



NATIONAL HEALTH
LABORATORY SERVICE

National Priority Programmes

GeneXpert Xpert MTB/RIF
National report
March 2018





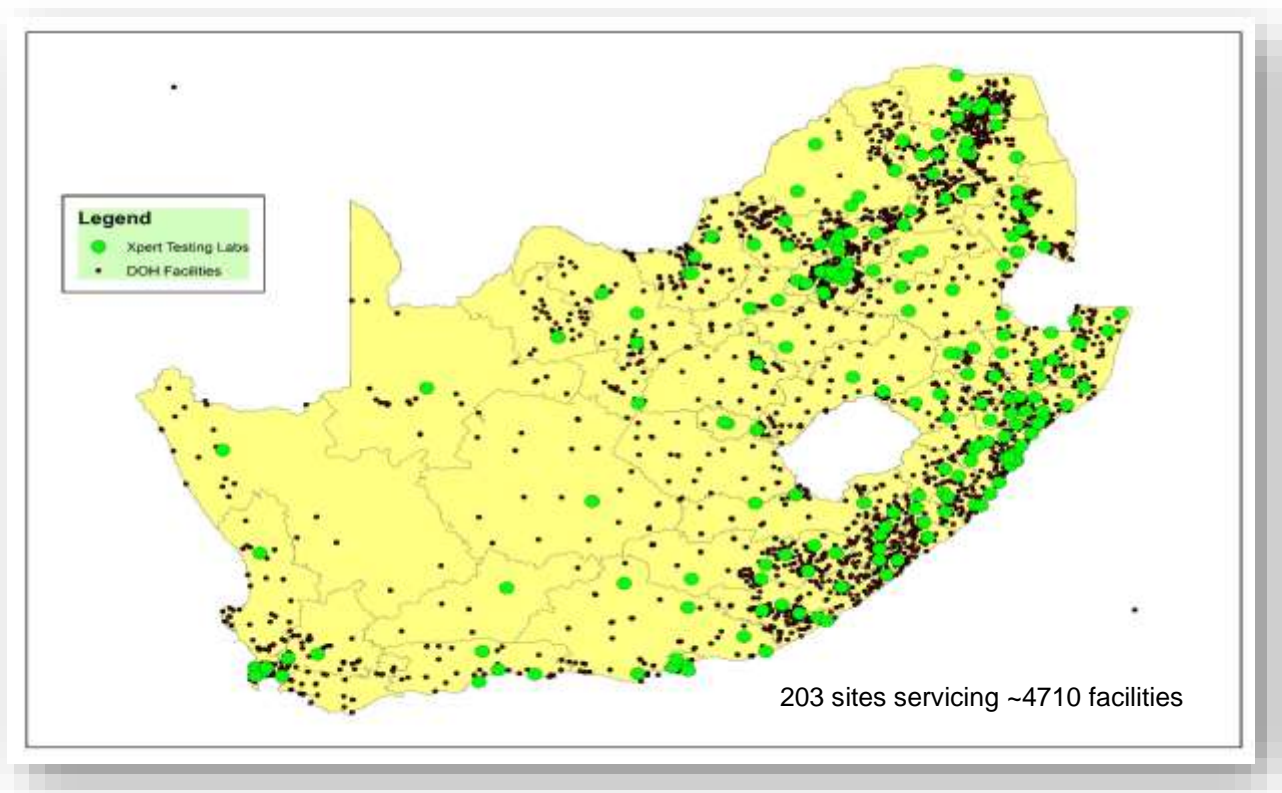
1. Background to Project

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" to improve TB healthcare services due to its increased sensitivity for TB detection and reduced testing time.

In 2014, 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. Seven on-site laboratories at Correctional Services and six mobile laboratories were established.

GeneXpert Placements

Figure 1: Current GeneXpert Placements (203 testing centers, 325 analysers, GX4: 127; GX16-8: 1; GX16: 189; GX48:1; GX80: 8)



2. Assays performed to date

In summary, a total of 12,770,380 specimens have been processed to date (31 March 2018). In March 2018 a total 194,422 specimens were processed. The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 8.73% (16 974).





