



NATIONAL HEALTH
LABORATORY SERVICE

GeneXpert MTB/RIF

Progress Report

September 2016



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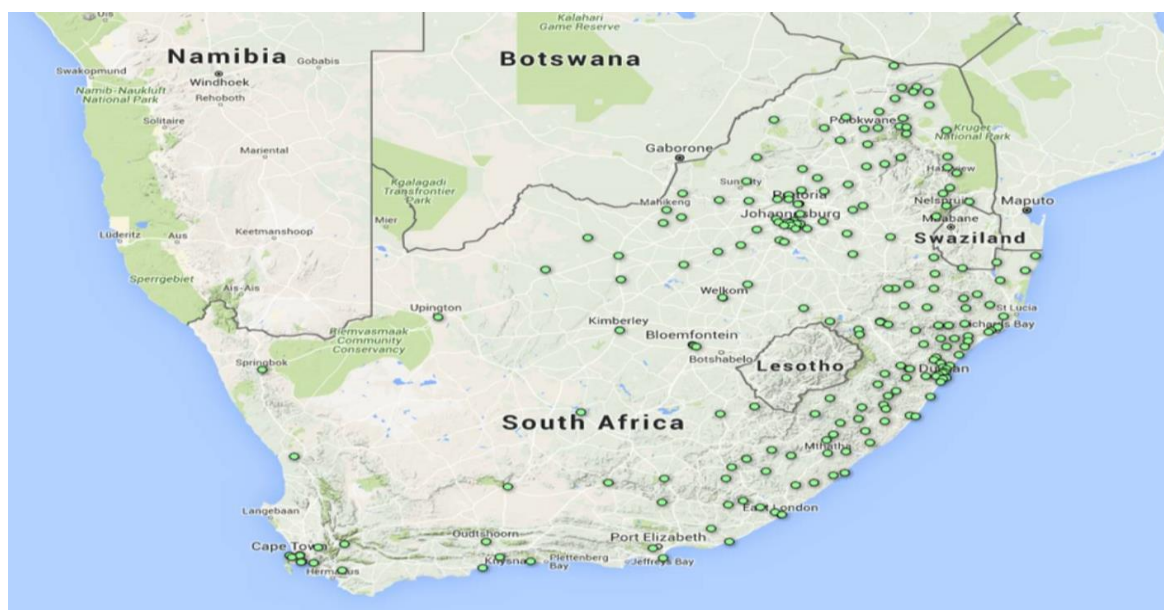
1. Background to Project

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 9,485,632 specimens have been processed to date (30 September 2016). In September 2016 a total 248,440 specimens were processed. The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 8.68% (21 554).

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	245 916	2 343 403	57 217	2 646 536	9.29
2016	169 289	1 669 982	36 601	1 875 872	9.02
TOTAL	993 569	8 262 090	229 973	9 485 632	10.47

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	3 288	15 043	227 358	227	245 916	6.12
2016	1 889	10 502	156 771	127	169 289	6.20
Total	17 966	68 751	903 890	2 962	993 569	6.92

