



# **RCPA HAEMATOLOGY QAP MOLECULAR DIAGNOSTICS REPORTING SYSTEM – AN OVERVIEW**

***SUE ARENTZ***



# Agenda

- Overview
- Reporting system for Quantitative modules
- Reporting system for Qualitative modules
- Introduction to on-line data entry



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- **Overview**
- Reporting system for Quantitative modules
- Reporting system for Qualitative modules
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# Molecular Diagnostic Modules

RNA and DNA samples supplied for the below modules

- Module 1 – Factor V Leiden
- Module 2 - Hereditary Haemochromatosis
- Module 3 – bcr-abl
- Module 4 – Igh/TCR, bcl-1 / bcl-2
- Module 5 – Chimerism
- Module 6 – Thalassaemia
- Module 7 – JAK2
- Module 8 – PML-RARa



# Molecular Diagnostic Modules

- Chimerism module (Module 5)
  - Quantitative assessment of participant results
- Remaining modules
  - Qualitative assessment of participant results
- Possibility of assessing the quantitative component for other modules, such as bcr-abl or JAK2.
  - Decision will be made by the committee, which will base this on our current survey samples and the methodology used amongst participants.



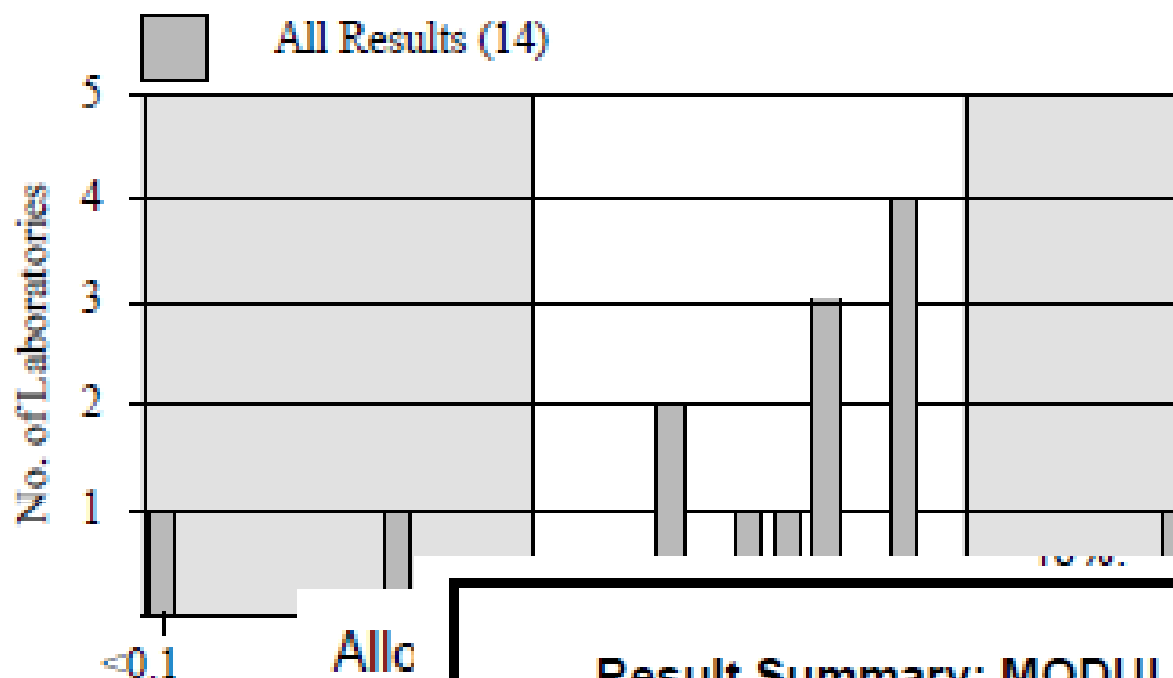
# Agenda

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## MD10-02c

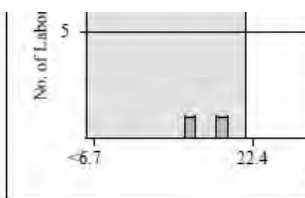
### PARTICIPANT RESULTS



	c. %2	d. %2	e. %2
	10.0	15.0	30.0
	9.0	17.0	31.0
	3.0	9.0	17.0
	7.0	15.0	30.0
	8.4	17.8	29.5
	8.0	16.0	33.0
	8.9	15.5	30.7

