either of us" means either we or you
- d. "both of us" means both we and you

## A2 The Agreement

In 2008 both of us entered into a Health and Disability Services Agreement (the Agreement). The Agreement commenced on 1 July 2008 and ends on 30 June 2013 and is numbered (646463 / 325236/00).

## A3 Variation

This is the 03 variation to the Agreement and modifies service details. This variation to the Agreement begins on 01 February 2012 and ends on 30 June 2015.

## A4 Section B

The attached Section B includes all of the adjustments to this Agreement as a result of this variation.

## A5 Remainder of Agreement

The remaining terms and conditions of the Agreement are confirmed in all respects except for the variations as set out in this document.


## A6 Signatures

Please confirm your acceptance of the Agreement by signing where indicated below.

For **Waikato DHB:**

For **Pathlab Waikato Limited:**

 (signature)

 (signature)

Name Brett Paradine

Name Stephen John May

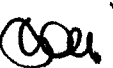
Position General Manager  
Planning & Funding

Position Director

Date Waikato DHB

Date 28.2.12

19/3/2012

RL  


## B: PROVIDER SPECIFIC TERMS AND CONDITIONS

### B1 It is agreed that the following details apply to this Variation

Legal Entity Name	Pathlab Waikato Limited
Legal Entity Number	646463
Agreement Number	325236 / 03
Variation Commencement Date	01 February 2012
Variation End Date	30 June 2015

### B2 Details of all purchase units which apply to this Variation

Purchase Unit (PU ID)
CS02002 Community Laboratory

### B3 Provider Specific Terms & Conditions

This variation has been agreed between us and is a variation to your Agreement number 328922/00 for the provision of Laboratory Tests

The variation relates to:

SECTION I: SCHEDULE TEST PURCHASE LIST

Start date of this variation is 1 February 2012

#### Variation to schedule test purchase list

We have both agreed that some individuals need to have the tests listed below repeated by a different method due to having either a haemoglobin variant (Hb1Ac) or in the case of some immunology tests (predominantly TSH T 4 and T 3 ) the presence of a heterophile antibody e.g. anti goat.

We have also agreed you are able to do these tests in your library. *Laboratory RR*

Accordingly this variation amends the test price schedule to allow you to **claim twice for the same tests on the same individual** in the circumstances detailed above only.