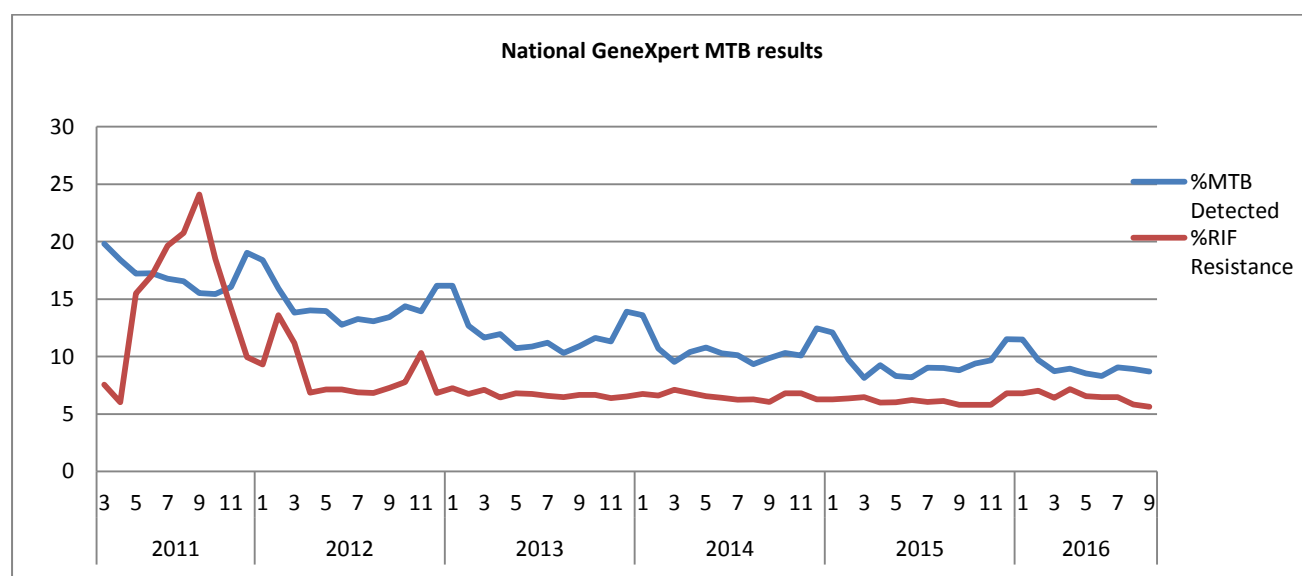
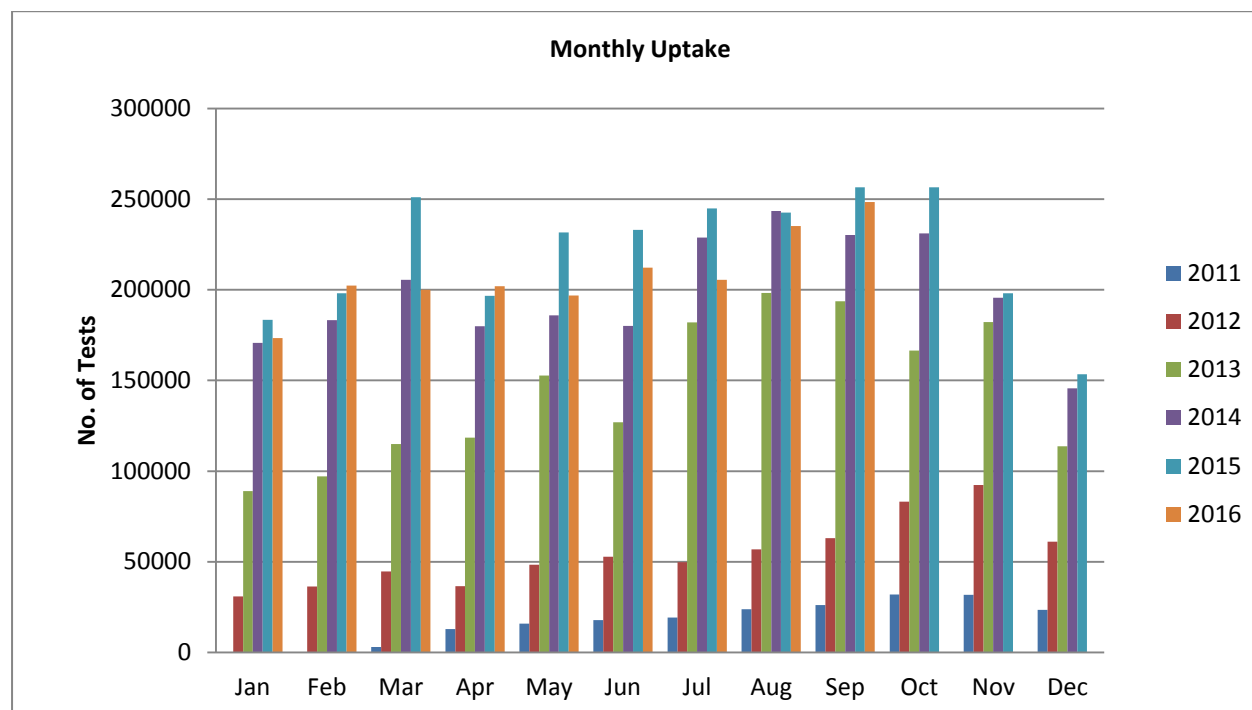
Figure 2: MTB Positivity and RIF Resistant rates overtime


Figure 3: GeneXpert Monthly Uptake



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 258,819 specimens have been processed to date (30 September 2016). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 4.51% (11,664).

Table 3: Correctional Service GeneXpert MTB Results (Cumulative)

Year	MTB Detected	MTB Not Detected	Test Unsuccessful	Total	% MTB Detected
Oct- Dec 2013	662	7236	142	8040	8.23
Jan- Dec 2014	3620	55995	1004	60619	5.97
Jan- Dec 2015	4831	124589	2216	131636	3.67
Jan -Sep 2016	2551	54866	1107	58524	4.36
Total	11664	242686	4469	258819	4.51

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	3323	2	3620	5.19
Jan - Dec 2015	190	99	4530	12	4831	3.93
Jan -Sep 2016	104	29	2417	1	2551	4.08
Total	509	242	10896	17	11664	4.36

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 62,274 specimens have been processed to date (30 September 2016). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 1.10% (666).