### Result Summary: MODULE 5 - CHIMERISM

SAMPLE	YOUR RESULT %	TARGET RESULT %
MD10-02c	10.0	8.0
MD10-02d	15.0	16.0
MD10-02e	30.0	32.0



#### COMMENTS:

This survey was designed to evaluate in varying ratios. The concentration of

Sample	Individual 1
CH9-02a	100%
CH9-02b	0%

tures of the two DNAs

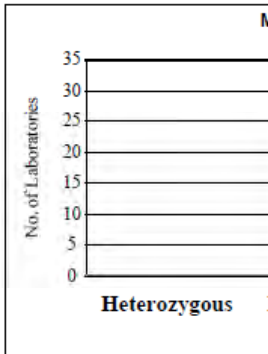


# Agenda

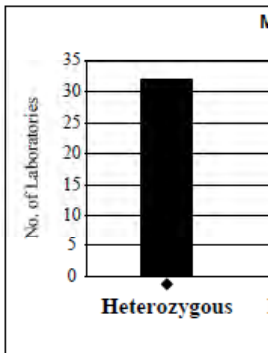
- Overview
- Reporting system for Quantitative modules
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Due Date : 2/03/2010



Target Result



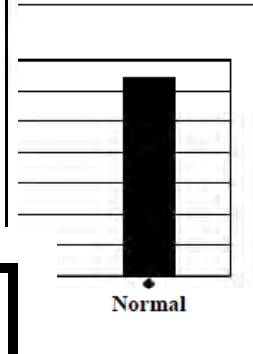
Target Result

COMMENTS:  
All participants' responses for C)

## MD10-02b



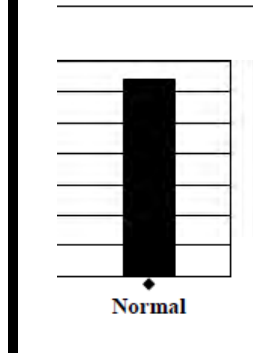
Number 11



Normal

## Result Summary: MODULE 2 - CYS282TYR

SAMPLE	YOUR RESULT	TARGET RESULT
MD10-02a	Homozygous	Homozygous
MD10-02b	Normal	Normal
MD10-02c	Normal	Normal
MD10-02d	Heterozygous	Heterozygous
MD10-02e	Normal	Normal

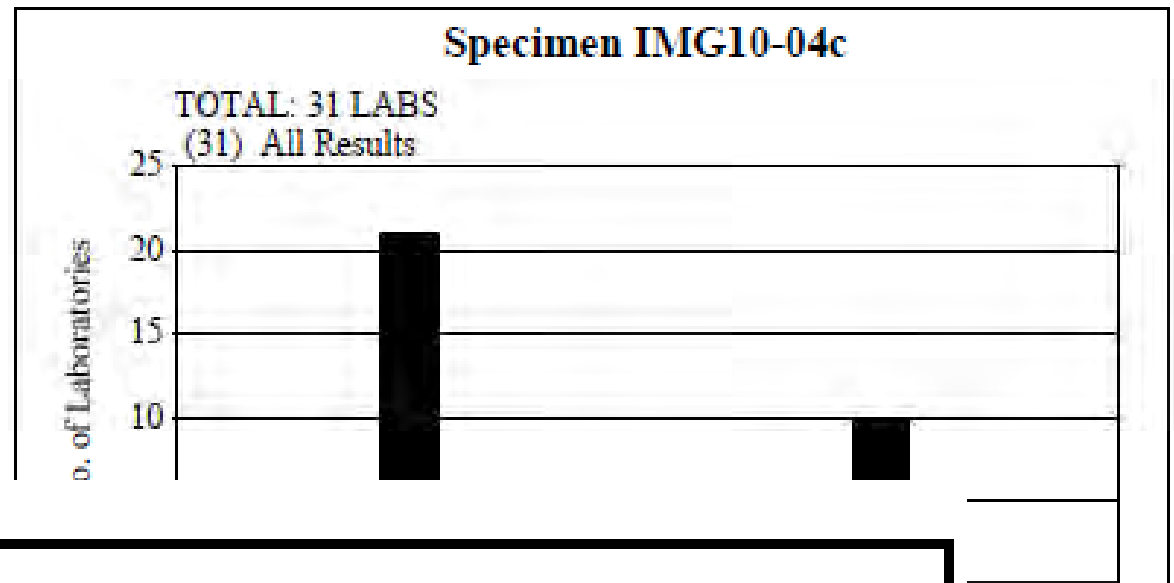
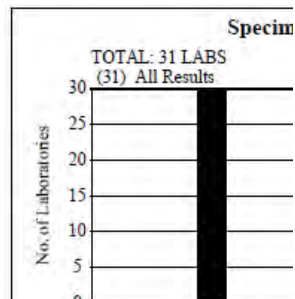
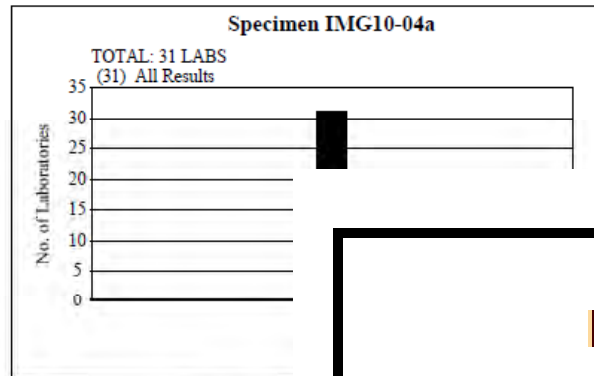


