LFA Training 2019/2020 – Health Product Management - Diagnostics – Case Studies

1. Malaria microscopy

Year	No. of laboratories	Patients tested with microscopy in 2018	Giemsa (100gr)	Methanol (2.5l)	Glycerol 2.5l	Slides (50/box)	Gloves (100/box)	Lancets (200/box)	Immersion Oil (1l)	Cotton (500gr roll)
2019	500	645'051	490	1'548	1'290	12'901	6'451	3'225	323	645

Assumptions & calculations			
10ml of Giemsa Stain per patient	6'450'510		
ml into L (1000ml)	6'451		
7.6gr giemsa, 500ml Methanol & 500ml Glycerol to make 1L of solution AND 1ml Methanol to fix the slide	49'024	3'870	3'225
no. of packs of giemsa (100gr), Methanol (2.5L) & Glycerol (2.5L)	490	1'548	1'290

Malaria incidence is declining in Country Z. The Program estimates that 12,907,621 "people presenting with fever" will require a malaria test in 2019. Testing for suspected malaria cases through smear microscopy is performed in 5% of cases. The PR has submitted the following information to the LFA in support of the products and quantities included in the LoHP.

Please review the information provided and determine whether, or not, the CT should approve it. Please provide a recommendation to the CT.

2. HIV laboratory reagents

Reagent	Units	Quantities
BD FACS Count – CD 4/8 reagent kit	50 tests	9'600
BD FACS Count – FacsClean	5 L	1'000
BD FACS Count – FacsRinse	5 L	100
COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0	1 pack of 48 tests	45'000
Cobas Ampliprep Flapless Sample Processing Units	1 pack of 12x24	65'000
COBAS AmpliPrep/COBAS TaqMan Wash Reagent	1 bottle	25'000

In Country X, 476,667 CD4 tests and 2,000,000 VL tests must be done in 2019. The PR has included the following items and quantities in the LoHP and submitted the LoHP to the CT for approval.

Please review the information provided and determine whether, or not, the CT should approve it. Please provide a recommendation to the CT.

3. In country X, a recent OIG audit revealed that over US$ 13 million of lab reagents expired and a deeper analysis revealed that the country has approximately 30 different hematology analyzers, 20 different chemistry analyzers, and 8 different types of molecular technologies for viral load/EID. The country has included the list of reagents for all these different platforms in the LoHP.

   The CT is in a dilemma on what to do, what advice will you give the CT? What data should you review in order to advise the CT? How will you go about resolving the situation and how will you handle the powerful vested interests?

4. In country X, recent data reveals that there are 500 GeneXpert machines, 50% of these have no maintenance, utilization is about 30%. TB Case detection is very low and only 10% of the MDRTB cases are detected.

   Here are some of the challenges identified:

- There is high donor dependency
- There is a widespread shortage of lab workers
- Infrastructure to support GeneXpert fleet is not adequate – power outages, dusty environments etc.
- Specimen rejection rates and invalid rates are high >15%
- 30% utilization
- Specimens are bought to the testing labs whenever a health worker comes, or the patient goes to the testing lab
- 50% of GeneXpert machines (4-module) not functioning or yielding high failed results due to poor handling (dust, power interruptions), poor maintenance (module failure, cartridge issue or other problem) or machine use beyond calibration date
- Delayed or non-reporting of equipment breakdown by lab staff and mentors beyond warranty period
- Quality of results cannot be guaranteed as there is no quality system in place.
- Results are not getting back to the clinician and patient in a clinically relevant time period.
- There is strong political advocacy to use GeneXpert for all TB suspects and procure more machines. CT is under pressure to improve access and find the missing cases using the latest technology.

   What advice will you give the CT and what data will you use to provide the CT with evidence-based advice?

5. Country X has 12 conventional Viral Load testing labs and most of the specimens are coming from the health centers within a 15 km radius. The quality of the testing is assured and TAT for VL and EID is 40 days. A new project to introduce new POC technologies came into the country 5 years ago through the PMTCT program and NACP, but the lab director has been unaware of the project until the time that the project was closing.

   The funder of the project now wants to 'transition the project to the Global Fund grant' and the PR has added these reagents to the LOHP. Costs are not known but the transition is imminent, and all the political levers are being used by the project funder. What data will you gather to assist the CT make an informed decision and what advice will you give?