



RCPA HAEMATOLOGY QAP PARTICIPANT HANDBOOK 2012



NATA Accredited Proficiency Testing Scheme Provider Number: 14863

This facility is accredited by the National Association of Testing Authorities Australia, and complies with the requirements of ILAC G13. **Site Number 15363**

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1 WELCOME

Welcome to the 2012 RCPA Haematology Quality Assurance Program. Your enrolment package should include the following items:

- **2012 samples** for the following Programs – in which your institution has enrolled;-
 - Haemostasis
 - Additional Factors
 - Haemoglobinopathy
 - D-Dimer
 - G-6-PD
 - POC-INR

All other samples will be sent throughout the year.

- **RESULT SHEET AND FORMS MASTER BOOKLET** – this booklet contains ALL result sheets for all General Haematology and POC-INR Programs. The Instructions for Participants for each of these Programs are included on the reverse of the result sheet. Further specific information will be included on the insert sent with each survey. This booklet also includes forms commonly used by participants:-
 - HQF 232 Notification of Contact information change
 - HQF 231 Notification of Instrument or Reagent change
 - HQF 18 Participant Concerns / Feedback
 - HQF 150 Request for Additional Sample/Result Amendment/Report Reprints

At the back of this Booklet is a Program Schedule and Sign off sheet which replaces the previous Declaration Form.

- **2012 RCPA HAEMATOLOGY QAP PROGRAM PLANNER**
- **2012 DESCRIPTION AND DIAGNOSIS CODES – Morphology, Malaria, Haemoglobinopathy**
- **NEW PARTICIPANTS** also receive the following:
 - Online Data Entry Instructions
 - Data Analysis and Report Style Information Booklet
 - Interim and End-of-Cycle Report Interpretation Booklet
- Special Haemostasis result sheets are undergoing review and will be sent separately prior to the first survey of 2012.
- CD34, Oncology Immunophenotyping, PNH and Molecular Diagnostics result sheets are sent with each dispatch.

If you have not received any of these items please contact the Haematology QAP.

ABOUT THE RCPA QUALITY ASSURANCE PROGRAMS PTY LTD

Enrolments and accounts are centralised with the Enrolment Office [(+612) 9045 6010, enrolment@rcpaqap.com.au] located in Sydney, NSW. Each program has a Program Chairperson who works in conjunction with the QA Program and the RCPA QAP Pty Ltd Board of Directors. The RCPA Haematology QAP is located at 1/1B Kleins Road, Northmead 2152, NSW.

The RCPA Haematology QAP is accredited to ILAC Guide 13: 2007 *Guidelines for the Requirements for the Competence for Providers of Proficiency Testing Schemes*, which is based on ISO Guide 43-1: 1997 and the relevant elements of ISO/IEC 17025: 2005, ISO 15189: 2003 and ISO 9000: 2005.

Accreditation by a third party is a basis for demonstrating competence as a provider of proficiency testing schemes. Accreditation provides a guarantee and assurance to participants of the standard and quality of services provided by the proficiency testing program.

2 SURVEY DISTRIBUTION AND DATES 2012 - GENERAL

Following survey dispatch all closing dates are fixed. Laboratories are responsible for the return of all survey results either by post, facsimile or direct data entry via the Haematology QAP website. Wherever possible additional time has been allocated to allow for public holidays.

GENERAL HAEMATOLOGY PROGRAM

SURVEY	DATE POSTED	RESULTS DUE
JANUARY	09.01.2012	24.01.2012
FEBRUARY	30.01.2012	15.02.2012
MARCH	27.02.2012	13.03.2012
APRIL	02.04.2012	19.04.2012
MAY	07.05.2012	23.05.2012
JUNE	04.06.2012	19.06.2012
JULY	02.07.2012	18.07.2012
AUGUST	06.08.2012	21.08.2012
SEPTEMBER	03.09.2012	18.09.2012
OCTOBER	08.10.2012	HAA (28 – 31/10) 24.10.2012
NOVEMBER	05.11.2012	20.11.2012
DECEMBER	26.11.2012	11.12.2012