Normal

# Qualitative Ass

Printed  
Aug 27 09:28:12 2010

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ABN 32 003 520 072



## Result Summary: MODULE 4 - IgH

SAMPLE	YOUR RESULT	TARGET RESULT
MDIMG10-04a	NMG	NMG
MDIMG10-04b	NMG	NMG
MDIMG10-04c	NMG	IgH
*121116118-01c-	NMG	NMG

Code	Pattern
IgH	Monoclonal IgH gene rearrangement
NMG	No monoclonal gene rearrangement
SU	Sample not suitable for testing

Molecular Diagnostics Program



# Qualitative Assessment

Printed  
Aug 27 09:28:12 2010

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ABN 32 003 520 072

Prepared by:  
RCPA Haematology QAP

## MOLECULAR DIAGNOSTICS MODULE 4 - Immunogenotyping

Laboratory Number

### COMMENTS:

#### Expected Findings

Sample IMG10-04a: No monoclonal gene rearrangement  
 Sample IMG10-04b: No monoclonal gene rearrangement  
 Sample IMG10-04c: Monoclonal IgH gene rearrangement  
 Sample IMG10-04d: Monoclonal TCR gene rearrangement  
 Sample IMG10-04e: Monoclonal IgH gene rearrangement

#### Results from participants

Combined IgH and TCR Immunogenotyping Results					
Part.No	Sample 10-04a	Sample 10-04b	Sample 10-04c	Sample 10-04d	Sample 10-04e
11	NMG	NMG	NMG	TCR	IgH
20	NMG	NMG	NMG	TCR	IgH
162	NMG	NMG	NMG	TCR	IgH
229	NMG	NMG	NMG	TCR	IgH
2012	NMG	NMG	TCR	TCR	IgH/TCR
2019	NMG	NMG	IgH	TCR	IgH
2035	NMG	NMG	NMG	TCR	IgH
2155	NMG	NMG	IgH	TCR	IgH
3002	NMG	NMG	IgH	TCR	IgH
3011	NMG	NMG	NMG	TCR	IgH
3015	NMG	NMG	IgH	TCR	IgH
3017	NMG	NMG	IgH	TCR	IgH
3067	NMG	NMG	IgH	TCR	IgH
4003	TCR	NMG	IgH	TCR	IgH
5003	NMG	NMG	IgH	TCR	IgH
5006	NMG	NMG	IgH	TCR	IgH
6001	TCR	NMG	NMG	TCR	IgH
7004	NMG	NMG	IgH	TCR	IgH
7062	NMG	NMG	IgH	TCR	IgH
8011	NMG	NMG	NMG	TCR	IgH
8015	NMG	NMG	IgH	TCR	IgH
8019	TCR	TCR	IgH/TCR	TCR	IgH
8021	NMG	NMG	IgH	TCR	IgH
8022	NMG	NMG	NMG	TCR	IgH
8032	NMG	NMG	IgH	TCR	IgH
8134	NMG	NMG	IgH	TCR	IgH
8214	NMG	NMG	IgH	TCR	IgH
8232	NMG	NMG	IgH	TCR	IgH
8299	NMG	NMG	IgH	TCR	IgH
8381	NMG	NMG	IgH	TCR	IgH
8636	NMG	NMG	IgH	TCR	IgH



# Qualitative Assessment

## *Comments for Immunogenotyping samples IMG10-04a to IMG10-04e dispatch 2/2010*

As shown in the tables of participants' results, almost all participants reported the target IgH result for samples IMG10-04a, -04b, -04d and -04e. It was unexpected for sample IMG10-04c (B-cell small lymphocytic lymphoma/chronic lymphocytic leukemia) that only 21 of 31 participants would be able to detect a monoclonal IgH recombination. As there is insufficient consensus we are unable to score this sample. Interestingly, as shown in the tables showing participants' results according to primers used, the majority of these participants used only an Fr3 primer-based method. This sample shows the importance of using multiple primer sets (Fr1, Fr2 and Fr3) to detect IgH recombinations. All participants reported monoclonal TCR gene rearrangement for IMG10-04d (Sezary syndrome with mycosis fungoides). Four participants reported false positive TCR gene rearrangements, this is especially of concern in the benign samples (IMG10-04a and -04b).

