



**THAMES AUDIT GROUP: Audit of Macroanalytes**

**March 2020**

**Part 1: About Your Laboratory**

Name of your laboratory: [Click here to enter text.](#)

- a. Teaching hospital
- b. DGH
- c. Specialist
- d. Other

Network status:

- a. Part of a network
- b. Not part of a network

If (a), please confirm whether your answers are on behalf of:

- a. Your site only
- b. All sites within network/organisation

If (b), please specify number and type of sites: [Click here to enter text.](#)

**Part 2: Feedback from Audit of Externally Referred Tests November 2019**

Did your laboratory participate in the audit on tumour markers service provision?

Yes  No

Did you implement any changes in practice following this audit?

Yes  No

If yes, please specify: [Click here to enter text.](#)

**Part 3: Macroprolactin** *\_(Please skip the section if not relevant)*

**Please attach protocol, if happy to share. [Click here to enter text.](#)**

**[Section A: Requesting]**

1. Does your laboratory perform macroprolactin screens or does your laboratory refer macroprolactin to an external laboratory?

[Click here to enter text.](#)

- a) Macroprolactin screen performed in house [Click here to enter text.](#)
- b) Macroprolactin screen referred to another lab [Click here to enter text.](#)

2. Estimated workload each year

- a) For total prolactin [Click here to enter text.](#)
- b) For macroprolactin screen [Click here to enter text.](#)

3. How are macroprolactin screens requested?

- a) Requested by user
- b) Reflexed by LIMS
- c) Reflexed by BMS
- d) Reflexed by Clinical Scientist
- e) Other (please state)  [Click here to enter text.](#)

4. Criteria for requesting/reflexing a macroprolactin screen (e.g. ? based on clinical presentation or prolactin results)

Please give details: [Click here to enter text.](#)

5. Frequency of requesting: If there was a previous macroprolactin result available, how many years apart would warrant a repeat for a previous negative macroprolactin?

[Click here to enter text.](#)

6. Do you repeat a macroprolactin screen in patients with macroprolactin (i.e. low recovery on a previous sample)? [Click here to enter text.](#)

7. Case study:

Date of sample	Today	10.2019	02.2019	10.2018	02.2018
Prolactin	1900 mU/L	450 mU/L	400 mU/L	1700 mU/L	1900 mU/L
Macroprolactin recovery					70%

Would you add a macroprolactin screen? [Click here to enter text.](#)

Are there any other factors you would consider when making this decision?

[Click here to enter text.](#)

**[Section B: Operation and Analysis]**

1. Which platform/analytical method is in use for a prolactin measurement?

[Click here to enter text.](#)

2. What is the reporting unit for prolactin?

[Click here to enter text.](#)

3. What is your assay's susceptibility to the hook effect? ( i.e. assay analytical range and any dilution protocol to extend the analytical range)

[Click here to enter text.](#)

4. What is the target turn-around time for prolactin measurement? What is the target turn-around time for the macroprolactin screen?

[Click here to enter text.](#)

5. How frequent is the macroprolactin screen run?

- As required through the day
- Daily in batch
- Weekly in batch, please state frequency [Click here to enter text.](#)
- Others, please state details [Click here to enter text.](#)

6. What is the target turn-around time for the macroprolactin screen?

[Click here to enter text.](#)

7. Assay protocol

- a) Are you using a precipitation method?

- If yes, please fill in if relevant

Minimum sample volume required	
Desired sample type	
A brief description of the precipitation method (including volume of samples/PEG solution, vortex time, incubation time, speed (in g) and length of centrifugation etc ).	<a href="#">Click here to enter text.</a>
Are you running each patient sample in singlet or duplicate? If run in duplicates, how is it reported and what is the acceptance criteria?	<a href="#">Click here to enter text.</a>

- If no, please provide details for the alternative method: [Click here to enter text.](#)

b) Source of the protocol if known: [Click here to enter text.](#)

If the original assay protocol has been modified, has verification been completed? : [Click here to enter text.](#)

c) Polyethylene glycol (PEG) solution

- What percentage of PEG is in use? What is the full name of the PEG (e.g. PEG2000)

[Click here to enter text.](#)

- Are you using deionised water or diluent buffer to make up the PEG solution? (Please specify the manufacturer, scientific name of the buffer and composition of the diluent if known)?

[Click here to enter text.](#)

- What are the storage conditions for PEG, how stable is the working PEG solution and has any verification been completed? (e.g. kept in Fridge or Room temperature)

[Click here to enter text.](#)

- If PEG solution is stored in the fridge, is it allowed to return to room temperature before use? Please include any detailed instructions if any.

