



NATIONAL HEALTH
LABORATORY SERVICE

GeneXpert MTB/RIF

Progress Report

March 2016

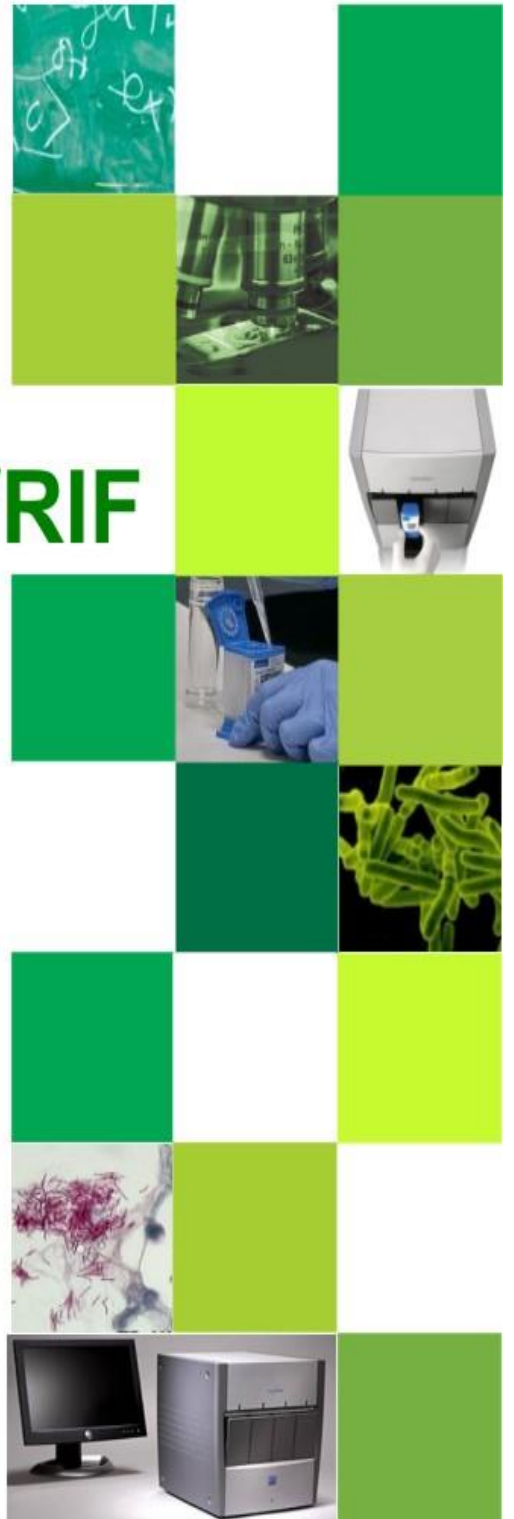




Table of Contents

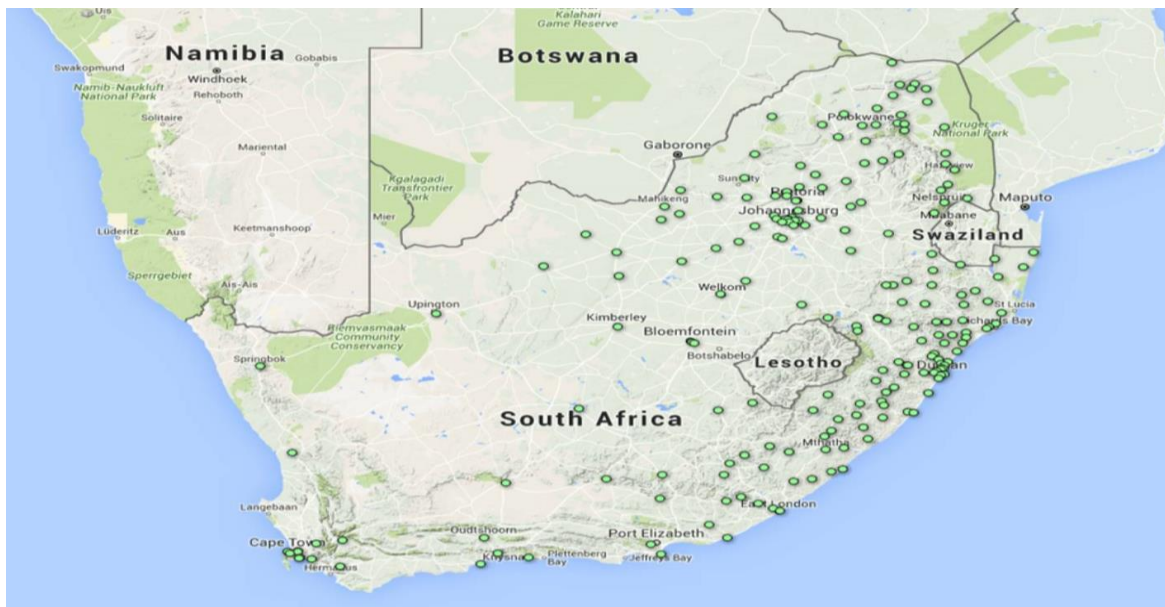
Background to project	3
Assays performed to date	3
Correctional Services	5
Peri-Mining	6
Rif Concordance	7
Training: Laboratory and Clinical	7
Challenges identified during the course of the project to date	8
Upcoming Plans	8