## *Histopathology descriptions for samples IMG10-04a to IMG10-04e*

### **IMG10-04a**

DNA sample from snap-frozen, bilateral, tonsillectomy tissue from a 38 year old male. Histological examination showed non-specific reactive follicular hyperplasia and tonsillar crypts focally distended with keratinous and inflammatory debris. There was no malignancy.

### **IMG10-04b**

DNA sample from snap-frozen, enlarged tonsillar tissue from a 35 year old female tonsillectomy patient who had recurrent, bilateral tonsillitis. Histological sections showed elongated crypts lined by squamous epithelium; lymphoid aggregates with activated germinal centres were also seen. There was no evidence of suppuration, atypical lymphoid proliferation or malignancy. The diagnosis was reactive lymphoid hyperplasia with no evidence of lymphoma.

### **IMG10-04c**

DNA sample from an axillary lymph node excision biopsy from a 68 year old male with extensive lymphadenopathy. The patient had a history of melanoma on the back and a T9 vertebral metastasis. Biopsy of the T9 vertebral body had revealed atypical lymphocytes in addition to metastatic melanoma. Subsequent fine needle aspiration cytology to investigate axillary and cervical lymphadenopathy revealed B-cell small lymphocytic lymphoma/CLL. This was followed by an excisional lymph node biopsy. Macroscopically, the lymph node cut surface had a "fish flesh" appearance without necrosis or haemorrhage. Microscopically, there was a diffuse infiltrate of small mature lymphocytes with interspersed pale pseudoproliferation centres. Immunohistochemical staining of the abnormal lymphocytes showed they were positive for CD20, CD5, CD23, CD43, PAX-5, IgM and BCL-2; and were negative for CD10, BCL6, CD21 and IgD. The MIB-1 proliferation index was less than 10%. Flow cytometry of the lymph node revealed a CD19, CD20, CD5, CD23 and CD45 positive population that had lambda light chain restriction and was negative for CD10, CD79b and surface IgM. The diagnosis was B-cell small lymphocytic lymphoma/chronic lymphocytic leukemia.

### **IMG10-04d**

DNA sample from peripheral blood leucocytes from a 63 year old male. The patient had a history of epidermotropic and erythrodermic T-cell lymphoma (mycosis fungoides) involving the back, forehead and forearm, generalised lymphadenopathy and peripheral blood atypical lymphocytosis (lymphocytes  $10 \times 10^9/L$ ). A bone marrow trephine showed a hypercellular marrow containing an atypical CD3 positive lymphoid infiltrate that was negative for CD4, CD8 and CD7, consistent with involvement by T-cell lymphoma. An axillary lymph node biopsy showed replacement of lymph node architecture by a diffuse atypical lymphoid infiltrate of mainly small and intermediate sized lymphocytes having hyperchromatic nuclei with angular, cleft or cerebriform morphology and with a distinct rim of pale cytoplasm. Immunohistochemical staining showed the lymphoma cells were positive for CD2, CD3, CD5, CD30 <20%, CD99, beta-F1, and negative for CD1a, CD4, CD8, CD7, CD34, TdT, TIA-1. Flow cytometry study of the peripheral blood showed a marked T-cell lymphocytosis with 87% of the lymphocytes having an abnormal T-cell phenotype positive for CD2 and CD3, and negative for CD4, CD7 and CD8. The tissue immunohistochemical studies and flow cytometry results were concordant and established an abnormal T-cell phenotype. Identical clonal TCR beta and TCR gamma gene rearrangements were found in skin and lymph node biopsies. While a CD4 and CD8 negative phenotype is unusual in mycosis fungoides, it may occur and given the typical clinical setting, a diagnosis of mycosis fungoides/Sezary syndrome was made.

### **IMG10-04e**

DNA sample from snap-frozen, enlarged, cervical lymph nodes from a 51 year old male. A previous bone marrow trephine biopsy showed diffuse infiltration by chronic lymphocytic leukemia/ small lymphocytic lymphoma. This was followed by excision biopsy of enlarged right cervical lymph nodes which had soft homogenous dark red cut surfaces. Histologic sections showed complete effacement of normal lymph node architecture with a diffuse proliferation of small lymphocytes that had slightly enlarged hyperchromatic nuclei, and which extended into the adjacent connective tissue. Immunohistochemical staining showed the lymphoma cells were positive for CD20, CD5, and CD23, and were negative for CD10 and cyclin D1. Flow cytometry of the lymph node showed a population of B cells that expressed CD19, CD20, CD5, CD23, dim surface IgM and were kappa light chain restricted. Cytogenetic study of all eight available metaphase cells showed a deletion at 11q23 which is associated with B-cell non-Hodgkin lymphoma. The diagnosis was B-cell chronic lymphocytic lymphoma/ chronic lymphocytic leukemia.