Program	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
FBC	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Haemostasis	Y	Y		Y	Y		Y	Y		Y	Y	
Additional Factors	Y		Y		Y		Y		Y		Y	
D-Dimer		Y			Y			Y			Y	
Haemoglobinopathy			Y		Y			Y		Y		
Morphology		Y			Y		Y			Y		
Differential	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
G6PD				Y						Y		
Auto Differential			Y			Y		Y			Y	
Malarial Parasite				Y							Y	
ESR		Y				Y			Y			Y
Reticulocytes		Y				Y			Y			Y

POINT OF CARE - INR

SURVEY	OPENING DATE	RESULTS DUE
FEBRUARY	30.01.2012	15.02.2012
APRIL	02.04.2012	19.04.2012
JUNE	04.06.2012	19.06.2012
AUGUST	06.08.2012	21.08.2012
OCTOBER	08.10.2012	24.10.2012

ONCOLOGY IMMUNOPHENOTYPING - MODULE 1

SURVEY	DATE POSTED	RESULTS DUE
FEBRUARY	30.01.2012	15.02.2012
MAY	07.05.2012	23.05.2012
AUGUST	06.08.2012	21.08.2012
OCTOBER	08.10.2012	24.10.2012

MOLECULAR DIAGNOSTICS

SURVEY	DATE POSTED	RESULTS DUE
FEBRUARY	30.01.2012	27.02.2012
APRIL	02.04.2012	30.04.2012
JUNE	04.06.2012	02.07.2012
AUGUST	06.08.2012	03.09.2012
OCTOBER	08.10.2012	05.11.2012

SPECIAL HAEMOSTASIS: MODULES A, B, C, D & E

SURVEY	DATE POSTED	RESULTS DUE
MARCH	27.02.2012	26.03.2012
AUGUST	06.08.2012	03.09.2012

CD34+

SURVEY	DATE POSTED	RESULTS DUE
FEBRUARY	13.02.2012	27.02.2012
JULY	18.06.2012	02.07.2012
OCTOBER	17.09.2012	01.10.2012

NOTE: If the survey parcel has not been delivered within one week of the dispatch date please contact the Haematology QAP.

Survey dispatch notification and information is also available on the Haematology QAP website homepage <http://www.rcpaqap.com.au/haematology/> under the "Latest News" section.

These dates are subject to change should there be difficulty in obtaining sample material or sample preparation. They are intended as a guide only. The October Survey of the General Haematology Program is planned to coincide with the HAA meeting.

RCPA/AIMS MORPHOLOGY WORKSHOPS

**Dates for 2012 workshops – 11th & 12th May
3rd & 4th August**

A Malarial Parasite Workshop to be held in conjunction with the Morphology Workshop is being considered and further information will be forthcoming. The application forms for the RCPA/AIMS Morphology Workshops will be posted onto the RCPA Haematology website. Participants will be notified once they are available.

4 PARTICIPATION

Laboratories participating in the Haematology QAP receive specimens to test and report their results back to the Haematology QAP. Participants receive notification from the Haematology QAP of the accuracy of their results after all participants' results have been evaluated.

Participants should test specimens in the same manner as patients' specimens.

- The specimens should be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.
- The participant should test specimens the same number of times that patient samples are routinely tested.
- Participants that perform tests on proficiency testing specimens should not engage in any inter-laboratory communications pertaining to the results of proficiency testing specimen(s) until after the due date for return of survey results to the Haematology QAP.
- Participants with multiple testing sites or separate locations should not participate in any communications or discussions across sites/locations concerning proficiency testing specimen results until after the closing date for the survey.
- The participant should not send proficiency testing specimens or portions of specimens to another laboratory for any analysis that it is accredited to perform in its own laboratory.
- The participant should maintain a copy of all records, including a copy of the completed result sheets, to record proficiency testing results.
- The Program Schedule and Sign off sheet included in the Results Sheet and Forms Master booklet (separate booklets for Specialised Programs) should be signed indicating samples were appropriately processed and results returned. The second sign-off indicates the report was reviewed, results discussed and action taken (if appropriate). This documentation should be kept for a minimum of three years from the date of the proficiency testing event.

