

**International Consortium for Harmonization of Clinical Laboratory Results**  
**Harmonization Oversight Group / Council Web Meeting**

**DATE:** 25 February 2019

**TIME:** 8:00-9:00 a.m. USA EST

| <b>HOG Member</b>          | <b>Present</b> | <b>Council Member</b>      | <b>Present</b> |
|----------------------------|----------------|----------------------------|----------------|
| Greg Miller (chair)        | x              | Gary Myers (chair, AACC)   | x              |
| Eunice Lee (Vice-Chair)    | x              | Gye Chol Kwon (KSLM)       |                |
| Joseph Passarelli          | x              | Akira Seki (JCCLS)         | x              |
| Steve Master               |                | Howard Morris (IFCC)       |                |
| Amy Saenger                |                | Tony Killeen (CAP)         | x              |
| Ian Young                  |                |                            |                |
| Masato Maekawa             |                |                            |                |
| Philippe Gillery (IFCC SD) |                |                            |                |
| Anja Kessler               |                | <b>Observer</b>            |                |
| Melissa Snyder             |                | Loretta Doan (AACC)        | x              |
| Yeo-Min Yun                | x              | Katsuyuki Nakajima (JCCLS) | x              |
| Andy Hoofnagle             |                |                            |                |
| Amrom Obstfeld             | x              |                            |                |
| Ross Molanaro              | x              |                            |                |

**Minutes:**

Council activity:

1. Gary Myers reviewed the draft financial statement for 2018. The entries for net revenue from dues minus credit card fees will be edited to show the amount of the dues and the credit card transaction fee separately. We no longer accept credit cards to avoid the bank transaction fee. The balance will be used to support a conference being organized by the ICHCLR and The IFCC SD, and to support start-up funds for harmonization projects. The final financial statement will be available following the outside audit of IFCC accounts.

HOG activity:

2. The draft program was reviewed for the ICHCLR and IFCC SD organized workshop on reference materials and regulatory issues in harmonization. The workshop will be 29-30 May 2020 following the IFCC WorldLab 2020 Seoul (24-28 May). The organizing committee

includes Greg Miller, Gary Myers, Jim Pierson Perry, Christa Cobbaert, Philippe Gillery. The current activity is to develop a budget for the workshop and then to solicit IVD manufacturers and other organizations for financial support. Joe Passarelli commented that the request for financial support to IVD industry should include a concise explanation of the purpose and outcomes expected from the workshop. He also informed that the request for financial support should occur not later than May.

3. We agreed on the last call to add a medical impact for all measurands irrespective of status of harmonization. Measurands with blank priority were reviewed and consensus medical impacts (priorities) were agreed. Three measurands (anti-nuclear antibody, folate, pregnancy associated plasma protein A) required expertise not present on the call and will be addressed by email.
4. Rita Horvath and Alex Chin, co-chairs of the AACC Evidence Based Laboratory Medicine committee, offered to collaborate with ICHCLR to identify and prioritize measurands used in guidelines. Rita and Alex have been invited to the March 25 call to discuss our collaboration.
5. An updated web posting for HBsAg and Anti-HBs Ab from Eunice was reviewed and approved.
6. From the previous call: A measurand summary for Anti-myeloperoxidase (MPO) antibody, IgG was reviewed and minor edits suggested. Melissa will make the edits and contact the chair of the IFCC Committee on Harmonization of Autoimmune Tests for current activity. The updated information will be posted to the web site.
7. The Table below shows measurand assignments for prioritization recommendations for review by HOG and posting to the measurands table.

**Next conference call meetings:** all 8 AM USA Eastern time: 2019; Mar 25, Apr 29. Note that USA will change to daylight saving time (EDT) on March 10 before the next call.

| <b>Measurand</b>                                  | <b>Assigned to</b> |
|---|--------------------|
| Hemoglobin and CBC parameters, blood – POCT to do | Amrom              |
| Hematocrit  | Amrom              |
| Iron saturation                                   | Amrom and Greg     |

| <b>Measurand</b>                | <b>Assigned to</b>  |
|---------------------------------|---|
| Iron binding total              | Amrom and Greg  |
| Apolipoprotein A1 and B         | Amy   |
| Pseudocholinesterase            | Amy   |
| Calcium urine                   | Amy   |
| Chloride urine                  | Amy   |
| Compliment CH-50                | Amy & Melissa   |
| Glucose, urine                  | Anja  |
| Calcium, ionized                | Anja will provide additional EQA data to support the recommendation draft from Greg |
| Chlamydia                       | Eunice  |
| HBV Ag and anti-HBs AB          | Eunice  |
| Vitamin B12                     | Greg  |
| Iron                            | Greg  |
| Protein urine                   | Greg  |
| Creatinine, urine               | Greg  |
| Hemoglobin, plasma free         | Greg was not able to find suitable information of harmonization status              |
| Methemoglobin                   | Greg was not able to find suitable information on harmonization status              |
| Lactate dehydrogenase           | Ian   |
| Lipoprotein(a)                  | Ian   |
| Anti SS-A                       | Melissa   |
| cytokeratin fragment 19 (CK19F) | Melissa   |

| <b>Measurand</b>             | <b>Assigned to</b>   |
|------------------------------|--|
| Elastase 1                   | Melissa  |
| Elastase 2                   | Melissa  |
| IgA                          | Melissa  |
| IgG                          | Melissa  |
| IgM                          | Melissa  |
| HIV-1 genotype               | Steve  |
| Beta-2 microalbumin          | Steve; difficult to find information                             |
| Albumin, CSF                 | Steve; Likely dependent on urine and serum albumin harmonization |
| BCR/ABL                      | Tony   |
| Hepatitis A Ab IgM           | Tony and Melissa   |
| Hepatitis A Ab IgG           | Tony and Melissa   |
| Hepatitis A Ab (Total)       | Tony and Melissa   |
| Hepatitis B core IgG and IgM | Tony and Melissa   |
| Hepatitis B core Ab          | Tony and Melissa   |
| Hepatitis B DNA quant        | Tony and Melissa   |
| Hepatitis C Ab               | Tony and Melissa   |

| <b>Measurand</b>  | <b>Assigned to</b> |
|---|--------------------|
| Drugs: acetaminophen, salicylate, theophylline, tobramycin, gentamycin, benzodiazepine, amphetamines, tacrolimus, serolimus, lidocaine, methotrexate, N-acetylprocainamide, procainamide, primidone, quinidine, valproic acid, amikacin, barbiturates, cyclosporine, cocaine urine, methadone | Yeo-Min            |