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# RCPA Haematology QAP

## On-line data entry

- Register for on-line data entry
  - <https://haematology.rcpaqap.com.au/>
  - Follow prompts with questions relevant to the user
  - Once completed a password will be emailed to the registered user
- More than 1 registration / site is allowed
- Results need to be entered before the closing date to be accepted



# RCPA Haematology QAP On-line data entry

RCPA Quality Assurance Programs Pty Limited

## Haematology QAP

[Home](#)

### Haematology QAP

#### Participant Use

This section of the website allows participants who are currently enrolled in the Haematology QA programs access to an area where they can enter results and review previous results in the QAP database.

**On-Line Registration**

New User? [Register Here](#)

**Registered Member Login**

Enter your Laboratory Number, UserID and Password below, then click Login.

Lab Number:

UserID:

Password:

**Forgotten Password?**

[Click here](#) to get your password.



# RCPA Haematology QAP On-line data entry

RCPA Quality Assurance Programs Pty Limited

## Haematology QAP

Home

### Online Registration - User Identification

Please enter a user ID to be used for identification.

This must be a unique identifier for each laboratory number. The User ID may be up to 20 alphanumeric characters with spaces acceptable. For example *John Citizen01, Hitachi01, Hitachi02, Stat Lab, etc.*

All fields marked with an asterisk (\*) must be completed in order to register.

Once registered, an acknowledgement will be sent to your registered email address. If you do not receive this after completing registration, verify your address and try again.

Notification of your password will be sent in a few days.

User ID:  (Up to 20 characters length)

Laboratory No.:




# RCPA Haematology QAP On-line data entry

RCPA Haematology QAP Login - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://haematologyqap.fmc.flinders.edu.au/haematology/index.htm>

RCPA Quality Assurance Programs Pty Limited  Haematology QAP

Home **Online Registration - Laboratory Details** Laboratory 999 [user: john.sioufi]

Please enter the following details for registration to the RCPA Web application. Use the laboratory details as submitted in enrolments. All fields marked with an asterisk (\*) must be completed.

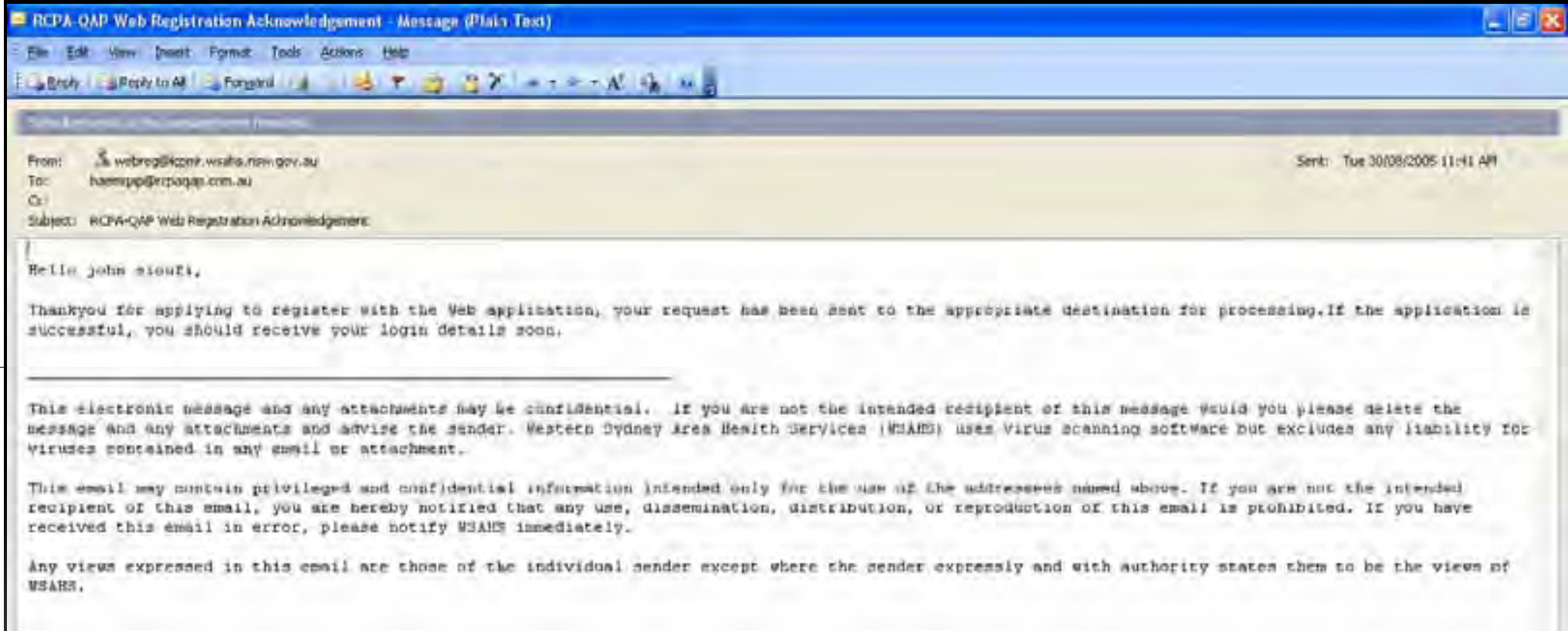
Contact Person	*	<input type="text" value="John Sioufi"/>
Organisation/Institution	*	<input type="text" value="RCPA QAP Pty Ltd"/>
Department		<input type="text" value="Haematology"/>
Postal Address	*	<input type="text" value="PO Box 50 Westmead"/>
Street Address	*	<input type="text" value="Westmead Hospital Cnr Hawkesbury Rd &amp; Darey Rd Westmead"/>
Postcode/Zip		<input type="text" value="2050"/>
Country	*	<input type="text" value="AUSTRALIA"/>
State		<input type="text" value="NSW"/>
Phone Number	*	<input type="text" value="+612 9845 7038"/>
Fax Number	*	<input type="text" value="+612 9891 5376"/>
Email Address	*	<input type="text" value="johns@icpmr.wsahs.nsw.gov.au"/>

