



In Search of Better Health

Leveraging Existing High-Throughput HIV Platforms for Molecular TB Testing in Busia, Kenya- Cost and Operational Insights

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Declarations

Roche funded the MTB Utilize Study

Roche will pay an honorarium for this presentation

Kenya's TB Diagnostic Gap

- Worldwide:
 - 10.7m infected, 1.23m deaths globally 2024
- Kenya:
 - 117k cases, 78% notified, 22% missing
- Busia:
 - Smear + GeneXpert are finding only 1/3 of the cases
 - Busia Treatment success: 86.5% vs target 92%
 - Active case finding can overwhelm extant testing capacity

Integrated Diagnostic Network (IDN)

Leadership and governance, Infrastructure, Service delivery models....

- WHO advocates shift from siloed to horizontal
- Leverage Cobas 8800 HIV platform for Cobas MTB and MTB-RIF/INH

Leveraging Existing HIV Platforms for Molecular TB Testing in Busia

- 1,208 remnant sputum samples, batched over 12 days on Cobas 8800
- 416 samples on GeneXpert across 73 days
- Costing: HE²RO Testing Platform Cost Model, ingredients-based, govt perspective
- Feasibility: qualitative survey

HE²RO Testing Platform Cost Model Inputs

- Reagents, consumables, staff, equipment annualized
- 5% discount, transport
- 18% overhead costs
- Several other assumptions were made

- 3 testing scenarios: Best, Expected, Worst

Estimated staff costs

Role	Average annual salary (USD)	Source	Working days	Working hours	Salary cost per hour
			per year	per day	(USD)
Laboratory technician	9,210	Study PI	244	8	5.11
Laboratory manager	10,674	Study PI	244	8	5.92
Laboratory pathologist	47,952	Study PI	244	8	26.61

Estimated equipment costs related to testing on the Cobas 8800 system

Equipment	Units	Rent/ purchase	Purchase price (USD)	Source	Shared? ^a
Cobas 8800 system	1	Purchase	600,000	ASLM database	No
Sonicator	1	Purchase	3,700	Study protocol	No
Biological safety cabinet	1	Purchase	6,500	Study protocol	Yes
Vortex (mixer)	1	Purchase	500	Study protocol	Yes
Centrifuge	1	Purchase	500	Study protocol	Yes
Refrigerator	1	Purchase	800	Study protocol	Yes
Pipettes (single channel)	3	Purchase	900	Study protocol	Yes
Autoclave	1	Purchase	450	Study protocol	Yes
Cooler boxes	3	Purchase	450	Study protocol	Yes

Activities required to conduct MTB testing on a Cobas 8800 system

	Activity	Staff	Time per test (minutes)
Activity 1	4 mL of MIS is added to 2 mL of raw sputum	Laboratory tech	1.0
Activity 2	Combined samples are vortexed for 30–60 seconds under biosafety cabinet	Laboratory tech	0.016
Activity 3	Samples are incubated for 60 minutes at 15–30°C	Laboratory tech	0.016
Activity 4	The samples are vortexed a second time after incubation for 30–60 seconds	Laboratory tech	0.016
Activity 5	1.2 mL of sample is pipetted into a 16mL testing tube suitable for the Cobas 8800 system	Laboratory tech	1.0
Activity 6	Samples are loaded onto a sonicator for a total time of 5 minutes	Laboratory tech	0.016
Activity 7	Samples are centrifuged for ≤ 1 minute at 3000 rpm	Laboratory tech	0.016
Activity 8	Samples are loaded onto Cobas 8800 system testing rack	Laboratory tech	0.082
Activity 9	Perform lab administrative tasks, including result verification	Laboratory supervisor	2.0

Material costs of testing on the Cobas 8800 system

Item	Cost (USD)	Source	Cost per unit (USD)	Cost per test (USD)
Reagents: Cobas MTB and Cobas MTB-RIF/INH tests	8.90	Study protocol	8.90	8.90
Sputum containers	86.73	Study protocol	0.09	0.09
Sterile homogenization glass beads	337.24	Study protocol	337.24	0.86
Sterile polypropylene centrifuge tubes	198.89	Study protocol	0.40	0.40
Pipette tips	129.71	Study protocol	0.14	0.14
Gloves	52.39	Study protocol	0.05	0.05

INH, isoniazid; MTB, *Mycobacterium tuberculosis*; RIF, rifampicin; USD, United States Dollars.

Estimated equipment costs related to testing on the GeneXpert 4-module system (base case analysis)

Equipment	Units	Rent/purchase	Purchase price (USD)	Source	Shared? ^a
GeneXpert 4-module system	1	Purchase	17,000	ASLM database	No
Laptop	1	Purchase	1,500	ASLM database	No
Biological safety cabinet	1	Purchase	6,500	Study protocol	Yes
Vortex (mixer)	1	Purchase	500	Study protocol	Yes
Centrifuge	1	Purchase	500	Study protocol	Yes
Refrigerator	1	Purchase	850	Study protocol	Yes
Autoclave	1	Purchase	800	Study protocol	Yes
Cooler boxes	3	Purchase	450	Study protocol	Yes

ASLM, African Society for Laboratory Medicine; USD, United States Dollars.

^aEquipment that is shared across all tests conducted in the laboratory (i.e., general equipment).

