Event

On-site training for IQC, and verification/validation at Takeo Hospital Lab

- **Date:** November 12- 15, 2018
- **Venue:** **Medical Laboratory of Takeo Provincial Hospital, Meeting room**
- **Participants:** Reference**,** National & CPA3 Lab; MoH, DMDP, ITECH, WHO & Intern
- **Posted:**
- **Theme:** Biology Laboratories Sciences and Activities
- **Type:** In-service Training
- **Language:** English and Khmer

In-service training on IQC and verification/validation automate and reagent is aim to provide knowledge to quality officer, equipment officer and involved staff of Laboratory in Cambodia to have concept and participation in improving laboratory quality in term of producing reliable results to the patients and physicians. IQC and verification machines testing and reagent following the ITECH's SOP is one key among some activities in Quality Assurance System.

Output: The 12 sites laboratories under implementation of ITECH project is starting to perform IQC and verification following ITECH's SOP and fulfillment of CamLQMS section 8.9; 8.10 and 1.5.27; 5.3; ISO15189:2012 Clause 5.3.1.2; 5.5.1.

Agenda

Day 1	**Session's**	**Speaker(s)/ Moderator(s)**
8:00 - 8:30	Registration	Secretariat BMLS/ITECH
8:30 - 8:45	Welcome remarks	Director of Takeo Hospital
8:45 - 9:00	Opening remark	Ms. UCH Monipheap Deputy Chief BMLS/DHS
9:00 – 9:15	Photo session	All
9:15 – 9:45	IQC lecture-overview	DR. ONG Siew Kim
9:45 – 10:15	Practicum on IQC handling	Facilitator BMLS/ITECH
10:15 - 10:30	**Break**	
10:30 - 12:10	Practicum on IQC handling	Facilitator BMLS/ITECH
12:10 - 13:30	**Lunch**	
13:30 - 14:00	IQC	Mr.SEK Sophat
14:00 – 15:00	Practicum on LJ chart	Facilitators

15:00 – 15:15	**Coffee break**	
15:15 – 16:45	Westguard rules violation and corrective actions	Mr. SONG Sophanna
16:45 – 17:00	Debrief	ITECH
Time Day 2	**Session**	**Speaker(s)/ Moderator(s)**
8:00 – 8:05	Attendance	ITECH
8:05 – 8:45	Summary from day 1	Dr. ONG Siew Kim
8:45 – 9:45	Overview on verification/validation studies	Dr. ONG Siew Kim
9:45 – 10:00	**Coffee break**	
10:00 – 12:00	Practicum Verification 1	Facilitators
12:00 – 13:00	**Lunch**	
13:00 – 15:00	Practicum Verification 2	Facilitators
15:00 – 15:15	**Coffee/tea break**	
15:15 – 16:45	Practicum Verification 3	Facilitators
16:45 – 17:00	Debrief	ITECH
Time Day 3	**Session**	**Speaker(s)/ Moderator(s)**
8:00 – 8:05	Attendance	ITECH
8:05 – 8:45	Summary day 2	Mr. SEK Sophat
8:45 – 9:45	Verification/validation: interference	Dr. ONG Siew Kim
9:45 – 10:00	**Coffee/tea break**	
10:00 – 12:00	Practicum Verification 4	Facilitators
12:00 – 13:30	**Lunch**	
13:30 – 15:00	Verification/validation: Report writing	Facilitators
15:00 – 15:15	**Break**	
15:15 – 16:45	Practicum Verification 5	Facilitators

16: 45 – 17:00	Debrief	I-TECH
Time Day 4	**Session**	**Speaker(s)/ Moderator(s)**
8:00 - 8:05	Attendance	I-TECH
8:05 – 8:45	Summary day 3	Mr. SONG Sophanna
8:45 – 9:45	Verification/validation SOP	Dr. ONG Siew Kim
9:45 – 10:00	**Break**	
10:00 – 12:00	Practicum Verification 6	Facilitators
12:00 – 13:30	**Lunch**	
13:30 – 15:00	Practicum Verification 7	Facilitators
15:00- 15:15	**Break**	
15:15 – 16:45	Verification lessons learned	Dr. ONG Siew Kim
16:45 – 17:00	Debrief	I-TECH

Report of the workshop

The meeting was being held at Medical Laboratory in Takeo province from 12-15 November 2018 with 41 participants:

- The training started with presentation of the aim and agenda by Dr. Siew Kim ONG about Objective for IQC:
    - Learn the procedure on handling QC:
        1 checking on bottle
        2 reconstitution (SOP)
        3 aliquots
    - Choice of pipette and pipette check
    - Plot Levey-Jenning charts (L J plot)
    - Westgard rules and implementation
- All participants do exercise of practicum on IQC handling with the examination from the Trainers and feedback with video shown.
- Slide presentation of Mr. SEK Sophat on **Important of QC** with example history Data of Kandal Biochemistry lab *(explained by the presenter from that lab).* Continued with handout exercise focus on Mean, Cv, Min and Max.