Note: This address will be used to send the registration password.



# RCPA Haematology QAP

## On-line data entry



# RCPA Haematology QAP On-line data entry

RCPA Quality Assurance Programs Pty Limited

## Haematology QAP

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New User? [Register Here](#)

**Registered Member Login**

Enter your Laboratory Number, UserID and Password below, then click Login.

Lab Number:

UserID:

Password:

**Forgotten Password?**

[Click here](#) to get your password.



# RCPA Haematology QAP


## On-line data entry

RCPA QAP - Haematology - Windows Internet Explorer provided by RCPA Quality Assurance Programs

https://haematology.rcpaqap.com.au/login;sessionid=C2A637D922C22560063DE8A9C3F43C0C

File Edit View Favorites Tools Help

Home - RCPA Haematology ... RCPA QAP - Haematology

RCPA Quality Assurance Programs Pty Limited  Haematology QAP

Home

Previous Reports

**Data Entry**

Change Password

Unlock Users

Security

RCPA QAP Website

Logout

**Welcome**

Welcome *john sioufi*,  
You have successfully logged into the Haematology Quality Assurance Programs Web application.  
Click on the left-hand side menu to choose an option.

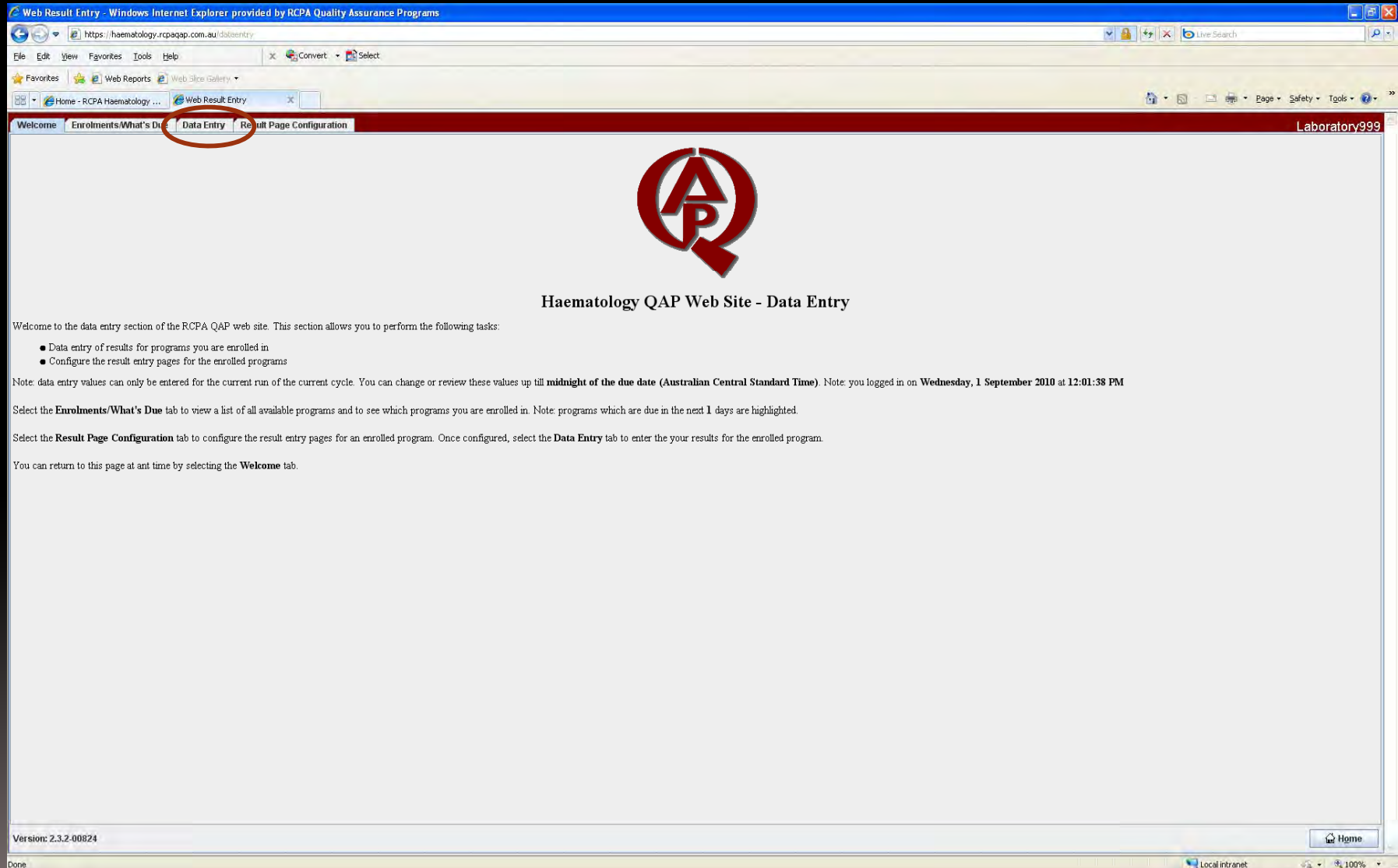
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The information contained in this website is the property of RCPA Quality Assurance Programs Pty Ltd and use of the data or reports other than for internal laboratory use must not be made without written approval.

Laboratory 999 [user:john sioufi]

Local intranet 100%



# RCPA Haematology QAP On-line data entry



The screenshot shows a Windows Internet Explorer browser window displaying the RCPA Haematology QAP web site. The address bar shows the URL <https://haematology.rcpaqap.com.au/dataentry>. The browser's menu bar includes File, Edit, View, Favorites, Tools, and Help. The address bar also shows a search engine (Live Search) and a search box. The browser's status bar at the bottom indicates "Done" and "Local intranet".