14 Schedule test purchase list

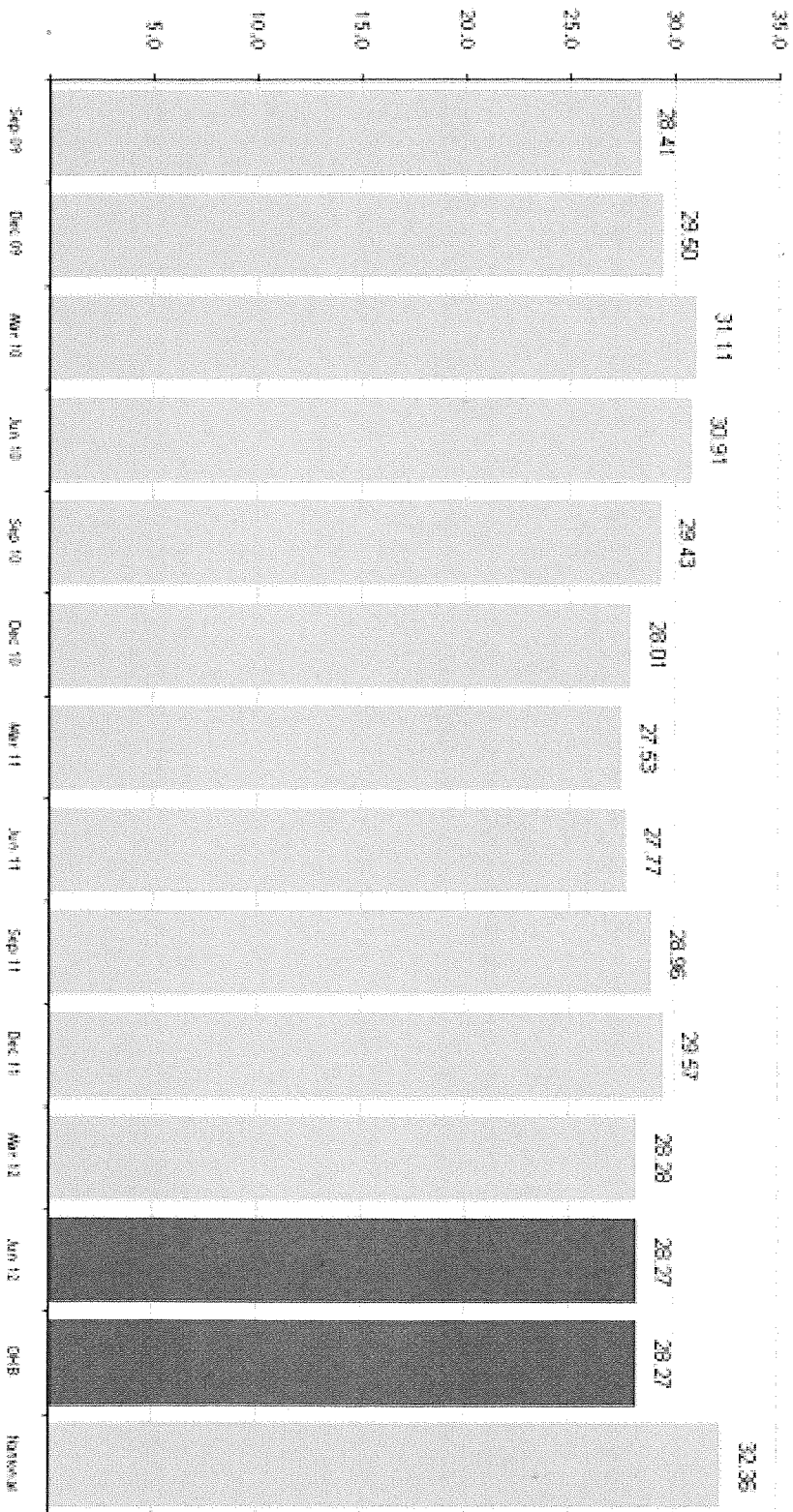
The amended list is as follows:

	<b>Test description</b>	<b>Maximum number</b>
BT2	Free thyroxin index or free T4	2
BT3	Serum free T3	2
BG2	Glycosylated haemoglobin (Hb1Ac )	2

All other term and conditions of your Agreement remain the same including the end date.

*RR*  
*RR*

No. of TSH / No. of FT4 (in ratio of X : 10)



According to the PHO Performance Programme report for the 12 months to 30-Sep-12 our DHB result was 30.13 : 10 With the programme goal being to be above 20 : 10. This means that approximately 3 times more TSH test were conducted than TS4 tests.

Also have this graph from last quarter's reports that show how Waikato DHB track going back a couple of years.

3 Sunrise Boulevard  
Tawa  
Wellington 5028

17th May 2017

Dear Ruth,

Thank you for your prompt reply and advice that Pathlab and Waikato Hospital Laboratory thyroid testing advice to referring medical practitioners reflecting BPAC recommendations.

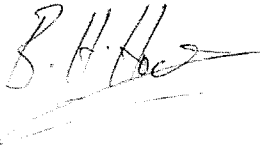
We sincerely appreciate that you have suggested that our letter be tabled for discussion at the next Waikato Clinical Laboratory Governance Group, a group which includes primary and secondary clinicians and pathologists from both your community laboratory services.

For a number of reasons it is important to our members that we meet in person with the Waikato DHB and Pathlab thyroid testing decision makers to talk through the issues in our letter, engage in dialogue about the content and work collaboratively towards a resolution. This is important for a number of reasons.

Please advise at what stage in the process we can do this.