1. Background to Project

This project was initiated at the request of the Honorable Minister of Health, Dr Aaron Motsoaledi, in early 2011, following the World Health Organization’s strong recommendation published in December 2010 which stated that “the new automated DNA test for TB be used as the initial diagnostic test in individuals suspected of MDR-TB or HIV/TB”. In essence this comprises the majority of those with presumptive TB in South Africa. The programme was further expanded to directly support the screening for TB and HIV in high risk populations in correctional centres and in peri-mining communities.

GeneXpert Placements

Figure 1: Current GeneXpert Placements (211 testing centers, 314 analysers, GX4: 115; GX16-8: 1; GX16: 189; GX48:1; GX80: 8)



2. Assays performed to date

In summary, a total of 8,185,277 specimens have been processed to date (31 March 2016). In March 2016, a total 200,034 specimens were processed. The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 8.71% (17 426).

3 | Disclaimer: This is a dynamic specimen dataset requiring regular update and it should be noted that figures may change as linkages to individuals tested are updated.



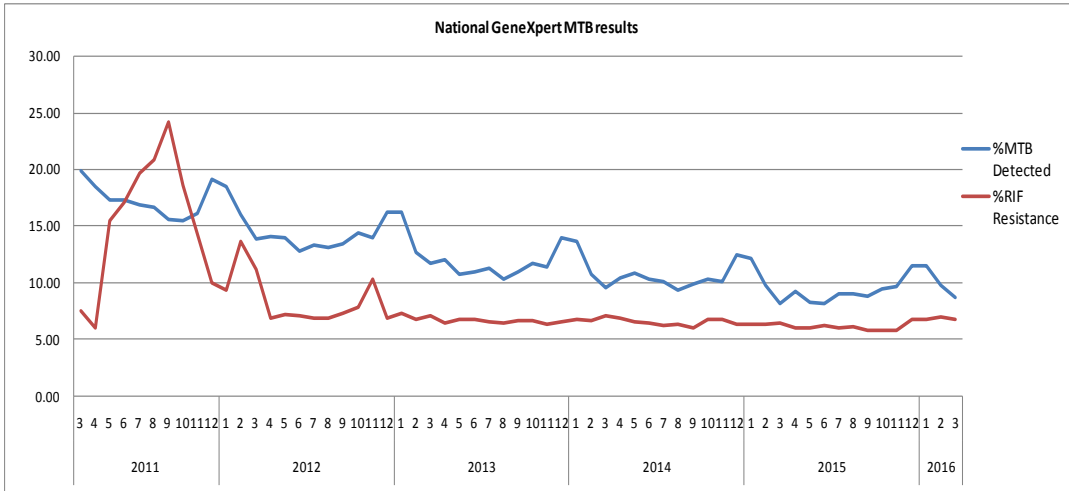
Table 1: National GeneXpert MTB Results (Cumulative)

Year	MTB Detected	MTB Not Detected	Test Unsuccessful	Total	% MTB Detected
2011	34,421	165,582	5,441	205,444	16.75
2012	93,248	544,109	16,903	654,260	14.25
2013	201,681	1,478,260	51,773	1,731,714	11.65
2014	249,014	2,060,754	62,038	2,371,806	10.50
2015	245,912	2,343,453	57,193	2,646,558	9.29
2016	55,814	505,184	14,497	575,495	9.70
TOTAL	880,090	7,097,342	207,845	8,185,277	10.75

Table 2: National GeneXpert RIF Results (Cumulative)

