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Connections

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Team Canada in Seoul

Every year Canadian laboratorians participate in the International Organization for Standardization (ISO) annual plenary meeting for Technical Committee 212 for in vitro diagnostics. This year Working Group 1 (WG1) which is responsible for the premier quality standard for medical laboratories, ISO 15189:2007, met with representatives from Working Groups 2 and 3 in Seoul, South Korea, home of palaces and villages and, of course, Hyundai and Kia.

For the last two years, WG1 has been revising the standard's second (2007) iteration of 15189, to make it more readable and self-explanatory. The next iteration of the standard is anticipated to be available in 2012 or 2013.

> **I am most pleased of Canada's participation and contributions and am proud to have had the opportunity to play a part.**
>
> *Dr. Michael Noble*

Canada has played an important role in the creation of this standard for quality and competence and not surprisingly, provinces from coast to coast have been showing an increasing interest on it. Team Canada: Dr. Michael Noble (British Columbia), Dr. Gregory Flynn (Ontario), and Sheila Woodcock (Nova Scotia), ensures that this new iteration of the standard remains consistent with medical laboratory practices in Canada. Canada has also raised a new work item proposal for a new standard to address the collection and transport of medical laboratory samples.

Dr. Noble was the initial organizer of the Canadian Advisory Committee to ISO Technical Committee in 1995 and has been the chair of the committee for the past 16 years. During that time he attended all the meetings and helped Canada host the international plenary meetings in Ottawa (1998) and Vancouver (2008). This year, Dr. Noble is stepping down from the chair position, "I am most pleased of Canada's participation and contributions and am proud to have had the opportunity to play a part," said Dr. Noble, "I look forward to the future contributions, as they come along."

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ISO 15189

ISO 15189 specifies requirements for quality and competence particular to medical laboratories.

It is for use by medical laboratories in developing their quality management systems and assessing their own competence.

It is being develped by the Technical Committee 212 (TC212) - Clinical laboratory testing and in vitro diagnostic test systems - which is composed by four Working Groups (WG):

WG 1 Quality and competence in the medical laboratory
WG 2 Reference systems
WG 3 In vitro diagnostic products
WG 4 Antimicrobial susceptibility testing

Palace, Seoul, South Korea

Team Canada, from left to right: Dr. Michael Noble, Dr Gregory Flyn, and Sheila Woodcock

Village, Seoul, South Korea

CMPT'S INTERNATIONAL EQA PROGRAM

Oman Delegation

Last May, Aisha Salim Al-Jaaidi and Mohamed Khudadat Al-Bulushi from Oman trained at CMPT's International EQA Program.

Apart from being in charge of the Microbiology Proficiency Testing (PT) program for Oman, Aisha and Mohammed are also responsible for a PT program sponsored by the World Health Organization (WHO) for countries in the Middle East.

Oman was chosen, Mohammed explains, because of their location and its continuous participation in WHO initiatives.

Since its independence in1964, Oman's health system has become one of the best in the region.

Oman's health care system is similar to Canada's, with public access and similar laboratory categories to the ones described in the CMPT program. Category C laboratories belong to family clinics, in Oman; there is one centre for every 10,000 people. These laboratories may collect the samples and submit to a bigger laboratory, perform Gram stains but not cultures. Category B centres process samples and have medium complexity. There is one per region (there are 11 regions in Oman) and three in the capital (Muscat). Category A laboratories are complex laboratories, usually in big hospitals like the university, the armed forces, and the Royal hospitals.

Around 26 countries, including four references laboratories, participate in the WHO program. Managing such a complex program is challenging because they don't have the proper infrastructure for it and only recently a microbiologist has joined the program.

As in CMPT, the PT program in Oman has an educational purpose. Aisha is able to track educational opportunities thanks to a detailed results form. The feedback report contains the expected results together with the participant's results and a detailed explanation of what went wrong and how to improve their performance. They also use other means of education, such as WHO guidelines for microorganism detection and identification, or clinical information about the importance of certain organism in a specific infection, similar to what we do with the CMPT critiques.

The time spent at CMPT has been very valuable, Mohammed explains they have improved their technique to prepare PT samples and have learned how to improve sample stability, something of great value to them because of the distances and the temperatures in the region.