Please note that if you want to forward a copy of this email and letter to Dianne McQueen at Pathlab and/or the others listed on your latest email; that is fine.

Kind Regards



Belinda Hodson  
Administrator &  
Member TANZI



Tracey Keen, Director TANZI



Jo Morris  
pp. Waikato Members of  
TANZI

25 Oram Avenue  
New Brighton  
Christchurch 8061

1st May 2017

To: Mark Spittal, Executive Director of Community & Clinical Support

On 7<sup>th</sup> April 2017 we wrote to you about the negative impact Pathlab's policies and procedures on thyroid testing are having on patients in the Waikato and Bay of Plenty regions. Pathlab's current policy on thyroid testing is based on clinical evidence that is outdated and inaccurate. Their policies and procedure reflect:

1. An **over-reliance** on the Thyroid Stimulating Test ('TSH Test' for short) to accurately measure thyroid function. The TSH test used on its own does not accurately detect the full range of thyroid patterns that occur across the thyroid patient population; nor how much Free T3 (the active thyroid hormone) is actively reaching patient's cells.

We have provided clinical evidence supporting this view e.g.

[http://www.medscape.com/viewarticle/870924?src=wnl\\_mdplsnews\\_161028\\_mscpedi\\_t\\_wir&uac=92500HJ&impID=1224287&faf=1](http://www.medscape.com/viewarticle/870924?src=wnl_mdplsnews_161028_mscpedi_t_wir&uac=92500HJ&impID=1224287&faf=1)

2. Pathlab's policy also reflects an **under-reliance** on other thyroid blood tests to accurately measure thyroid function; and a misunderstanding of the importance of these tests, in particular the Free T3 blood test.

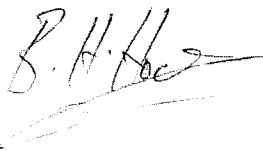
As a result, Pathlab are refusing in many circumstances to test patients Free T4, Free T3 (and in some instances thyroid antibodies), when these tests have been ordered by their doctor. This is leaving patients undiagnosed, mis-diagnosed and/or without an accurate measure of their Free T3 so their doctors can adjust treatment dose.

Since we wrote to you the situation for patients has deteriorated as an important test for determining whether or not a patient has Hashimotos thyroiditis called Thyroid antibodies – Anti-TG is being discontinued by Pathlab, announced on 6 March 2017 at:

<http://www.pathlab.co.nz/PicsHotel/PathLab/Brochure/Clinical%20Updates/2017/Nt-proBNP%20PTHrp%20anti%20Tg%20-%20Waikato%20DHB%20-%20April%2017.pdf>

We seek your help in resolving this issue via a fair and transparent process where our concerns as patients and the clinical evidence contained in our 7 April 2017 letter supporting our concerns are raised with Pathlab and discussed in a meaningful way. Can you please respond to the affirmative that you have received our letter and contact us to arrange a time and date to discuss the content. Contact: Belinda Hodson at: Phone: (027) 659-4450, [belinda.hodson@gmail.com](mailto:belinda.hodson@gmail.com).

Regards



Belinda Hodson  
Administrator &  
Member TANZI



Tracey Keen, Director TANZI



Jo Morris  
pp. Waikato Members of  
TANZI

## Memorandum

To: Clinical Directors  
From: Stephen du Toit, Chemical Pathologist & Clinical Director Laboratory  
Date: 6 March 2017

---

**SUBJECT:** Restriction of testing

---

### **Thyroid antibodies – Anti-TG will be discontinued**

Currently Anti-TPO and anti-TG (Thyroglobulin) antibodies are performed by WDHB when thyroid antibodies are requested. When the Anti-TG reagent runs out, (estimated in 2 - 3 weeks time) WDHB will discontinue anti-TG antibodies.

Anti-TPO antibodies offer better performance than anti-TG antibodies. The only indication for measuring anti-TG antibodies is to check for assay interference when Thyroglobulin is measured. Thyroglobulin is mainly used as a tumour marker in the follow-up of patients with thyroid cancer. A specific assay (Roche), validated for TG measurement is required. Results from other Anti-TG assays differ dramatically and can cause confusion with interpretation of the TG result. Pathlab has already discontinued anti-TG antibodies.

