

CLGGS (formerly IMCLGS) Meeting Summary (August 31, 2006)

31 August 2006

1. Our group's name has changed to Clinical and Laboratory Genomic and Genetic Standards, CLGGS

- Distribution list and website seem to be effective for current activity, www.imclgs.org
- Have received positive feedback, increased interaction
- Please send information you would like posted to marlys_walls@affymetrix.com. Please also have persons interested in being added to the contact list contact Marlys.

2. CLGGS web site update (www.imclgs.org)

- IFCC has offered to host the website and we have accepted. Thank you Francois Rousseau, Heinz Schimmel and Andrew Wootton of the IFCC. We are currently updating info on site and preparing for transfer. Please send me any content, links you would like added. More information will be coming once we have made the transfer to IFCC.

3. Works Manuscript update (draft outline below)

- a. Working Title: Recommendations for the characterization and qualification of analytical performance controls for DNA based genetic tests.
- b. Section working groups are formed. We still need a leader for section 9, Lisa Kalman/CDC was suggested, or perhaps someone from IFCC, EU? **Action: Janet Warrington will follow up with EurogenTest, IFCC. Ira Lubin and Jean Amos Wilson will follow up with Lisa Kalman.**
- c. Scope. Section leaders will meet to define the scope of the document. Goal to complete by mid-November. **Action: Janet Warrington will set up the scope meeting.**
- d. Timeframe/deadlines. Proposed dates discussed for completing scope and subsequently the detailed outline. If we can complete scope by mid November, we will have better idea for completion deadlines for detailed outline and draft manuscript.

4. Algorithm Meetings

Proposed to develop best practices for qualifying algorithms for highly multiplexed DNA based tests through a series of meetings to develop major concepts, build consensus. Ed Liu has proposed that we hold a series of meetings to discuss criteria and methods for qualifying algorithms for DNA based tests leading to development of recommendations for qualification of computational algorithms for clinical genetic tests. A planning committee is being formed. Need a globally balanced representation from public and private sectors, including clinical, government and commercial expertise. Planning committee: Ed Liu, Federico Goodsaid, Laura Reid, Dan Farkas, Ming Qi, Janet Warrington... **Others? EurogenTest ? JBA? IFCC?**

5. No new business

Next meeting date is determined.

DATE: Thursday, December 7, 2006
TIME: 7:30am pacific / 10:30am central / 11:30am eastern
DIAL-IN: 800-531-3250 – US/303-928-2693 - International*

*You will find a list of toll-free international numbers at the end of this email. Please contact Marlys Walls (marlys_walls@affymetrix.com) should you have questions regarding dial-in numbers.

CONF ID: 6248531 and PASSCODE: 45678

CLGGS DNA1 DRAFT OUTLINE and section writing groups

060831

Working title: Recommendations for the characterization and qualification of analytical performance controls for DNA based genetic tests

The purpose of this paper is to provide recommendations regarding technical/analytical performance controls for multiplex (microarray) DNA based genetic tests, including qualification/selection criteria, characterization, and metrics. The type and amount of control information furnished in the test report is also addressed.

1. Introduction

DNA based genetic tests history and state of the art: an international perspective.

The need for standardization and acknowledgement of the multiple efforts underway

Analytical/technical performance versus analyte performance.

Confirmed: David Barton/Ireland, Dr Nobori/JBA/Japan, Jean Amos Wilson/USA, Janet Warrington/USA, Rob Elles/UK, Orna Dreazan/Israel, Mike Zoccoli/USA, Helen Parkes/UK

Lead: David Barton

2. Nomenclature

Harmonized terminology, what's the same and what's different

Confirmed: Roberta Madej/USA, Philippe Corbisier/Belgium, Janet Warrington/USA

Orna Dreazen/Israel, Hilla Ben-David/Israel, Shuji Ogino/Japan

Lead: Janet Warrington

3. Existing guidelines/standards for RM development, what is important in development of control material, quality assurance, procedures that should be followed, and what's needed for multiplex microarray-based DNA tests, what would be ideal.

Confirmed: Els Dequeker/Belgium, Vince Vilker, USA, Roberta Madej/USA,

Jean Jacques Cassimain/EU, Carole Foy/UK, Jim Collins/USA

Lead: Roberta Madej

4. Recommended selection/qualification criteria

Expand on each of these desired characteristics and provide examples;

Fit for purpose, independently confirmed, stability, homogeneous, renewable and accessible, traceable, safety, purity, concentration, complexity (similarity to sample), discussion of super/meta/synthetic versus biological

Confirmed: Desiree du Sart/Australia, Els Dequeker/Belgium, Dr Noburi/Japan, Janet Warrington/USA, Jean A Wilson/USA, N.K.Ganguly/India, Mike Zoccoli/USA, Carole Foy/UK, Alicia Scheffer/USA

Lead: Jean Amos Wilson

5. Characterization of controls

Recommended methods of characterizing control material including integrity, quantification, evaluation pre and post extraction, amplification, labeling, pooling etc.

Confirmed: Elaine Gray/UK, Marie Early/USA, Harry Hanon/USA, Marie Early/USA, Helen Parkes/UK, Carole Foy/UK, Helen White/UK, Ming Qi/China, Vince Vilker/USA, Mike Zoccoli/USA

Lead: Helen Parkes

6. Use of controls in genetic tests; recommendations

Control measurement recommendations;

What to measure, when to measure, how to measure

Confirmed: Ishwar Verma/India, Vicky Pratt/USA, Jean-Jacques Cassimain/Belgium, Jorge Sequeiros/Portugal, Milan Macek/Czech Republic, Helen White/UK Wessex, Rob Elles/UK, Hilla Ben-David/Israel, Marie Early/CDC

Lead: Vicky Pratt

7. Reporting. Control report content; what to report; context of information, accessibility, language and metrics, harmonization, how much is enough, what is too little

Do comments on privacy and information protection fit here or because we are focused on just the controls and what is reported about control information to the laboratory do we need to address it?

Confirmed: Desiree du Sart/Australia, Jorge Sequeiros/Portugal, Philippe Corbisier/Belgium, Dr Nobori/Japan, Elaine Gray/UK, N.K.Ganguly/India, Orna Dreazen/Israel, Hilla Ben-David/Israel, Yeyang Su/China

Lead: Jorge Sequeiros

8. Common sources of error, issues

Vicky Pratt/USA, Roberta Madej/USA, Ed Liu/Singapore, David Barton/Ireland, Els Dequeker/Belgium

Lead: Els Dequeker

9. Access to shared controls and control information

Initiatives to share control information (databases) access to shared materials

Helen Parkes/UK, David Barton/UK, Dr Nobori/Japan, Helen White/UK Wessex, Carole Foy/UK

Lead: ??

10. Summary and Next Steps

Janet Warrington, David Barton

Note: Joe Boone, Jean Jacques Cassimain, Maria Chan, Dan Farkas, Laura Reid, Uwe Scherf, Vince Vilker and Bob Williamson have offered to act as reviewers and editors.