The web page has a red header bar with the text "Laboratory999" on the right. Below the header is a navigation menu with four tabs: "Welcome", "Enrolments/What's Due", "Data Entry", and "Result Page Configuration". The "Data Entry" tab is selected and circled in red.

The main content area features the RCPA logo (a stylized 'A' and 'P' inside a circle) and the title "Haematology QAP Web Site - Data Entry". Below the title, there is a welcome message and a list of tasks:

Welcome to the data entry section of the RCPA QAP web site. This section allows you to perform the following tasks:

- Data entry of results for programs you are enrolled in
- Configure the result entry pages for the enrolled programs

Below the list, there are two notes:

Note: data entry values can only be entered for the current run of the current cycle. You can change or review these values up till **midnight of the due date (Australian Central Standard Time)**. Note: you logged in on **Wednesday, 1 September 2010 at 12:01:38 PM**

Select the **Enrolments/What's Due** tab to view a list of all available programs and to see which programs you are enrolled in. Note: programs which are due in the next 1 days are highlighted.

Select the **Result Page Configuration** tab to configure the result entry pages for an enrolled program. Once configured, select the **Data Entry** tab to enter the your results for the enrolled program.

You can return to this page at any time by selecting the **Welcome** tab.

At the bottom left of the page, the version number "Version: 2.3.2-00824" is displayed. At the bottom right, there is a "Home" button.