"We learned a lot," Aisha says, she doesn't have time to experiment new techniques and samples so what she learned here will be very useful in Oman. In terms of their experience in Vancouver, Mohammed thinks people in the program are very friendly and he says he had a lot of fun.

Back in Oman they will try to buy new supplies they need for the new methods and involve more people as it is important for the success of the program that they have enough help and time to prepare the proper samples.

Mohammed explains they would also like to start making their own Parasitology and Mycology samples so they can have a more established Mycology and Parasitology PT programs.

CMPT has provided international training programs in Thailand, Zimbabwe, South Africa, Belgium, China, and Oman.

Aisha Salim Al-Jaaidi (left), Mohamed Khudadat Al-Bulush (middle), and Dr. Michael Noble at CMPT.

South Africa Delegation

Vivian Fensham, Bhavanni Poonsamy, and Dr. Olga Perovic, from the National External Quality Assessment Program in South Africa received training in External Quality Assessment in Microbiology.

This is the second time delegates from South Africa train at CMPT. Please see the next issue of Connections for a complete interview with the delegates about the PT program in South Africa and their experience at CMPT.

From left to right: Dr. Michael Noble, Vivian Fensham, Dr. Olga Perovic, and Bhavanni Poonsamy.

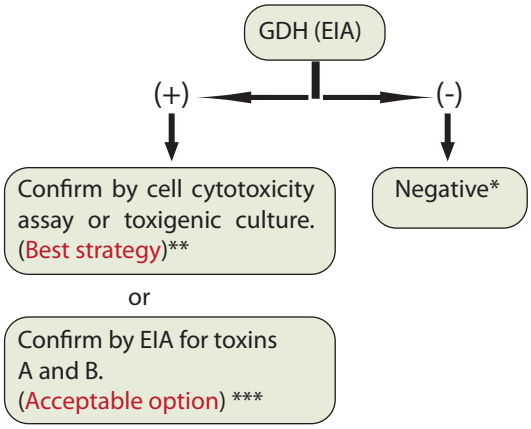
Algorithm for the diagnosis of *Clostridium difficile* infection.

This article has the intention of summarizing the current recommendations by the SHEA and IDSA [1] regarding laboratory diagnosis of Clostridium difficile infection. Further discussion on the strategy will be presented in an upcoming issue of Connections.

Documenting *C. difficile* disease has become a high profile issue because of the increasing awareness of *C. difficile* as both an institutional infection control and as a community based problem. The Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) have recently developed new consensus guidelines1 which include testing recommendations.

These guidelines recommend a two step strategy to diagnose CDI in the clinical laboratory.

TESTING STRATEGY ALGORITHM



The IDSA and SHEA stress that there is currently no testing strategy with optimal sensitivity and specificity so this approach remains an interim recommendation.

NOTES

*A stool sample negative for glutamate dehydrogenase (GDH) test is considered negative for the pathogen. Although most studies have shown a high negative predictive value for the GDH assay, some studies have questioned its sensitivity.

**The sensitivity of cytotoxin detection as a single test for the laboratory diagnosis of CDI is reported to range from 67% to 100%. Toxigenic culture is considered the most sensitive methodology, but it could take up to 9 days to obtain results.

***EIA tests to identify toxins are faster and easier to perform however, the sensitivity of these tests is suboptimal (63% - 94%) when compared with more time-intensive methodologies. Because toxin EIAs have suboptimal specificity, when used alone, the positive predictive value of the results can be unacceptably low.

PCR tests for toxigenic C. difficile are sensitive and specific but more data on utility are necessary before it can be recommended for routine testing.

TO TEST OR NOT TO TEST

To test: diarrheal (unformed) stool; may test formed stool if ileus due to *C. difficile* is suspected.

Not to test: asymptomatic patients, test of cure.

The guidelines also state that repeat testing during the same episode of diarrhea is of limited value and should be discouraged, however, recognizing that with the poor sensitivity of many EIA kits for toxin detection, it is possible for patients with *C. difficile* associated diarrhea to not be confirmed (false negative result). In that situation, it may be reasonable to consider a single repeat test.

1. Cohen S, Gerding D, Johnson S, et al. Clinical practice guidelines for *Clostridium difficile* infection in adults: 2010 update by the society for healthcare epidemiology of America (SHEA) and the infectious diseases society of America (IDSA). Infection Control and Hospital Epidemiology. 2010;31:431-455.