Table 1: National GeneXpert MTB Results (Cumulative)

Year	MTB Detected	MTB Indeterminate	MTB Not Detected	Test Unsuccessful	Total	% MTB Detected
2011	30,079		158,220	2,756	191,055	15.74
2012	90,700		538,865	10,853	640,418	14.16
2013	208,923		1,533,342	50,356	1,792,621	11.65
2014	249,987		2,075,895	61,909	2,387,791	10.47
2015	245,517		2,341,813	56,306	2,643,636	9.29
2016	223,309		2,142,180	48,540	2,414,029	9.25
2017	207,673	1,634	1,940,483	33,227	2,183,017	9.51
2018	52,958	7,092	449,723	8,040	517,813	10.23
Total	1,309,146	8,726	11,180,521	271,987	12,770,380	10.25

Table 2: National GeneXpert RIF Results (Cumulative)

Year	RIF Unsuccessful	Resistant	Sensitive	No RIF Results	Total	% RIF Resistant
2011	284	2,138	27,535	122	30,079	7.11
2012	1,262	6,560	82,164	714	90,700	7.23
2013	5,335	13,810	188,574	1,204	208,923	6.61
2014	6,081	16,329	227,078	499	249,987	6.53
2015	3,289	14,997	226,938	293	245,517	6.11
2016	2,391	13,808	206,949	161	223,309	6.18
2017	2,267	12,121	193,197	88	207,673	5.84
2018	931	2,802	49,179	46	52,958	5.29
Total	21,840	82,565	1,201,614	3,127	1,309,146	6.31