5 CONTACT DETAILS

It is the responsibility of each participant to ensure that contact details held by the Haematology QAP are up-to-date. The Haematology QAP cannot take responsibility if specimens or reports are addressed to an individual or an address that is no longer relevant, if there has been no notification of the change. To ensure there is no breach of confidentiality or malicious tampering with database information the Haematology QAP must be able to authenticate the source of any request for change. For that reason we request the previous contact name (as would be stored in our database) as a security check.

The Haematology QAP labels specimen boxes and reports clearly in order to avoid non-delivery or delays in delivery. All participants should check the dispatch dates, provided in this handbook or available online so that they can plan their work flow.

ONLINE DATA ENTRY

The Haematology QAP is unable to change the email information linked to the online data entry system. If the email address for a ODE user changes they must re-register for ODE and request the deletion of their previous account. To ensure there is no breach of confidentiality or malicious tampering with result entry an organisation should notify the Haematology QAP if a staff member with ODE privileges leaves your organisation. Their username will be deleted from the system and they will have no further access to their account.

6 PACKAGING

Specimens are transported at ambient temperature in packaging appropriate for 'Exempt Human Specimens'. Suitably stable material for the Haemostasis, Additional Factors, Haemoglobinopathy, D-Dimer, POC-INR and G-6-PD Programs are sent in a bulk shipment upon enrolment. Vials are packed into Program specific, clearly labelled boxes which contain all samples for the survey year. FBC, Manual Differential, Automated Differential, Morphology, Malaria, ESR and Reticulocyte Program samples will be sent separately in the survey month.

7 PRICING

Prices for participation are listed on the Enrolment Forms included with the 'RCPA QAP Enrolment Book 2012' – available from the RCPA Quality Assurance Programs Pty Limited Enrolment Office - enrolment@rcpaqap.com.au.

8 CONFIDENTIALITY

Participants are given a Participant Number and are always referred to by that number. At no time and under no circumstances is the identity of a participating laboratory revealed. Report reviewers who assess results and provide comments/discussions and an educational component for each report are unaware of the identity of the participants and also sign a confidentiality agreement with the RCPA Haematology QAP.

9 CERTIFICATE OF ENROLMENT

Certificates of Enrolment will be sent by the RCPA Enrolment Office and not the Haematology QAP, once enrolment fees have been received. Please contact Allan Chapman on Ph (+ 61 2) 9045 6010 or enrolment@rcpaqap.com.au if you have finalised your account but have not received your Certificate.

10 CERTIFICATE OF PARTICIPATION

Certificates of Participation will be mailed to participating laboratories at the end of each program cycle. This will be at the end of the year for all programs except the Full Blood Count Program, which has 2 cycles per year.

11 HAEMATOLOGY QAP SAMPLES

Various aspects of the proficiency test scheme may from time to time be subcontracted. When subcontracting occurs it is placed with a competent subcontractor and the Haematology QAP is responsible to participants for the subcontractor's work.

The Haematology QAP prepares some test material in-house and uses both blood and blood products. These supplies may be sourced from the Australian Red Cross Blood Service (ARCBS), patient donors, spare patient samples or commercial companies.

- The Full Blood Count, Automated Differential and ESR Option 2 test material is purchased from R&D Systems and is supplied by Vital Diagnostics in Australia.
- The ESR Option 1, Reticulocyte and CD34+ samples are purchased from STRECK Laboratories Inc. and are supplied by Diagnostic Solutions in Australia.
- The Haemostasis and Additional Factors samples are purchased and supplied by Diagnostica Stago.
- The D-Dimer (Option 1) samples are purchased from Bio-Rad Laboratories.
- The G-6-PD samples are purchased from Dialab, supplied by Banksia Scientific in Australia.
- Haemoglobinopathy samples may be made in-house or purchased from Canterbury Scientific in New Zealand.

The supply of some samples may be subcontracted to laboratories involved in the relevant testing and who have a ready source of the material. The subcontracted laboratories ensure the material is non-infectious (relative to current testing protocols) and is suitable for assessing the performance of participating laboratories.