M101-3 *Shigella sonnei* - Reporting susceptibility and following guidelines.

In this recent challenge, susceptibility to ampicillin was performed by the majority of laboratories but discrepancies in the reported results were observed. Seventy-two percent of laboratories reported the isolate as susceptible, 13% reported it as intermediate, and 14% reported it as resistant.

When analyzing the MIC values, it was clear that the discrepancy in results was due to the MIC being at the upper limit of susceptibility but also because of errors in interpretation of MIC breakpoints.

Although according to the CLSI breakpoints none of the laboratories obtained an MIC value in the resistant category (≥32mg/L), 10 participants reported the strain as resistant to ampicillin. Six of those labs obtained an MIC of 8mg/L, susceptible according to the CLSI guidelines.

CMPT does not usually evaluate MIC values, however, how those MIC values are interpreted and then reported is important.

For more on this, please check M101-3 critique.

If laboratories do testing but then don't use guidelines for interpretation, or misinterpret them, the final report is affected.

For ampicillin susceptibility, the MIC of the organism was found to be 8mg/L by most laboratories. This value is at the upper end of the susceptible range and, not surprisingly, some laboratories had results of 16mg/L (intermediate by CLSI standards). If we accept the MIC +/- 1 dilution, which is the usually accepted range of error with susceptibility testing, then MICs of 4, 8, and 16 are to be expected and "I" result is not unreasonable in that circumstance (and it is not an uncommon practice for labs to report I as R). Laboratories that obtained a MIC of 8mg/L should have reported their results as "S" and not "R" which is considered a major error.

Laboratories that use standards other than the CLSI standards (e.g. EUCAST) should indicate that a different interpretive standard is being used.

"Your favourite bacteria" contest

CMPT's coordinator Esther Kwok launched a contest to find out the participant's favourite bacteria. We had a very good response with thirty entries and very interesting explanations on why they are their favourites.

Some love them because of their looks, others because of their "brains". In the world of Microbiology, our hearts can't help having favourites. No matter how nasty they can be to us, microbiologists have developed a certain admiration for these little fighters.

It comes to no surprise that many still prefer them for their beauty. Lovely *Pseudomonas aeruginosa* grabbed the first place with its "lovely aroma" and the lustrous sheen on blood agar plates, "reminds me of the ocean," according to one of the participants.

Streptococcus "milleri" has proven the old proverb that says "The way to a microbiologist's heart is through her/his stomach." In second place, this "caramel smelling" bug caught the hearts of many and left others dreaming of "butterscotch sundaes".

A good challenge can be as attractive as good looks: "I always feel very good about my analyzing skills when I get [*Pasteurella multocida*] right!" "There is a sense of accomplishment When you identify [*Erysipelothrix rhusiopathiae*]," "whenever we have one [*Eikenella corrodens*], we make sure the students see it."

Some love the microbial "Houdinis": the illusionist *Haemphilus influenzae* "The colony almost disappears when you hold up the blood agar," the escapists: *Leptospira* "Have a fascinating way of avoiding the immune response", *Klebsiella pneumoniae* "Is one of those organisms that fit the notion that the bacteria will always figure out how to win!" or *Clostridium difficile* with its spores "Resistant to chemicals, heat, alcohol and antibiotics," and the acrobats: the tumbling *Listeria monocytogenes* and the darting *Campylobacter*.

There are those who have a weakness for the "bacterium next door", the smiley *Mobiluncus*, the friendly *Lactobacillus*, or our old friend *E. coli*. Others instead prefer the danger of a sometimes "very aggressive" *Neisseria meningitidis*, a "chilling … not wimpy" *Clostridium perfringens*, the unpredictable *Staphylococcus aureus*, or a *Shigella* that "could unleash such a torrent (literally) of havoc on one's system!"

Maybe it is because they are fun to say: *Arcanobacterium haemolyticum*, *Malassezia furfur*, or *Haemophilus aphrophilus*, or they allow us to play our favourite sport (*Moraxella catarrhalis*); whatever it is, they have won our hearts and they continue to fascinate us in many interesting and sometimes, strange ways.