### **PTHrp**

Secretion of PTHrp is the commonest cause of tumour related hypercalcaemia. Survival times in these patients are short, often less than 2 months. Other causes of hypercalcaemia in malignancy include osteolytic metastasis, unregulated production of 1.25 OH Vitamin D and very rarely ectopic PTH production.

PTHrp may be helpful in patients with unexplained hypercalcaemia and a low/suppressed PTH but without obvious evidence of malignancy. Testing is not indicated if malignancy is present. The turnaround time for PTHrp is up to 4 months. Samples need to be collected in special tubes and require specific sample handling by the laboratory.

PTHrp will only be performed when pre-approved by a chemical pathologist and samples will only be processed during office hours.

### **BNP (NT-proBNP)**

NT-pro BNP is a useful but expensive test, results < 35 pmol/L rule out heart failure. There are many causes of an elevated BNP. Follow-up within 2 weeks is rarely indicated.

Samples collected within 48 hours of a previous reported result will not be processed to avoid unnecessary duplication of requests. When testing is declined, a comment is added with instructions for contacting the laboratory to organise testing if testing is indicated.

Kind regards,














Stephen du Toit


# Community Laboratory Services Clinical Governance Group

Friday 2 June 2017  
8.00 – 10.00 am  
Pathlab Boardroom (cnr Tristram & Thackeray St.)

## AGENDA

Item	Topic	Presenter
1	Welcome	
2	Apologies – Ross Lawrenson, Julie Wilson, Kate Yeo	
3	Approval of minutes from 7 April 2016 meeting	 Minutes 070417.docx
4	Correspondence	
5	<b>Matters Arising</b> 5.1 Action points 5.2 Indici – update on developments 5.3 Pertussis – confirmation of decision <div style="text-align: center;">             Pertussis diagnosis            pCR vs culture - quer         </div> 5.4 Nurse initiated testing – further discussion <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;">             POLICY Registered            Nurse management o         </div> <div style="text-align: center;">             CLCGG Guideline for            RN management of la         </div> <div style="text-align: center;">             CLCGG RN            laboratory policy - cla         </div> </div>	Various  Claudio Turilli  Ruth Rhodes   Kate Yeo
	<b>Other Business</b> 6.1 Skin Prick Testing – referral pathway – <b>For discussion</b> <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;">             Consultation on            Referral Pathway for         </div> <div style="text-align: center;">             Response - Damian            Tomic.msg         </div> <div style="text-align: center;">             Response - Stephen            May.msg         </div> <div style="text-align: center;">             Update - Michael            Addidle.msg         </div> </div> 6.2 Thyroid testing – <b>For discussion</b> <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;">             2017-05-03 Letter            from TANZi re discont         </div> <div style="text-align: center;">             2017-05-30 Letter            from TANZI - respons         </div> </div> 6.3 Nurse-initiated testing at Tokoroa – <b>For discussion</b>	Claudio Turilli      Claudio Turilli / Ruth Rhodes   Stephen du Toit



	 <p>Nurse initiated testing at Tokoroa - L</p> <p>6.4 Changes in CLCGG membership</p>	Stephen du Toit
	<b>Date/time for next meeting:</b> Friday 4 Aug 2017; 8-10 am; Pathlab Boardroom	



11 October 2017

Jo Morris  
8 Bay View Road  
Raglan 3225  
Email: [morrisij1@xtra.co.nz](mailto:morrisij1@xtra.co.nz)

Dear Jo

**RE: Official Information Request**

In response to your request under the Official Information Act to provide you with the following information in respect to the Waikato District Health Board:

- 1. Can you tell me if there have been any amendments made to the contract or the Schedule Test Purchase List since it was first signed? If so can I please have copies of the changes made and how should the table read now, also - why was it changed and what supporting data was used to support the changes?***

There have been a number of changes to the original contract.