Activities required to conduct MTB testing on a GeneXpert 4-module system

Futura	Activity	Staff	Time per test (minutes)
Activity 1	Label each Xpert MTB/RIF assay cartridge with the sample ID	Laboratory tech	0.668
Activity 2	Carefully open the lid of the sputum collection container. Pour or pipette (pipette not provided) approximately 2 times the volume of the sample reagent into the sputum (2:1 dilution, sample reagent: sputum).	Laboratory tech	2.0
Activity 3	Replace and secure the lid. Shake vigorously 10–20 times or vortex for ≥ 10 seconds	Laboratory tech	1.332
Activity 4	Incubate the sample for a total of 15 minutes at 20–30°C. Between 5–10 minutes into the incubation period, shake vigorously 10–20 times or vortex for ≥ 10 seconds.	Laboratory tech	1.332
Activity 5	Open the cartridge lid, then open the sample container. Using the provided transfer pipette, aspirate the liquefied sample close to the line on the pipette.	Laboratory tech	2.0
Activity 6	Dispensing the sample slowly to minimize the risk of aerosol formation, transfer the sample reagent-treated sample into the sample chamber of the Xpert MTB/RIF cartridge.	Laboratory tech	1.0
Activity 7	Turn on the GeneXpert Instrument System. Log on to the GeneXpert Instrument System software. In the GeneXpert System window, click 'Create Test'. Scan or type in the patient ID and the sample ID. Scan the barcode on the Xpert MTB/RIF assay cartridge. Click 'Start Test'.	Laboratory tech	1.0
Activity 8	Perform lab administrative tasks, including result verification	Laboratory supervisor	1.0

Material costs of testing on the Xpert system

Item	Cost, (USD)	Source	Cost per unit (USD)	Cost per test (USD)
Xpert MTB/RIF assay cartridge	7.97	Literature	7.97	7.97
Sputum containers	86.73	Study protocol	0.09	0.09
Tubes	198.89	Study protocol	0.40	0.40
Latex gloves	52.39	Study protocol	0.05	0.05

MTB, *Mycobacterium tuberculosis*; RIF, rifampicin; USD, United States Dollars

Genexpert 4 module testing at hospital laboratory- TAT

	Collection to arrival			Arrival to testing			Testing to result dispatch		
# of days	N	Laboratory% ^a	Real% ^b	N	Laboratory% ^a	Real% ^b	N	Laboratory% ^a	Real% ^b
Same day	334	72.50	22.90	77	16.90	5.30	442	96.90	30.30
1	48	10.40	3.30	212	46.50	14.50	14	3.10	1.00
2	25	5.40	1.70	67	14.70	4.60	0	0.00	0.00
3	13	2.80	0.90	26	5.70	1.80	0	0.00	0.00
4	17	3.70	1.20	24	5.30	1.60	0	0.00	0.00
5–7	19	4.10	1.30	4	0.90	0.30	0	0.00	0.00
8–30	5	1.10	0.30	25	5.50	1.70	0	0.00	0.00
>30	0	0.00	0.00	21	4.60	1.40	0	0.00	0.00
Total	461	100.00%	—	456	100.00%	—	456	100.00%	—
Missing ^c	999	—	68.40%	1004	—	68.80%	1004	—	68.80%
Grand total	1460	—	100.00%	1460	—	100.00%	1460	—	100.00%

^aLaboratory % refers to the turnaround time for samples tested when cartridges were available to execute.

^bReal% refers to the turnaround time for overall samples collected, independent of implementation limitations, which in this case were stock-outs.

^cMissing due to stockouts during the study period.

Sample transport costs to laboratories

	Samples per trip	Cost per Km, KES	Distance (Km)	Cost per sample, KES	Cost per sample, USD
Roche (Ave)	25	30	70	84	0.73
GXP (Ave)	25	30	20	24	0.21

Km, kilometers; KES, Kenyan Shillings, PI, principal investigator; USD, United States Dollars.

Operational findings

1. Throughput Reality - Consistent vs Sporadic

- Cobas: Median 94/day, Mean 101, 12 days/month STABLE
- GeneXpert: Median 4/day, Mean 5.7, 9.1 days/month SPORADIC

2. Cost Result - Stability Wins

- Cobas Expected \$17.48, range \$16.04-\$18.97 = \$2.93 variance
- GeneXpert Expected \$23.53, range \$16.47-\$78.63 = \$62.16 variance

3. Cost Drivers

Cobas:

- Cobas: 69% reagents, equipment \$0.03
- GeneXpert: Equipment 48.4%, \$9.65 expected to \$61.29 worst

Operational findings -

3. Feasibility - Usability

- 4/4 technicians unanimous: effective & feasible
- +1 hour HIV turnaround, negligible
- Resilience Argument
- -GeneXpert delays up to 97 days, many samples never got result
- - Hub-and-spoke fallback

Study Limitations

- Single county,
- no clinical outcomes,
- assumes spare capacity

Conclusions

Feasible, acceptable, cost-efficient, superior economic stability

Policy Implications

- Scale integrated to COMPLEMENT near-patient, not replace
- Focus on total cost of ownership



In Search of Better Health

Dramatis personae

Mary Inziani, Lucy Okubi, James Sitati, Roche, Joanne Sickler, Nedu Ilhezurike, James Karichu, Susie Perez, Jesse Canchola, Anna Barcena, Holly MacAllister. ROCHE. KEMRI. Port Victoria SCH, Khunyangu SCH, Kocholia SCH. Busia County Government.