Veronica Restelli

"My favorite organism is the bacteria formerly known as "CDC group Ve2".The new name, Falvimonas oryzihabitans has a cool chic French sound to it and its growth from a smooth, satiny-yellow colony to a wrinkled crusty old yellow one overnight mimics my 37 year career in the laboratory where I too changed my name, (Italian not French) and morphed overnight into a wrinkled old lady."

Submitted by Kathleen Cimaglia

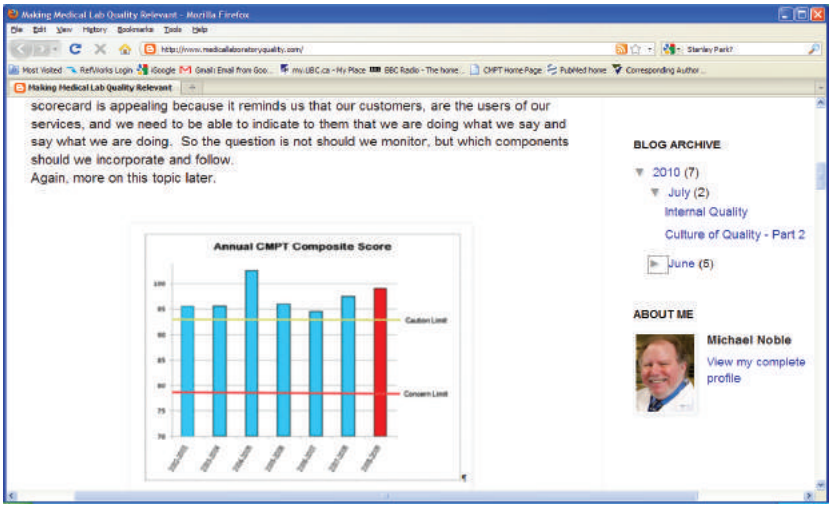
Kathleen Cimaglia is the winner of "Your favourite bacterium" contest, Sarah Armstrong and Jaswal Balbir are the runner ups.

*CMPT would like to thank **VWR** for the donation of prizes for the contest.*

The winners were randomly chosen from the pool of entries. Thank your participation, stay tune for other fun contests!

Announcements

"Making Medical Lab Quality Relevant," a blog by Dr. Michael Noble.



The blog, as Dr. Noble announces it, is "A discussion site for folks interested in improving the quality of medical laboratories."

You can access the blog following the link: http://www.medicallaboratoryquality.com/ or follow it on CMPT's website: www. cmpt.ca

Upcoming events

August

XIIth International Congress of Parasitology (ICOPA)

August 15-20th, 2010 - Melbourne, Australia

Congress website: http://www.asnevents.com.au/icopa/

September

50th ICAAC

September 12-15, 2010 - Boston, MA

Interscience Conference on Antimicrobial Agents and Chemotherapy, organized by the American Society for Microbiology.

Conference website: http://www.icaac.org/

First Annual Neglected Global Diseases Symposium at UBC: Creating Partnerships

September 18th and 19th - UBC- Vancouver ,BC

Event website: http://www.research.ubc.ca/EventView.aspx?eventID=251

MICROBE 2010

September 24 - 26, 2010 - Shefield, UK

More information: http://www.microbe.org.uk/

2nd ASMET - The ASM Emerging Technologies Conference

September 26 - 30, 2010 - Cancun, Mexico

More information

October

ILAC/IAF 2010 Joint Annual Meetings

20 - 29 October - Shanghai, China

Meeting website: http://www.ia lac2010.cn/

48th Annual Meeting of the Infectious Diseases Society of America

21 – 24 October, 2010 - Vancouver, BC

Meeting website: http://www.idsociety.org/IDSA2010.htm

November

Blood Cultures: Current Methods/Future Trends

November 4 • 1:00–2:00 PM Eastern (US)

CLSI teleconference LINK.

December

AST for Infrequently Isolated or Fastidious Bacteria

December 2 • 1:00–2:00 PM Eastern (US)

CLSI teleconference LINK.

ABOUT CONNECTIONS

"Connections" is published quarterly by CMPT and is aimed to the Micribiology Laboratory staff.

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We want to hear from you.

Have an idea for an article? Is there a topic you'd like to see covered? Do you have any questions or want to announce an event? Drop us a line.

Don't like something we're doing? Let us know.