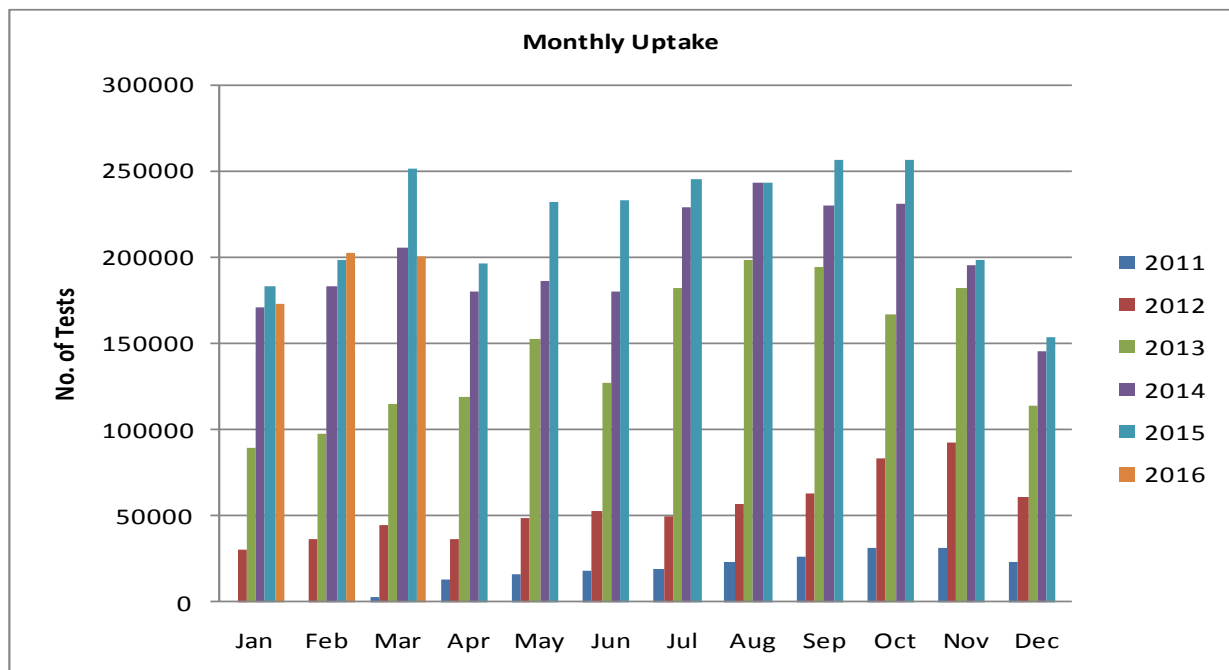
Year	Inconclusive	Resistant	Sensitive	No RIF Result	Total	% RIF Resistant
2011	311	5,634	28,171	305	34,421	16.37
2012	1,288	7,809	83,321	830	93,248	8.37
2013	5,122	13,451	182,015	1,093	201,681	6.67
2014	6,068	16,312	226,254	380	249,014	6.55
2015	3286	15042	227357	227	245,912	6.12
2016	585	3425	51756	48	55,814	6.14
Total	16,660	61,673	798,874	2,883	880,090	7.01

Figure 2: MTB Positivity and RIF Resistant rates overtime



4 | Disclaimer: This is a dynamic specimen dataset requiring regular update and it should be noted that figures may change as linkages to individuals tested are updated.

Figure 3: GeneXpert Monthly Uptake



Decrease in number of tests reported for the month of March 2016 compared to March 2015 due to the Easter Holidays falling in the month of March instead of the usual April month.

3. Correctional Services

In order to improve TB control in all 242 correctional facilities in South Africa, the NHLS is working in partnership with the Department of Correctional Services (DCS), NDoH, Aurum Institute, TB/HIV Care Association and Right to Care to ensure access to regular HIV- and TB-related screening, testing and treatment of up to 150,000 offenders through the Global Fund programme. Xpert MTB/Rif testing is being provided at either one of the 7 on-site labs, or at the nearest NHLS referral laboratory. Total of 225,127 specimens have been processed to date (31 March 2016). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 4.46% (10,044).

Table 3: Correctional Service GeneXpert MTB Results (Cumulative)

Year	MTB Detected	MTB Not Detected	Test Unsuccessful	Total	% MTB Detected
Oct- Dec 2013	662	7,236	142	8,040	8.23

Jan- Dec 2014	3,620	55,995	1,004	60,619	5.97
Jan- Dec 2015	4,831	124,589	2,216	131,636	3.67
Jan -Mar 2016	931	23,369	532	24,832	3.75
Total	10,044	211,189	3,894	225,127	4.46

Table 4: Correctional Service GeneXpert RIF Results (Cumulative)

Year	Resistant	Inconclusive	Sensitive	No RIF Result	Total	% RIF Resistant
Oct- Dec 2013	27	7	626	2	662	4.08
Jan - Dec 2014	188	107	3,323	2	3620	5.19
Jan - Dec 2015	190	99	4,530	12	4831	3.93
Jan -Mar 2016	34	10	887	0	931	3.65
Total	439	223	9,366	16	10,044	4.37

4. Peri-Mining Communities

NHLS, together with the Aurum Institute, has been appointed by NDoH (under the Global Fund grant) to provide services to implement interventions aimed at improving TB and HIV/AIDS management for vulnerable peri-mining communities (estimated at around 600,000 people) in 6 main mining districts. Six staffed and GeneXpert-equipped mobile TB units undertake Xpert MTB/RIF testing for TB in these communities. A total of 48,756 specimens have been processed to date (31 March 2016). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 1.08% (528).