[Click here to enter text.](#)

d) Case study: what would the lab do where the original prolactin result is above the upper limit of assay range on a neat sample (e.g. a prolactin of 5000). Are samples diluted prior to macroprolactin screen or post PEG treatment?

[Click here to enter text.](#)

8. Analysis of the results

a) Formula in use for calculating macroprolactin recovery and for bioactive monomeric prolactin (BMP).

[Click here to enter text.](#)

b) What is the assay acceptance criteria?

[Click here to enter text.](#)

c) Are calculations for % recovery and BMP done manually or automatically?

Please give details [Click here to enter text.](#)

d) Are calculations double checked by a second person?

Please give details [Click here to enter text.](#)



9. If the final results are manually entered into your LIMS, is there a transcription check?

- Yes by whom? [Click here to enter text.](#)
- NO
- N/A

10. What IQCs are in use for the macroprolactin screen?

- a) Known patient samples  please give details [Click here to enter text.](#)
- b) Commercial QC  please give details of the product and how target QC range is derived [Click here to enter text.](#)
- c) Other  please give details [Click here to enter text.](#)

11. Have you registered with an EQA scheme for macroprolactin or do you have other arrangements in place for external quality control?

- Yes Please give details [Click here to enter text.](#)
- No How do you justify the quality control of this test? [Click here to enter text.](#)

12. Is macroprolactin in scope for UKAS?

[Click here to enter text.](#)

**[Section C: Interpretation and Reporting]**

1. What results are reported?

	Cut-off range of % recovery	Results being reported			
		Total Prolactin	Macroprolactin Recovery	Monomeric Prolactin	Others, please specify
When negative for macroprolactin	Click here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
When positive for macroprolactin	Click here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
If relevant, When equivocal for macroprolactin	Click here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Click here to enter text.
Note	What is the literature reference for the % cut-off in use, if known? Click here to enter text.				

2. What are the reporting reference ranges in use?

	Female	Male
Total prolactin	Click here to enter text.	Click here to enter text.
Monomeric prolactin	Click here to enter text.	Click here to enter text.
Note:	What is the literature reference for the reference range in use, if known? Click here to enter text.	

3. In the specified scenarios below, in your routine practice, would you report the macroprolactin results with a comment? What comment would be provided and by whom is the comment written?

When Negative for Macroprolactin Screen	
a) New patients with a prolactin concentration greater than the gender specific decision cut off.	Click here to enter text.
b) Is the comment the same if the prolactin is significantly raised?	<input type="checkbox"/> Yes <input type="checkbox"/> No      what comment is given? What is the cut-off in use to define a significant raise in total prolactin Click here to enter text.
When Positive for Macroprolactin Screen	
c) New patients with a monomeric prolactin concentration less than the gender specific decision cut off.	Click here to enter text.
d) New patients with a monomeric prolactin concentration greater than the gender specific decision cut off.	Click here to enter text.

4. Would you hold back a total prolactin result until the macroprolactin result is available before reporting? How about for new patients with a significantly raised prolactin? What is the cut-off when you would phone the clinician?

Click here to enter text.

5. Have samples ever been sent to a referral lab for confirmation? And by which method? Were there any false positives being detected and any potential causes identified?

Please give details    Click here to enter text.

6. Case study: a sample from a 16 y/o girl whose prolactin was initially about 1500 mu/L with only about 15% recovery after PEG. Her monomeric prolactin was within the reference range



for your local assay. The clinical details given were Galactorrhoea. What would you do? (?  
Reporting results without any further comment or reflex further testing)

[Click here to enter text.](#)

7. Do you have Trust guidelines available for the investigation of raised prolactin, in particular to rule out drug effects?

[Click here to enter text.](#)

Please attach if happy to share.

**Part 4: Macroamylase**

*\_(Please skip the section if not relevant)\_*

**Please attach protocol, if happy to share. [Click here to enter text.](#)**

1. Which platform/analytical method is in use for the amylase measurement?

[Click here to enter text.](#)

2. Is macroamylase in your test repertoire? if yes, please include your criteria for doing the test.

Please give details [Click here to enter text.](#)

3. Estimated workload of macroamylase each year or how many cases have there been in the past? [Click here to enter text.](#)

4. If macroamylase is not offered, what other protocol do you have for the investigation of an unexpected raised amylase (e.g. urine amylase, lipase, electrophoresis).

[Click here to enter text.](#)

5. **Does your laboratory**

- perform macroamylase screens

please give details of the testing method and procedure

[Click here to enter text.](#)

OR

- refer macroamylase to an external laboratory

which referral centre and which method is used? (Skip question 6-7)

[Click here to enter text.](#)

6. How is the quality of the macroamylase assay ensured? (i.e. IQC/EQA consideration).

[Click here to enter text.](#)

7. Is macro-amylase in scope for UKAS?

[Click here to enter text.](#)

8. Reporting of the results: i.e. what is the cut-off % in use for positive macroamylase and how is it reported? If it is a send-away test, how do you report? Are there any additional comments being added?