- Slide presentation by Mr. SONG Sophanna on **Levey Jenning Chart and Westguard Rules:** 6 important points: 1_{2s} 1_{3s} 2_{2s} R_{4s} 4_{1s} $10_{X,}$ systematic & random errors, trend, shift. Continued with exercise of violation errors on LJ chart; Q & A with explanation: every 100 run QC, 5 out of +/- 3sd (out of range), this call random error, this is normal (95%).
- 10 points in Learning Objectives on <u>verification/validation of equipment</u> by Dr.KIM: participant need to refer to read CamLQMS 1: Section 1.5.27 and 2: Section 5.3. Continued with sharing experience from participant:

Activity	Explanation by Dr.KIM
Precision verification : Presented by Ms. IN Thyda, Ang Duong Hospital & KHUM Ravy, Preah Kossamak Hospital, Using real data sheet,	Calculation CV (%) and SD. * Criteria for verification: All calculation of inter CV (mean of 5 days CV) must be ≤ to CV's manufacturer provided in insert kit. * Calculation intraday (3 times/day) should also do for clarifying any query (for look back). * Any fail criteria for verification (lab CV %), before repeat, must look 5: Maintenance (daily, weekly, monthly, preventive maintenance), Temperature chart, QC + Reagents (storage), Pipette QC check, Staff competency * If after repeating, still fail, attach doc and send letter to Manufacturer for solution
Exercise of measuring trueness: find bias by plot number (bias plot) on grilled paper between 2 machine	Linearity data, Y = aX + b: slop, intercept, Y new machine, a slop, X old machine, b intercept (%). *If differ between 10% (old machine has bigger value of 10% than new machine). *If b equal zero, mean Y and X has no differ.
Detection limits (lowest level for detection)	Can repeat run 3 times testing on 1 dilution sample that think the machine gave the result not as expected (theory result).
Diagnostic characteristics (Recovery and linearity study): example of KCH and kandal with graph linearity and correlation acceptable	<u>Linearity Study:</u> KCH data: - Linearity range studied was 51 – 429mg/dL (low 51 and high 431) - Slop = 0.99 - R^2 = 0.99 Kandal data: - Linearity range studied was 36 – 445mg/dL(convert to 20-584 coz chosen low 40 and high 600, using Y = aX+b formula) - Slop = 1.05 - R^2 = 0.96
Analytical interferences (why need to study interference?)	*<u>Interference study (hemoglobin)</u>* 1) *Serum (see insert kit state about interfere with analytes)* 2) *How to calculate volume by using C1V1 = C2V2; some interference (decrease value if using water instead of saline).*
Step 6 carry over,7 Stability,8 Verify all instrument measuring the same test,9 Implementation and 10 Documentation were explained in short summary: - Carry over occurs need corrective action	

- How long you keep your document of equipment? (as long as with the equipment)
- 5.3.1.7 Equipment record of ISO15189 (some points no need to do coz each lab have only 1 lab-not big one)
- Quality indicators table: monthly, on book weekly and follow up with weekly meeting is the key to success for quality improvement (follow quality tool of ITECH developed for 12 labs)
- All reports of verification must have content table
- Experiment design: if run precision test need comparison test

- Question and Answer: When we do verification machine?
- within 2 years if no problem; For Reagents do verification within 6 months
- When spare parts changing the engineer will do (eg. Accuracy, precision,….ect)
- When buy the same batch of machine the same time, verification on 1 machine, the other do on accuracy with monitoring by checking the stability (the same if moving machine in case moving lab facility); if difference time, must do, even the same model/batch.

Result: The workshop finished at noon of 15th November with some interested messages:

- CAP accredited lab never buy ISO; (CAP strict than ISO)
- Clinical trial: chose the lab do testing the patients for this clinical trial research; so Singapore lab got CAP to accept clinical trial (eg. Drug clinical trial of Pfizer company)
- Dec 24-27: Management Review Workshop: (Hospital Director), the below point that all 12 staffs prepare for finding solution, could ask for mentors to help preparing on:
  1. Specimen rejection
  2. TAT
  3. Criteria IRS
  4. Temp chart
  5. Equipment
- Audit: March 2019: external audit; 4 labs occupied by KIM, 4 labs by Nayah, and 4 labs by other oversea person

Photos of the workshop: see attached files

Presentation: see attached files