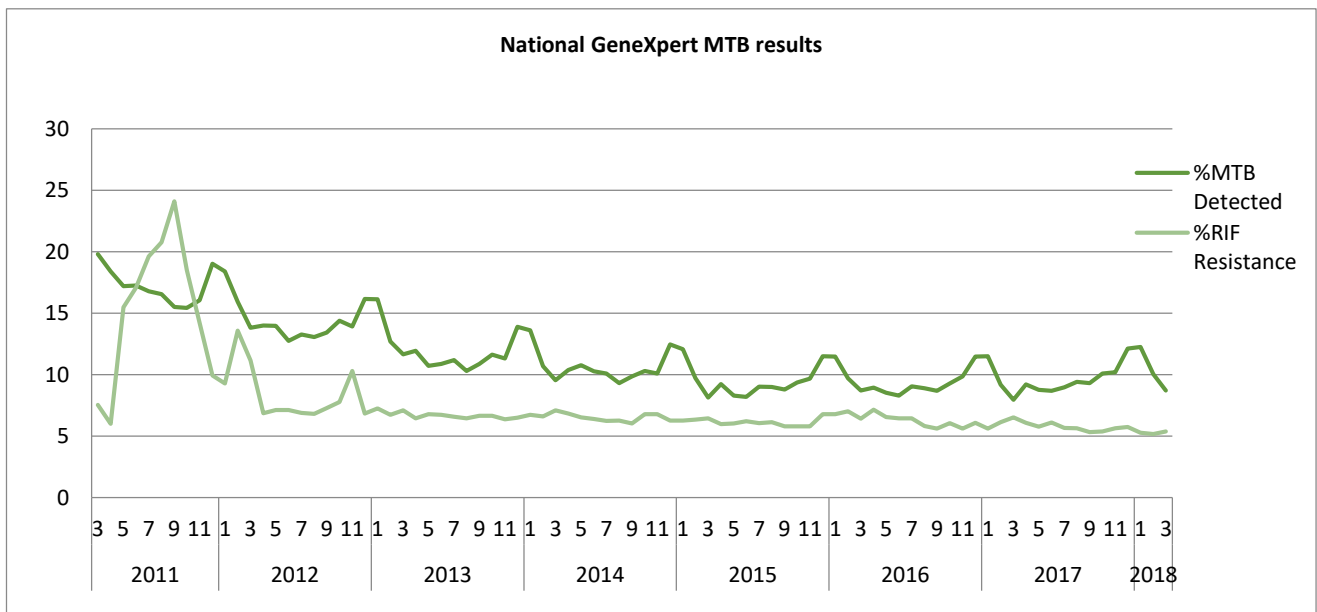


Figure 2: MTB Positivity and RIF Resistant rates overtime



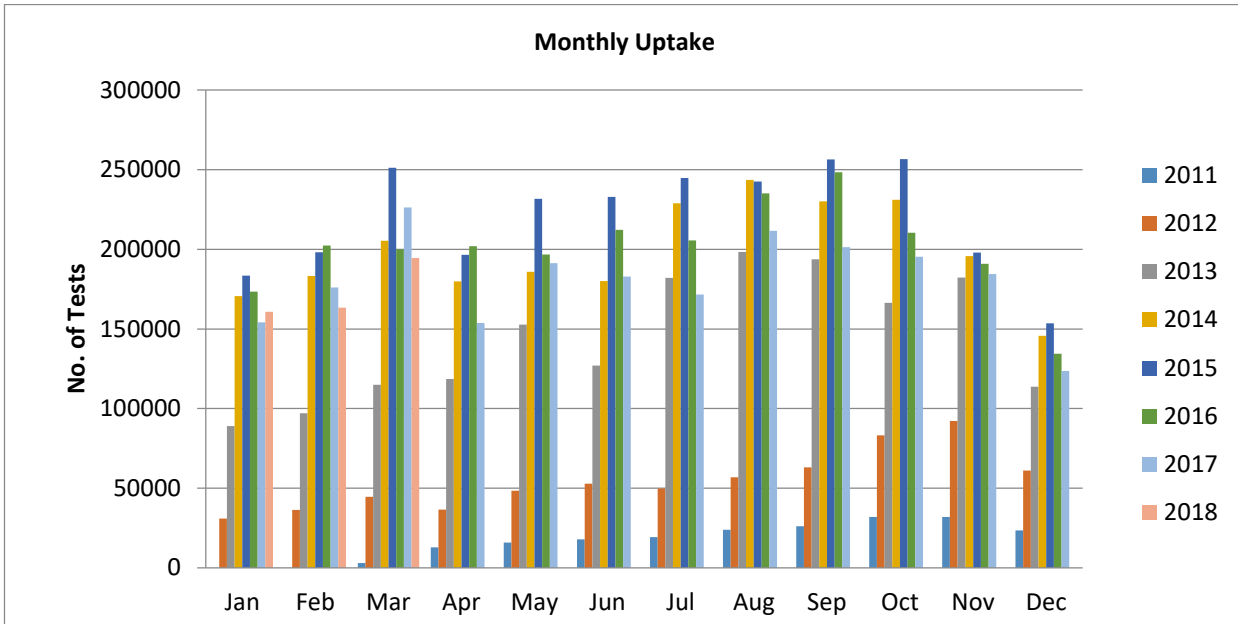


Figure 3: GeneXpert Monthly Uptake

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 347,987 specimens have been processed to date (31 March 2018). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 4.66% (16,210).

Table 3: Correctional Service GeneXpert MTB Results (Cumulative)

Year	MTB Detected	MTB Indeterminate	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 -Dec 2016	3,333		68,003	1,308	72,644	4.59
Jan -Dec 2017	3,042	20	57,514	755	61,331	4.96
Jan -Mar 2018	722	233	12,556	206	13,717	5.26
Total	16,210	253	325,893	5,631	347,987	4.66

Table 4: Correctional Service GeneXpert RIF Results (Cumulative)





Year	RIF Unsuccessful	Resistant	Sensitive	No RIF Result	Total	% RIF Resistant
Oct- Dec 2013	7	27	626	2	662	4.08
Jan - Dec 2014	107	188	3,323	2	3,620	5.19
Jan - Dec 2015	99	190	4,530	12	4,831	3.93
Jan -Dec 2016	35	149	3,146	3	3,333	4.47
Jan -Dec 2017	34	124	2,877	7	3,042	4.08
Jan -Mar 2018	10	23	689		722	3.19
Total	292	701	15,191	26	16,210	4.32

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 100,975 specimens have been processed to date (31 March 2018). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 1.26% (1,271).