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

Year	MTB Detected	MTB Not Detected	Test Unsuccessful	Total	% MTB Detected
Jun to Dec 2014	55	2410	66	2531	2.17
Jan to Dec 2015	406	37021	609	38036	1.07
Jan to Sep 2016	223	21058	426	21707	1.03
Total	684	60489	1101	62274	1.10

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

Year	Inconclusive	Resistant	Sensitive	No RIF	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 Sep 2016	8	14	194	7	223	6.28
Total	21	43	609	11	684	6.29

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 54,225 Rif Resistant cases were reported between 1 March 2011 and 10 June 2016, 49% 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 89% between GeneXpert and LPA.

Table 8: Rif Concordance by LPA or DST (from March 2011 to 10 June 2016)

		GeneXpert Confirmation & Rif Concordance									
Province	Rif Resistant Cases	MGIT					LPA				
		Confirmed		Rif Concordance		Pre-analytical /No result	Confirmed		Rif Concordance		Indeterminate
		#	%	#	%		#	%	#	%	
Eastern Cape	10 399	390	3.8%	257	65.9%	3	3 565	34.3%	3 285	92.1%	18
Free State	3 069	224	7.3%	122	54.5%	0	980	31.9%	801	81.7%	189
Gauteng	7 583	267	3.5%	183	68.5%	4	1 939	25.6%	1 733	89.4%	31
Kwazulu-Natal	16 423	4 575	27.9%	4265	93.2%	0	4 724	28.8%	4 228	89.5%	188
Limpopo	2 449	93	3.8%	70	75.3%	2	624	25.5%	495	79.3%	20
Mpumalanga	3 923	803	20.5%	788	98.1%	0	1 483	37.8%	1 280	86.3%	4
North West	2 880	257	8.9%	179	69.6%	0	928	32.2%	727	78.3%	55
Northern Cape	1 674	331	19.8%	251	75.8%	3	701	41.9%	537	76.6%	35
Western Cape	5 825	227	3.9%	81	0.0%	0	4 611	79.2%	4 232	91.8%	3
National	54 225	7 167	13.2%	6 196	86.5%	12	19 555	36.1%	17 318	88.6%	543

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

7. Training: Laboratory and Clinical

A total of 2,141 laboratory staff and 11,514 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 9: Laboratory staff trained for September 2016

Date	District	Laboratory	No of Participants
12-Sep-16	Lejweleputswa	Welkom	4
13-Sep-16	City of JHB	Helen joseph	3
14-Sep-16	Ekhuruleni	Thelle Mogoerane	9
15-Sep-16	West Rand	Dr Yusuf Dadoo	3
22-Sep-16	Capricon	Lebowakgomo	2
23-Sep-16	Nkangala	Kwamhlanga	2
27-Sep-16	Amathole	Butterworth	3
30-Sep-16	Motheo	Pelonomi	6

Table 9: Health Care workers trained for September 2016

Date	District	Facility	No of Participants
09-Sep-16	Ekhuruleni	NSB	20
13-Sep-16	Ekhuruleni	SSD	27
14-Sep-16	Tshwane	ODI	10
15-Sep-16	Tshwane	Kgosi Mampuru DCS	12

15-Sep-16	Nkangala	Siyabuswa	22
16-Sep-16	Ekhuruleni	ESB	34
22-Sep-16	Ethekwini	Charles Johnson Hospital	29
23-Sep-16	Tshwane	Themba CHC	15
27-Sep-16	Ekhuruleni	Leeukop DCS	17
27-Sep-16	Madibeng	District office	20
28-Sep-16	Tshwane	Jubilee	14
29-Sep-16	Tshwane	District office	15

8. Rejected Specimens

Rejections of GeneXpert specimens mostly occur as a result of Clerical errors (incorrect labelling and or incomplete request forms), cancellations (clinical errors), unsuitable specimens and insufficient volumes. In September, 13 719 (5.23%) specimens were rejected. On-going training remains a practical tool to guarantee improvement in specimen collection and labelling.