[Click here to enter text.](#)

9. Have samples ever been sent to a referral lab for confirmation? And by which method?

Any suggestion to clinical follow-up of the patients and good cases to share?

[Click here to enter text.](#)

10. If you have an interesting case of macroamylase,

a) Can you provide a brief description of the case?

[Click here to enter text.](#)

b) Would you be willing to present at the next TAG meeting? [Click here to enter text.](#)

**Part 5: Macro-troponin**

*\_(Please skip the section if not relevant)*

**Please attach protocol, if happy to share. [Click here to enter text.](#)**

1. Which platform/analytical method is in use for the troponin measurement?

[Click here to enter text.](#)

2. Is macro-troponin in your test repertoire? if yes, please include your criteria for doing the test.

Please give details [Click here to enter text.](#)

3. Estimated workload of macro-troponin each year or how many cases have there been in the past? [Click here to enter text.](#)

4. If macro-troponin is not offered, what other protocol do you have for the investigation of an unexpected raised troponin?

**[Click here to enter text.](#)**

5. **Does your laboratory**

perform macro-troponin screens

please give details of the testing method and procedure

[Click here to enter text.](#)

OR

refer macro-troponin to an external laboratory

which referral centre and which method is used? (Skip question 6-7)

[Click here to enter text.](#)

6. How is the quality of the macro-troponin assay ensured? (i.e. IQC/EQA consideration).

[Click here to enter text.](#)

7. Is macro-troponin in scope for UKAS? Or is it just for in house use?

[Click here to enter text.](#)

8. Reporting of the results: i.e. what is the cut-off % in use for positive macrotroponin and how is it reported? If it is a send-away test, how do you report? Are there any additional comments being added?

[Click here to enter text.](#)

9. Have samples ever been sent to a referral lab for confirmation? And by which method? Any suggestion to clinical follow-up of the patients and good cases to share?

[Click here to enter text.](#)

10. If you have an interesting case of macro-troponin,  
c) Can you provide a brief description of the case?

[Click here to enter text.](#)

- d) Would you be willing to present at the next TAG meeting? [Click here to enter text.](#)

Part 6: Macro-TSH

*(Please skip the section if not relevant)*

**Please attach protocol, if happy to share. [Click here to enter text.](#)**

1. Which platform/analytical method is in use for the TSH measurement?

[Click here to enter text.](#)

2. Is macro-TSH in your test repertoire? if yes, please include your criteria for doing the test.

Please give details [Click here to enter text.](#)

3. Estimated workload of macro-TSH each year or how many cases have there been in the past? [Click here to enter text.](#)

4. If macro-TSH is not offered, what other protocol do you have for the investigation of an unexpected raised TSH?

[Click here to enter text.](#)

5. **Does your laboratory**

perform macro-TSH screens

please give details of the testing method and procedure

[Click here to enter text.](#)

OR

refer macro-TSH to an external laboratory

which referral centre and which method is used? (Skip question 6-7)

[Click here to enter text.](#)

6. How the quality of the assay is ensured? (i.e. IQC/EQA consideration).

[Click here to enter text.](#)

7. Is macro-TSH in scope for UKAS?

[Click here to enter text.](#)

8. Reporting of the results: i.e. what is the cut-off % in use for positive macro-TSH and how is it reported? If it is a send-away test, how do you report? Are there any additional comments being added?

[Click here to enter text.](#)

9. Have samples ever been sent to a referral lab for confirmation? And by which method? Any suggestion to clinical follow-up of the patients?

[Click here to enter text.](#)

10. If you have an interesting case of macro-TSH,

- a) Can you provide a brief description of the case?

[Click here to enter text.](#)

- b) Would you be willing to present at the next TAG meeting? [Click here to enter text.](#)

**Part 7: Other Macroanalytes**

*\_(Please skip the section if not relevant)\_*

Are there any other macroanalytes testing available in your trust?

Please give details of

- 1) Criteria for testing
- 2) Does your laboratory perform the screens or does your laboratory refer the tests to an external laboratory?
- 3) Workload
- 4) Method for testing and details of procedure
- 5) Quality control (IQC/EQA)
- 6) Is it on scope for UKAS?
- 7) Reporting and interpretation of the results
- 8) If you have a case of other macroanalytes which are not listed in this questionnaire, can you give a brief description of the case and would you be willing to present at the next TAG meeting?

**Many thanks for completing this questionnaire. Please send completed questionnaires to Danni Fan ([danni.fan@nhs.net](mailto:danni.fan@nhs.net)) by 30<sup>th</sup>May2020**