- Malaria slides are obtained from Royal Brisbane Women's Hospital QLD, ICPMR Westmead Hospital NSW or other donating institutions and are supplied as Virtual images of thick and thin films.
- Oncology Immunophenotyping samples are supplied by ICPMR Westmead Hospital NSW
- Molecular Diagnostics samples are supplied by ICPMR Westmead Hospital NSW, Monash Medical Centre VIC and PathWest WA.
- Special Haemostasis modules are lyophilised samples and are prepared in-house in accordance with Haematology QAP Laboratory Methods.
- Blood or plasma that is donated for the preparation of Haematology QAP specimens has to be tested and cleared for HIV, Hepatitis B and C.

12 HOMOGENEITY AND STABILITY

The Haematology QAP subcontracts homogeneity and stability testing on representative, randomly selected specimens from every batch to ensure their integrity before they are issued to participants. This testing is performed by NATA accredited testing laboratories.

FBC samples are tested at room temperature over the 14 day testing period to ensure stability of samples. All lyophilised material is tested at room temperature and at 37°C over a 7 day period to ensure stability. Transit samples, which are sent to two remote centres within Australia, are also tested after each closing date to ensure stability.

13 RESULT RETURN

Participants are given a minimum of 10 working days to perform testing and to submit survey results (the length of time varies depending on the program being surveyed).

Instructions to Participants detailing the storage, processing and interpretation of the various sample modules are located on the reverse of the Result sheets and are also available to download from the Haematology QAP website. Result sheets are provided at the time of enrolment to the program in the Result Sheet and Forms Booklet and are also available from the Haematology QAP website.

Results may be entered via the RCPA Haematology website. Instructions to use this facility are available on the RCPA Haematology website. The Haematology QAP takes no responsibility for completed result sheets that have been faxed to the wrong number or emailed by participants to the incorrect email address.

14 LATE / AMENDED RESULT RETURN

The Haematology QAP is constantly striving to reduce turn-around-time between the closing date of a survey to the posting of the report to participants. Late results delay report preparation - if your results arrive after the closing date they will be flagged as "LATE" on the interim report.

Amended results are permitted and must be accompanied by the form HQF150 - Request for Additional Sample, Results Amendment and Report Reprint. Requests will no longer be accepted over the phone or via email without this form being submitted. Requests need to be received prior to the issue of reports for the following run (e.g. requests for reprints for the July survey will not be accepted after the issue of the August reports).

It is possible to download reports for most programs from the Haematology website and all will soon be fully functional. At present the reports need to be viewed as individual analytes.

15 PARTICIPANT RESPONSIBILITIES

- Ensure the instrument / reagent information in the Haematology QAP database is current
This information is recorded on every report to allow checking and is visible online during entry of results. Reprints due to incorrect method classifications will not be issued after the dispatch of results for the following run. To notify the Haematology QAP of any Instrument or Reagent changes please submit HQF 231, included in the Result Sheet and Forms Booklet.
- To check reports upon receipt
A letter included with the reports lists all reports dispatched. If a report is missing or incorrect contact the Haematology QAP immediately. Reports will no longer be reissued after the dispatch of results for the following run. When results have been sent and reports reviewed please sign the Program Schedule and Sign off sheet at the back of the Result Sheet and Forms Booklet.
- Contact the Haematology QAP if reports are not received
The Haematology QAP website "Latest News" section notifies participants of the date of dispatch and a list of reports included in the dispatch.
- Keep address and contact information current
Please notify the Haematology QAP of any Contact information change using HQF 232, included in the Result Sheet and Forms Booklet.
- Work with the Haematology QAP to solve any delivery problems
If a participant experiences ongoing delivery problems for reports or samples they must contact the Haematology QAP to discuss options. Asking the Haematology QAP to reprint reports or resend samples is not the solution.
- Participants have an obligation to enrol in, and return all results for the appropriate subscription modules. It is essential that the module chosen is a true representation of your laboratory's testing procedures.
- Laboratory staff are encouraged to actively participate, especially in the more difficult and subjective morphology component.
- It is not the role of the QA Programs to police laboratories in any way but to evaluate performance in comparison to peer laboratories and to provide participants with feedback so that they can make any necessary adjustments to their testing procedures.
- The RCPA Haematology QAP does not permit falsification or collusion of survey results. Subscribers are reminded to treat survey samples as closely as possible to patient samples.
- The statistics and other derived information on the Participant Result Evaluation forms is subject to strict copyright and must not be used without permission.