# RCPA Haematology QAP On-line data entry

Web Result Entry - Windows Internet Explorer provided by RCPA Quality Assurance Programs

https://haematology.rcpaqap.com.au/dataentry

File Edit View Favorites Tools Help

Home - RCPA Haematology ... Web Result Entry

Welcome Enrolments/What's Due Data Entry Result Page Configuration Laboratory999

Reticulocyte Program Special Haemostasis - Module A Special Haemostasis - Module B Special Haemostasis - Module C Special Haemostasis - Module D (FVII Inhibitor) Special Haemostasis Module E: PFA-100

Haemoglobinopathy Program Haemostasis Program Malaria Parasite Molecular Diagnostics Program Morphology Diagnosis Program NEQAP Haematology Malaysia - FBC Program Oncology Immunophenotyping Program Point of Care - INR

Additional Factors Automated Differential Program Blood Film Differential CD34+ Program D-DIMER - Option 1 (Automated) D-Dimer - Option 2 (Semi-Quant/Qual) ESR Program Full Blood Count G6PD Program

### Molecular Diagnostics Program

Due Date: Wed, 5 May 2010

Cycle No: 10 Run No: 2 Lab No: 999

Edit Late/Amended

Module 1 Module 4 TCR Module 4 IgH Module 7

Analyte Name	Specimens
	10-04a
a - Factor V Leiden	<input type="checkbox"/> Heterozygous <input type="checkbox"/> Homozygous <input type="checkbox"/> Normal
a - Prothrombin G20210A	<input type="checkbox"/> Heterozygous <input type="checkbox"/> Homozygous <input type="checkbox"/> Normal
a - MTHFR (Ala677Val)	<input type="checkbox"/> Heterozygous <input type="checkbox"/> Homozygous <input type="checkbox"/> Normal
	10-04b
b - Factor V Leiden	<input type="checkbox"/> Heterozygous <input type="checkbox"/> Homozygous <input type="checkbox"/> Normal
b - Prothrombin G20210A	<input type="checkbox"/> Heterozygous <input type="checkbox"/> Homozygous <input type="checkbox"/> Normal
b - MTHFR (Ala677Val)	<input type="checkbox"/> Heterozygous <input type="checkbox"/> Homozygous <input type="checkbox"/> Normal
	10-04c
c - Factor V Leiden	<input type="checkbox"/> Heterozygous <input type="checkbox"/> Homozygous <input type="checkbox"/> Normal
c - Prothrombin G20210A	<input type="checkbox"/> Heterozygous <input type="checkbox"/> Homozygous <input type="checkbox"/> Normal
c - MTHFR (Ala677Val)	<input type="checkbox"/> Heterozygous <input type="checkbox"/> Homozygous <input type="checkbox"/> Normal
	10-04d

Home Reset Save



# RCPA Haematology QAP On-line data entry

Web Result Entry - Windows Internet Explorer provided by RCPA Quality Assurance Programs

https://haematology.rcpaqaap.com.au/dataentry

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Home - RCPA Haematology ... Web Result Entry

Welcome Enrolments/What's Due Data Entry Result Page Configuration Laboratory999

[Reticulocyte Program](#)
[Special Haemostasis - Module A](#)
[Special Haemostasis - Module B](#)
[Special Haemostasis - Module C](#)
[Special Haemostasis - Module D \(FVIII Inhibitor\)](#)
[Special Haemostasis Module E: PFA-100](#)
[Haemoglobinopathy Program](#)
[Haemostasis Program](#)
[Malarial Parasite](#)
[Molecular Diagnostics Program](#)
[Morphology Diagnosis Program](#)
[NEQAP Haematology Malaysia - FBC Program](#)
[Oncology Immunophenotyping Program](#)
[Point of Care - INR](#)

[Additional Factors](#)
[Automated Differential Program](#)
[Blood Film Differential](#)
[CD34+ Program](#)
[D-DIMER - Option 1 \(Automated\)](#)
[D-Dimer - Option 2 \(Semi-Quant/Qual\)](#)
[ESR Program](#)
[Full Blood Count](#)
[G6PD Program](#)

### Molecular Diagnostics Program

Due Date: Wed, 5 May 2010

Cycle No: 10 Run No: 2 Lab No: 999 [Edit Late/Amended](#)

[Module 1](#)
[Module 4 TCR](#)
[Module 4 IgH](#)
[Module 7](#)

Analyte Name	Specimens
a - T-Cell Receptor Gene	IMG10-04a
b - T-Cell Receptor Gene	IMG10-04b
c - T-Cell Receptor Gene	IMG10-04c
d - T-Cell Receptor Gene	IMG10-04d
e - T-Cell Receptor Gene	IMG10-04e

Note: codes must be separated by a space (e.g. A s)

Entry Code	Short Descriptor	Full Descriptor
NMG	NMG	No monoclonal gene rearrangement
TCR	TCR	Monoclonal TCR gene rearrangement

[Home](#)
[Reset](#)
[Save](#)





Technical Questions

Email: [haematology@rcpaqap.com.au](mailto:haematology@rcpaqap.com.au)

*Thank you*