Table 5: Peri-mining GeneXpert MTB Results (Cumulative)

Year	MTB Detected	MTB Not Detected	Test Unsuccessful	Grand Total	% MTB Detected
Jun to Dec 2014	56	2410	66	2531	2.17
Jan to Dec 2015	405	37021	609	38036	1.07
Jan to Mar 2016	67	7,935	187	8189	0.82
Total	528	47366	862	48756	1.08

Table 6: Peri-mining GeneXpert RIF Results (Cumulative)

Year	Inconclusive	Resistant	Sensitive	No Results	Total	% Resistant
Jun to Dec 2014	3	2	51	0	56	3.57
Jan to Dec 2015	10	27	364	4	405	6.67

Jan to Mar 2016	1	3	57	6	67	4.48
Total	14	32	472	10	528	6.06

5. mHealth and Linkage-to-Care Programme for MDR-TB

Emocha (now called miLINC)

In 2015 a miLINC application was launched in South Africa to link thousands of patients afflicted with multi-drug resistant tuberculosis (MDR-TB) to specialised clinics for Care.

As of 31 March 2016, miLINC has screened over 7668 patients at 18 facilities. miLINC has linked 35/56 Rif Resistant patients into care in an average of 3 days and 8 hours.

Table 7: Summary from miLINC Dashboard (March 2015 to 10 February 2016)

*Provinces initiated	KZN, EC
Number of facilities initiated	28
Number of patients screened	8607
Rifampicin Resistant (R-R)	58(1%)
TB sensitive	10%
TB Negative	78%
R-R patients linked to care	35
Average time linked to care	3 days, 8 hours

Dashboard is currently only reporting on 18 facilities. The dashboard is still under construction. *Not all districts initiated.

6. RIF Concordance

A total of 45,486 Rif Resistant cases were reported between 1 March 2011 and 30 September 2015 by GeneXpert testing, 48% had a follow up confirmatory tests performed by either culture or LPA, of those there was a concordance of 86% for RIF resistance between GX and MGIT and 88% between GeneXpert and LPA.

Table 7: Rif Concordance by LPA or DST (from March 2011 to 30 September 2015)

		GeneXpert Confirmation & Rif Concordance									
Province	Rif Resistant Cases	MGIT					LPA				
		Confirmed		Rif Concordance		Pre-analytical/No result	Confirmed		Rif Concordance		Indeterminate
		#	%	#	%		#	%	#	%	
Eastern Cape	8,663	348	4.0%	233	67.0%	3	2,823	32.6%	2,612	92.5%	11
Free State	2,701	217	8.0%	120	55.3%	0	852	31.5%	699	82.0%	187
Gauteng	6,297	219	3.5%	146	66.7%	4	1,604	25.5%	1,437	89.6%	29
Kwazulu-Natal	13,869	3,737	26.9%	3473	92.9%	0	3,630	26.2%	3,252	89.6%	166
Limpopo	2,101	94	4.5%	71	75.5%	2	508	24.2%	406	79.9%	21
Mpumalanga	3,333	679	20.4%	667	98.2%	0	1,258	37.7%	1,079	85.8%	3
North West	2,397	203	8.5%	139	68.5%	0	769	32.1%	621	80.8%	52
Northern Cape	1,341	283	21.1%	215	76.0%	3	566	42.2%	432	76.3%	34
Western Cape	4,784	185	3.9%	64	0.0%	0	3,753	78.4%	3,470	92.5%	3
National	45,486	5,965	13.1%	5,128	86.0%	12	15,763	34.7%	14,008	88.9%	506

*table generated quarterly in order match GX RESULTS with follow up confirmatory tests

7. Training: Laboratory and Clinical

A total of 2,084 laboratory staff and 10,447 health care workers have been trained since December 2011. This will be an ongoing process to support NDoH training on clinical algorithm. Laboratory staff received both clinical and technical training.

Table 8: Laboratory staff trained for March 2016

Province	No. of Labs Trained	No. of Participants
Eastern Cape	1	6
Northern Cape	2	8
Mpumalanga	1	14

KZN (Advanced training)	30	30
-------------------------	----	----

Table 9: Health Care workers trained for March 2016

Province	No. of Facilities Trained	No. of Participants
Limpopo	56	56

8. Challenges identified during the month of December

- None

9. Upcoming plans

- Roll out Roll out of Xpert MTB/RIF Ultra assay towards the end of 2016
- Roll out of new software 4.7b for the GX16 and GX4 instruments.
- Continuous monitoring of sites through remote connectivity to improve program performance
- Development of the GeneXpert dashboard to improve program performance
- Recruitment of additional trainers to maximize service provided for NHLS labs and NDoH
- World TB Day event in Lephalale Limpopo

10. Publications

- None