Participants are always responsible for their own policies, decisions and outcomes. The RCPA Haematology QAP does not make regulations or enforce recommendations but we hope to share education, interest and knowledge. The key to our success as service providers is interaction, communication and consistency.

16 PARTICIPANT FEEDBACK

Feedback from participants is encouraged and used to further develop the Program. A Participant Concerns / Feedback form – HQF 18 is included in the Results Sheet and Forms Booklet, so that participants can immediately provide feedback for specific surveys. Please photocopy this sheet as required. The Haematology QAP responds to all comments with the report posting.

Participants may also find a 'Frequently Asked Questions' section on the website for the more frequent and general questions received by the program.

Participants may appeal their performance assessment by indicating their concerns in writing to the Chairperson. Correspondence with the Haematology QAP is encouraged. We can be contacted through the website, email, telephone or by mail.

Phone:	<i>(+612) 9045 6040</i>
Fax:	<i>(+612) 9933 0199</i>
email:	<i>haematology@rcpaqap.com.au</i>
website:	<i>www.rcpaqap.com.au/haematology</i>

17 WEBSITE / INTERNET ACCESS

The Haematology QAP website homepage has a "Latest News" section. This is an area where we can notify participants about survey dispatches, survey report posting dates, and any other important participant information. If you have a query please refer to the "Latest News" section on the homepage.

- Participants are required to register on the Haematology home page to perform on-line data entry and to review previous reports issued.
- Participants are required to register separately to access the Oncology Immunophenotyping on-line data entry facility.
- A laboratory is able to have multiple users registered for their institution – this allows individual log-in rather than log-in by institution.
- The Haematology QAP is unable to change the email information linked to the online data entry system. If the email address for a ODE user changes they must re-register for ODE and request the deletion of their previous account. To ensure there is no breach of confidentiality or malicious tampering with result entry an organisation should notify the Haematology QAP if a staff member with ODE privileges leaves your organisation. Their username will be deleted from the system and they will have no further access to their account. Please use HQF 232 Notification of Contact information change for this purpose.
- Data entry can only be performed while the survey is open. Results may be reviewed or amended at any time up to the closing date of a survey.
- It is mandatory to enter results for the Oncology Immunophenotyping survey via the Haematology QAP website.

18 RECENT DEVELOPMENTS

- Additional and detailed diagnosis educationals are now included with the Morphology Virtual DVD

19 STAFF AND COLLABORATORS

RCPA Haematology QAP Staff

Dr Katherine Marsden	Chairperson
A/Prof Mark Hertzberg	Deputy Chairperson
John Sioufi	Program Manager
Susan Neville	Deputy Program Manager
Roslyn Bonar	Senior Scientist
Gail Earl	Scientific Officer
Fifin Intan	Scientific Officer
Michael Crowther	Scientific Officer
Susane Arentz	Technical Officer
Emanuel Dales	Technical Officer
Gabriella Pena	Technical Officer
Allison Terrell	Technical Officer
Alex Arentz	Laboratory Aide
Rachel Luongo	Administration Officer

The Haematology QAP has appointed a number of advisory committees to provide advice on the development and operation of each area of the Proficiency Testing Scheme. The committees and their members are as follows:

Haematology Advisory Committee:

Dr Katherine Marsden	Chairperson, Haematology QAP (Royal Hobart Hospital), TAS
A/Prof Mark Hertzberg	Deputy Chairperson, Haem QAP (Westmead Hospital), NSW
Ross Brown	Royal Prince Alfred Hospital, NSW
Dr George Chan	Auckland Hospital, New Zealand
Dr Jill Finlayson	PathWest QEII, WA
Anne Gilbert	ICPMR, Westmead Hospital NSW
Michael Wheeler	Monash Medical Centre, VIC

Haemostasis Committee:

Dr Katherine Marsden	Chairperson, Haematology QAP (Royal Hobart Hospital), TAS
Dr Murray Adams	University of Tasmania
Roslyn Bonar	RCPA Haematology QAP
Jenny Butler	Monash Medical Centre, VIC
Elizabeth Duncan	IMVS, Adelaide, SA
Dr Emmanuel Favaloro	ICPMR, Westmead Hospital, NSW
Sarah Just	Price of Wales Hospital, NSW
Geoffrey Kershaw	Royal Prince Alfred Hospital, NSW

Morphology Committee:

Dr Katherine Marsden	Chairperson, Haematology QAP (Royal Hobart Hospital), TAS
Dr Janine Campbell	Royal Children's Hospital, VIC
Dr George Chan	Auckland Hospital, New Zealand
Dr Peter Davidson	QML Pathology, QLD
Dr Wendy Erber	University of Western Australia, WA
Dr Jill Finlayson	PathWest QEII, WA
Dr John Giannoutsos	Nepean Hospital, NSW
Dr Surender Juneja	Royal Melbourne Hospital, Melbourne, VIC
Dr Tee Beng Keng	Sullivan Nicolaides Pathology, Taringa, QLD
Dr Poomhal Kumar	Royal North Shore Hospital, NSW
Dr Jack Metz	Dorevitch Pathology, Fairfield, VIC
Dr Stephen Mulligan	Mayne Health Pathology, Nth Ryde, NSW
Gillian Rozenberg	Prince of Wales Hospital, Randwick, NSW
Robert Short	St Vincent's Hospital, NSW
Dr Lesley Survela	ICPMR, Westmead Hospital, NSW
Robyn Wells	Queensland Health Pathology Service (QHPS), QLD
Dr Paul Whiting	Capital Pathology, ACT, NSW

CD34+ Committee:

Dr Katherine Marsden	Chairperson, Haematology QAP (Royal Hobart Hospital), TAS
Dr Annabella Chang	St Vincent's Hospital, NSW
Peter Gambell	Peter MacCallum Cancer Centre, VIC
Prof David Ma	St Vincent's Hospital, NSW
Dr Scott Ragg	Royal Hobart Hospital, TAS

Molecular Diagnostics Committee:

Dr Katherine Marsden	Chairperson, Haematology QAP (Royal Hobart Hospital), TAS
A/Prof Mark Hertzberg	Deputy Chairperson Haem QAP, Westmead Hosp, NSW
Dr Susan Branford	Institute of Medical and Veterinary Science, SA
Linda Fletcher	Institute of Medical and Veterinary Science, SA
Anne Gilbert	ICPMR, Westmead Hospital, NSW
Dr Marcus Hinchcliffe	Royal Prince Alfred Hospital, NSW
Prof. Tim Hughes	Institute of Medical and Veterinary Science, SA
A/Prof Harry Iland	Royal Prince Alfred Hospital, NSW
Dr Paula Marlton	Princess Alexandra Hospital, QLD
David McDonald	ICPMR, Westmead Hospital, NSW
Russell Saal	Princess Alexandra Hospital, QLD
Dr Jeremy Taylor	Pathcentre, Nedlands, WA
Kerryn Weekes	Monash Medical Centre, VIC

Oncology Immunophenotyping Committee:

Dr Katherine Marsden	Chairperson, Haematology QAP (Royal Hobart Hospital), TAS
Dr David Fulcher	ICPMR, Westmead Hospital, NSW
Dr Surender Juneja	Royal Melbourne Hospital, Melbourne, VIC
Mary Sartor	ICPMR, Westmead Hospital, NSW
Sue Wong	ICPMR, Westmead Hospital, NSW

Malaria Committee:

Dr Katherine Marsden	Chairperson, Haematology QAP (Royal Hobart Hospital), TAS
Dr Rogan Lee	ICPMR, Westmead Hospital, NSW
Robyn Wells	Queensland Health Pathology Service (QHPS), QLD

Haemoglobinopathy Committee:

Dr Katherine Marsden	Chairperson, Haematology QAP (Royal Hobart Hospital), TAS
Dr Jill Finlayson	PathWest QEII
Anne Gilbert	ICPMR Westmead Hospital, NSW
Kerryn Weekes	Monash Medical Centre, VIC