Please find as requested the copies of variations and provider specific terms and conditions (PTSC) to the contract. These have been downloaded from the agreement and are attached as Appendix One. Some variations have come about because of national changes such as the Vulnerable Children's Act. We have included all PSTC related to recommendations of best use of tests from the Waikato Community Clinical Laboratory Group.

For your convenience the changes are summarised briefly. The rationale is detailed in the copies of the PSTC the Pathlab Agreement (other than the standard national amendments are):

- Amended the agreement to ensure delivery of community scheduled tests in a site in Huntly East
- Extended the term until 2015 and added tests previously done by Medlab to the test purchase list
- In 2012 we varied the schedule test purchase list for thyroxin tests, Lead Maternity Carers referrals and changed D 70 from Chlamydia PCR/LCR to Chlamydia/ Gonorrhoea PCR/LCR. All details in Appendix One
- In 2013 we varied the test purchase List to replace guaiac (FOB) tests with anti-human haemoglobin Faecal Immunochemical test (FIT)
- In 2014 we added named Physicians Assistants to the list of referrers claims to be processed and incorporated the Vulnerable Children Act
- In 2016 Clinical pharmacists with prescribing rights were added to referrer's column in the Test Purchase list
- In 2017 HPY H. Pylori serology replaced with HPY: H. Pylori antigen.

2. *The blood tests table – particularly page 43 of the attached contract – table/columns. And page 41 (c). ‘The maximum number of tests is listed in column 4’. (in the contract the information is actually in column 3). If you look at the part table attached (pdf) you will see that the 1st column references and the 2nd column descriptions do not line up. (circled in blue).*

*As line BT1 should read: Thyroid stimulating hormone, serum TSH*

*Line BT2 should read: Free thyroxine index or free T4\**

*Line BT3 should read: Serum free T3\**

*The reason for highlighting this is; when free T3 tests are ordered, Pathlab are refusing to do the test if the TSH is ‘normal’ even when the Dr specifically requests these tests (for reasons that only the Dr need know), yet Pathlab are over-riding the Dr and the patient history which Pathlab know nothing about, the response from Pathlab is that the Dr can phone and ask to do the free T3 test – but this is usually after the patient has attended the lab and days after the results are received before they realise it was omitted and quite inconvenient. Pathlab are also charging patients for the free T3 test if they return, when it is clearly funded. (could it be they are reading their own contract incorrectly – due to the table needing border adjustments?).*

Noted as a formatting error and addressed. The reason for Pathlab refusing further tests if the TSH is normal is outlined in the variation and was recommended by the clinical group reviewing best tests.

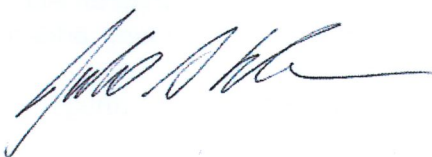
3. *Also with regard to Pathlab having the contract renewed without tendering - how are they able to have the contract renewed without it being tendered – when clearly they are cutting and pasting the same percentage results from previous years ‘success’ in the WDHB annual reports?*

Waikato DHB’s annual reports represent accurate reporting from all providers backed up by data analysis. KPIs are reported quarterly by Pathlab and are consistently monitored. Pathlab has always achieved higher than 98% on a turnaround time of all standard tests in less than 48 hours. From September 2012, Pathlab has consistently achieved a 100% on this KPI.

The Waikato DHB board accepted recommendations of extension to the contract with Pathlab, as the provider has consistently met all contractual requirements including quality, turnaround times, KPIs financial reporting, service delivery and audit processes. Pathlab has given the people of Waikato sustainable, community laboratory service with collection sites within easy reach of almost all general practice and excellent clinical and scientific services. The current extension was for five years from 2014 to 2019.

I trust this is of assistance and answers the requests under your query.

Yours sincerely



**Julie Wilson**  
**EXECUTIVE DIRECTOR, STRATEGY AND FUNDING**