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

Year	MTB Detected	MTB Indeterminate	MTB Not Detected	Test Unsuccessful	Total	% MTB Detected
Jun-Dec 2014	55		2,410	66	2,531	2.17
Jan-Dec 2015	406		37,021	609	38,036	1.07
Jan-Dec 2016	257		24,289	510	25,056	1.03
Jan-Dec 2017	418	21	28,472	600	29,511	1.42
Jan-Mar 2018	135	54	5,524	128	5,841	2.31
Total	1,271	75	97,716	1,913	100,975	1.26

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

Year	RIF Unsuccessful	Resistant	Sensitive	No RIF Results	Total	% Resistant
Jun-Dec 2014	3	2	51	0	56	3.57
Jan-Dec 2015	10	27	364	4	405	6.67
Jan-Dec 2016	9	15	225	8	257	5.84
Jan-Dec 2017	6	14	397	1	418	3.35
Jan-Mar 2018	2	8	125	0	135	5.93
Total	30	66	1,162	13	1,271	5.19





5. Training: Laboratory and Clinical

A total of 3,114 laboratory staff and 14,914 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 in the month of March 2018

Province	No. of Participants
Mpumalanga	14
Free state	4

Table 10: Health Care Workers trained in the month of March 2018

Date	Province	District	Facility	Number of Participants
07 March 2018	Gauteng	Tshwane	Sub-district 3	3
08 March 2018	Gauteng	Tshwane	Sub-district 2	12
09 March 2018	Gauteng	Tshwane	Sub-district 4	3
13 March 2018	Eastern Cape	OR Tambo	Mhlontlo and Nyandeni	48
14 March 2018	Eastern Cape	Nelson Mandela	Bisho	29
15 March 2018	Eastern Cape	Buffalo City Metro	Buffalo City	70
16 March 2018	Gauteng	Tshwane	Sub-district 3	5
20 March 2018	Free State	Mangaung, Fezile Dabi, Lejweleputswa & Thabo Mufutsanyane	Bloemfontein, Mathabeng, Nala & Mafube	14
28 March 2018	Gauteng	City of JHB	Region C	13
29 March 2018	Gauteng	City of JHB	Region E	5

6. 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 March 2018, 9 696 (4.98%) specimens were rejected. On-going training remains a practical tool to guarantee improvement in specimen collection and labelling.



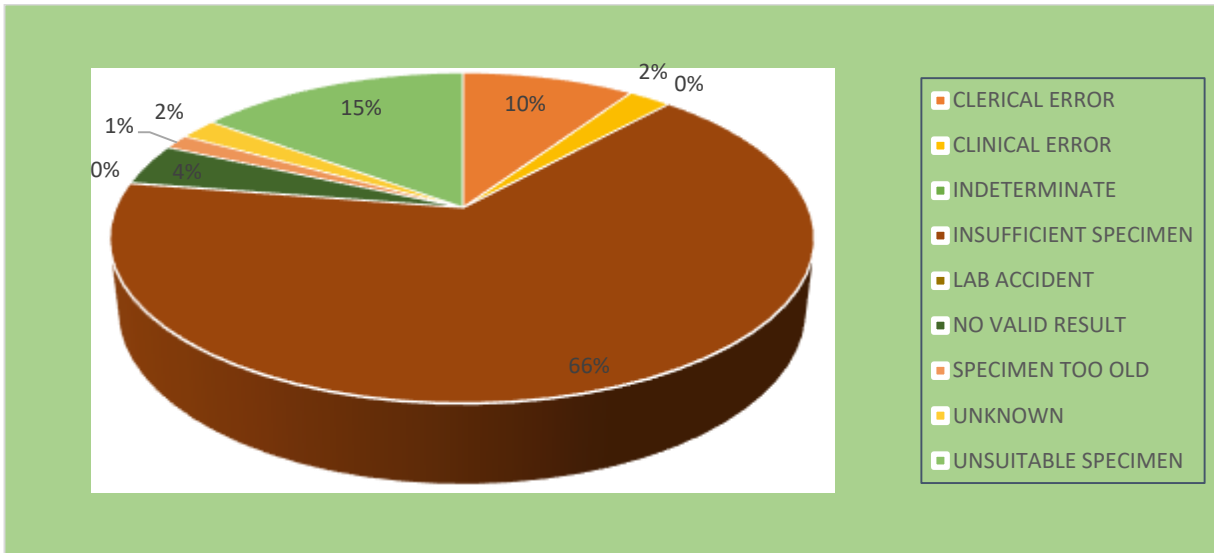


Figure 4: Rejections by reason

7. Challenges identified during the month of March 2018

- Sputum rejections due to provision of insufficient specimens, poor-quality sputum (mainly salivary), and contaminated specimens.

8. Upcoming plans

- Completion of the 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.

9. Publications

- None