Figure 4: Rejections rate (Jan to Sep 2016)

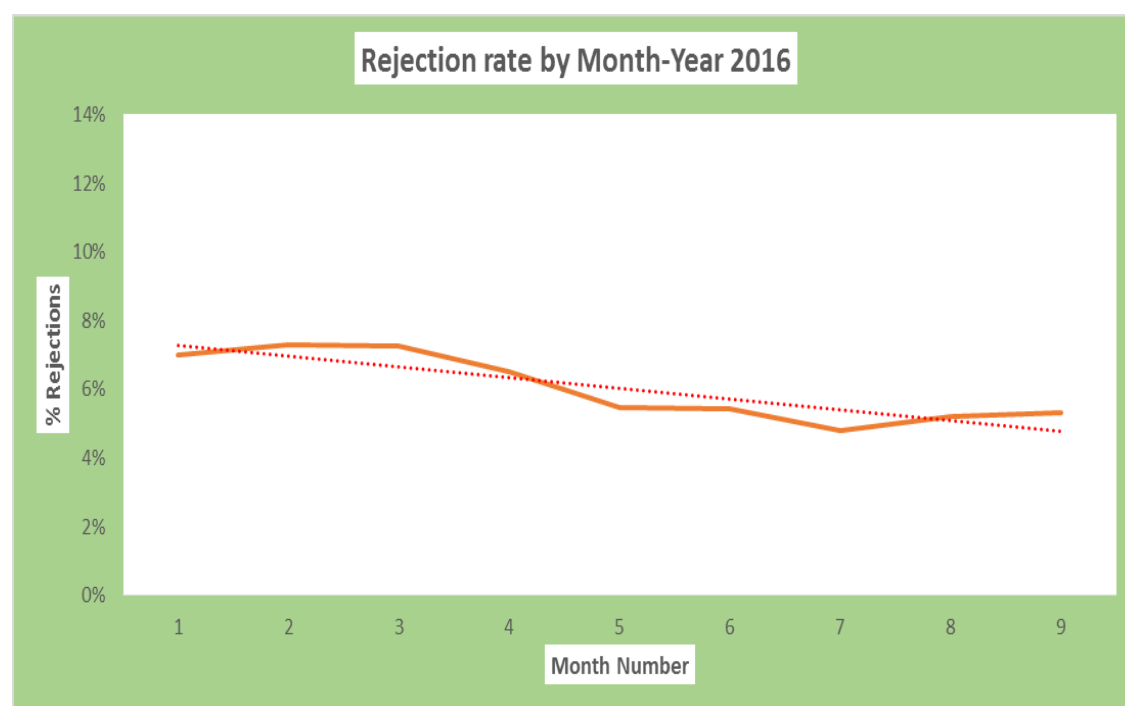
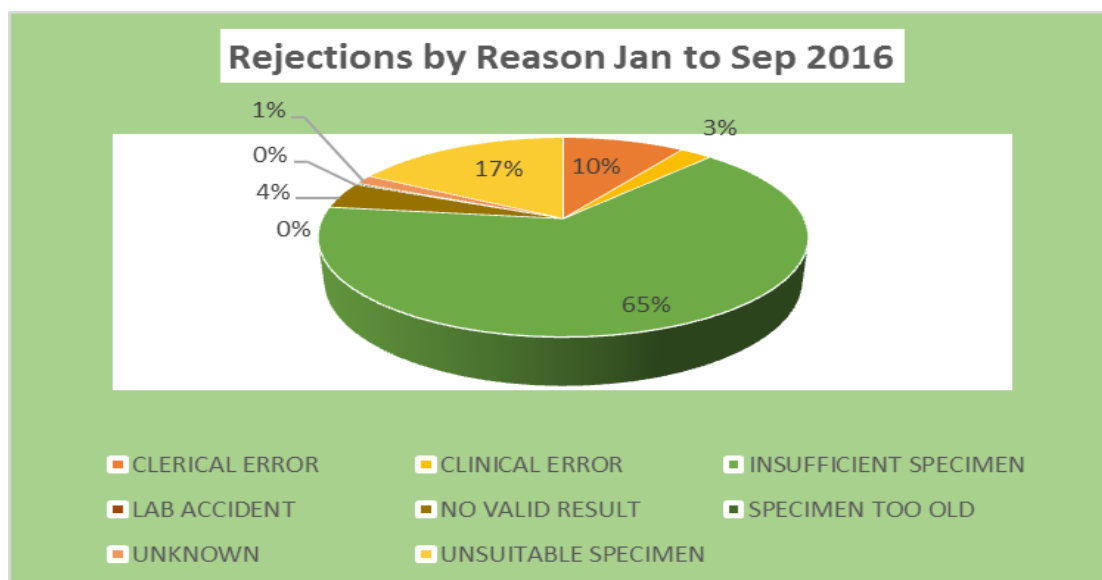


Figure 5: Rejections by reason



9. Challenges identified during the month of September 2016

- None

10. Upcoming plans

- Roll out Roll out of Xpert MTB/RIF Ultra assay.
- 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.

11. Publications

- None