2019 NEWSLETTER

SLMTA
STRENGTHENING LABORATORY MANAGEMENT TOWARD ACCREDITATION

Annual SLMTA Newsletter **February 2020**

SLMTA in Numbers

As of December, 2019

10	# years SLMTA has been implemented
52	# of countries that have implemented SLMTA
1347	# of laboratories enrolled in SLMTA
127	# of SLMTA laboratories that have been accredited to international standards

2020 Upcoming Events

Mark your calendar

Illuminating the Path to ISO15189 Accreditation*
Johannesburg, South Africa
May 5-15
(Tue-Sat on week 1 and Mon-Fri on week 2)

SLMTA TOT*
Johannesburg, South Africa
June 15-26

Quality Control and Method Validation*
Johannesburg, South Africa
August 17-2

5th ASLM International Conference
Kigali, Rwanda
December 5-10

*Course will be cancelled if the demand is low.

Photo from 2019 QC//MV course, at Roche Scientific Campus, Johannesburg, South Africa

In This Issue

Updates

The original SLMTA curriculum underwent a major update

This is the first major revamp since the program was launched in 2009. The new files (2019 version) are available on the SLMTA website under Toolkit. In addition to minor edits based on feedback gathered from previous TOT workshops, major revisions involve updating the Improvement Methodology in the following activities: ***Using the Model for Improvement*** (originally titled Using the Improvement Method), ***Planning Improvement Projects – Master Class***, and ***Reporting Improvement Projects***. The new version will debut in the 2020 TOT workshop.

The updated Quality Improvement (QI) Methodology in the 2019 version, with its templates, tools and job aids, borrowed heavily from the **LARC** (African Regional Collaborative for Laboratory) initiative - a sister program to SLMTA. LARC focuses on strengthening the laboratory-clinic interface to achieve a "leak proof" viral load cascade. With the testing quality assured, a natural extension is to ensure that laboratory test results are utilized by the clinicians for better patient care. Compared to the simple QI methodology introduced in the original SLMTA curriculum, the one used in LARC is more robust, comprehensive, and aligned with the Institute for Healthcare Improvement's (IHI) principles and materials.

More on LARC

Enhancing laboratory-clinic interface through a quality improvement learning collaborative

LARC is a learning collaborative initiative designed to enhance HIV (or other sectors of healthcare) service delivery by facilitating multidisciplinary teamwork in health facilities using the continuous quality improvement approach. The program is designed to strengthen the viral load cascade to achieve better patient result (i.e., viral load suppression) and to improve institutional capability for viral load scale-up. The program's goal is to "Make Every Test Count."

Continuous Quality Improvement (CQI) tools and methodologies are NOT unique to LARC; however, the emphasis on cross-cadre collaboration, empowerment of facility frontline workers, structured tool-based curriculum, as well as deliverable-driven and result oriented implementation are what made LARC stand out from other CQI programs.

Following a pilot in 6 PEPFAR-supported African countries, LARC was implemented in Kenya and is currently being rolled out in Zimbabwe, with marked improvements observed in all participating sites.

For more information, go to the LARC website. You may also be interested in the LARC Workbook, which contains a multitude of CQI job aids, tools and templates.

SLMTA 1, SLMTA 2, SLMTA 3 – what are the differences?

SLMTA 1 is the original curriculum launched in 2009. It was renamed SLMTA 1 after additional/supplemental programs were created. SLMTA 1 underwent significant revisions in 2019 in order to incorporate a more robust improvement methodology.

SLMTA 2 focuses on four quality system essentials (QSEs) that continued to challenge laboratories post- SLMTA implementation. These 4 QSEs are: corrective action, occurrence management, internal audit, and management review. SLMTA 2 was designed to help laboratories break through their glass ceiling of 2-3 SLIPTA stars and continue their ascent to 5 stars and accreditation. Unlike SLMTA 1, which is organized by the 12 QSEs and focuses on linkage to the SLIPTA checklist, SLMTA 2 uses a process-based approach with direct connections to ISO15189 requirements.

SLMTA 3 (short name for Illuminating the Path to ISO15189 Accreditation) merges SLMTA 1 and SLMTA 2 into a new curriculum using a process-based approach. It aims to facilitate the design of a cost-effective Quality Management System that meets ISO15189 requirements. The 2019 pilot version has been updated to reflect the revisions in SLMTA 1 2019 version.

Bottom Line — The SLMTA TOT still teaches the SLMTA 1 curriculum since it provides the basics. SLMTA 2 is no longer offered since it has been absorbed into SLMTA 3.

Group photo from the inaugural SLMTA 3 course, at Roche Scientific Campus, Johannesburg, South Africa

SLMTA 3 Successfully Piloted

In May 2019, we successfully piloted Illuminating the Path to ISO15189 Accreditation (SLMTA 3) in Johannesburg, where 28 lucky people from 15 countries were selected to attend out of a pool of 68 applicants. See below for some feedback:

- "This training has significantly simplified the work of translating the ISO15189 requirements into action for performance towards quality."
- "Africa has been blessed with this program. It is really making a difference to the whole country."
- "My life has changed and everything will be planned at the beginning. I feel illuminated with the knowledge."

CPD Credits To Be Offered for SLMTA 3 and QC/MV courses

Beginning 2020, we will be able to offer continuing professional development (CPD) credits from the Society of Medical Laboratory Technology of South Africa (SMLTSA) for the 2 courses conducted at Roche Scientific Campus: Illuminating the Path to ISO15189 Accreditation (SLMTA 3) and Statistical QC and Method Validation courses. Our thanks go to Roche and AFENET for making this possible.

Monitoring Molecular Instruments for Viral Load Testing: Clarification from Roche

How do you monitor the molecular instruments for your HIV viral load testing? Do you use the traditional Levey-Jennings Plots? The answer is no. Dr. Tina Kresfelder, Roche Scientific Campus (RSC) Manager in Johannesburg, South Africa, provided some clarification in this letter.

To Whom It May Concern

The Necessity of Levey-Jennings Plots in Monitoring Roche Molecular Instruments

Dear Customer

Please note that Levey-Jennings (LJ) Plots are not necessary for Roche Molecular Instruments. Roche Molecular instruments do not need calibration and run control drift does not need to be determined. The reason for this is that the High and Low Positive controls have specific Ct-ranges in which they must fall during every run. If either of the positive controls fall outside of these ranges, the entire run is invalid, as the samples may have fallen outside of the correct Ct-value as well.

The kit is linear and measures the correct concentration both with the high and with a low titer, thus instead of generating an incorrect result, the sample is resulted as being invalid.

As well as the run controls (viz. High and Low Positive), every sample has a Quantitation Standard (QS) added to it before the extraction process starts. As with the Positive runs controls, the QS must also fall within a specific Ct-range. If it does not, that sample will be resulted as invalid as the result will not be accurate. The QS is also involved in the calculation of the result, as the QS correlates a certain Ct with a certain concentration. With a formula, the algorithm behind the test ASAP/TDF can then calculate the target's concentration from the target's Ct-value.

The calibration of ranges for each QS and control lot is at production, and the encoding of this information is on the RFID/ reagent barcodes, which the instrument reads. This in turn allows the sample/run declaration as valid or invalid, depending on what the value of each QS and Positive control is.

Avoid using LJ plots as an indication of whether the controls drift; the incorporation of this information is in the result calculation. If there is a fault with the controls, the results will be invalidated.

If the control ranges are required, these are available on the DiaLog website under the eLabDoc tab (https://dialog.roche.com).

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