



NATIONAL HEALTH
LABORATORY SERVICE

National Priority Programmes

GeneXpert Xpert MTB/RIF
National report
December 2017





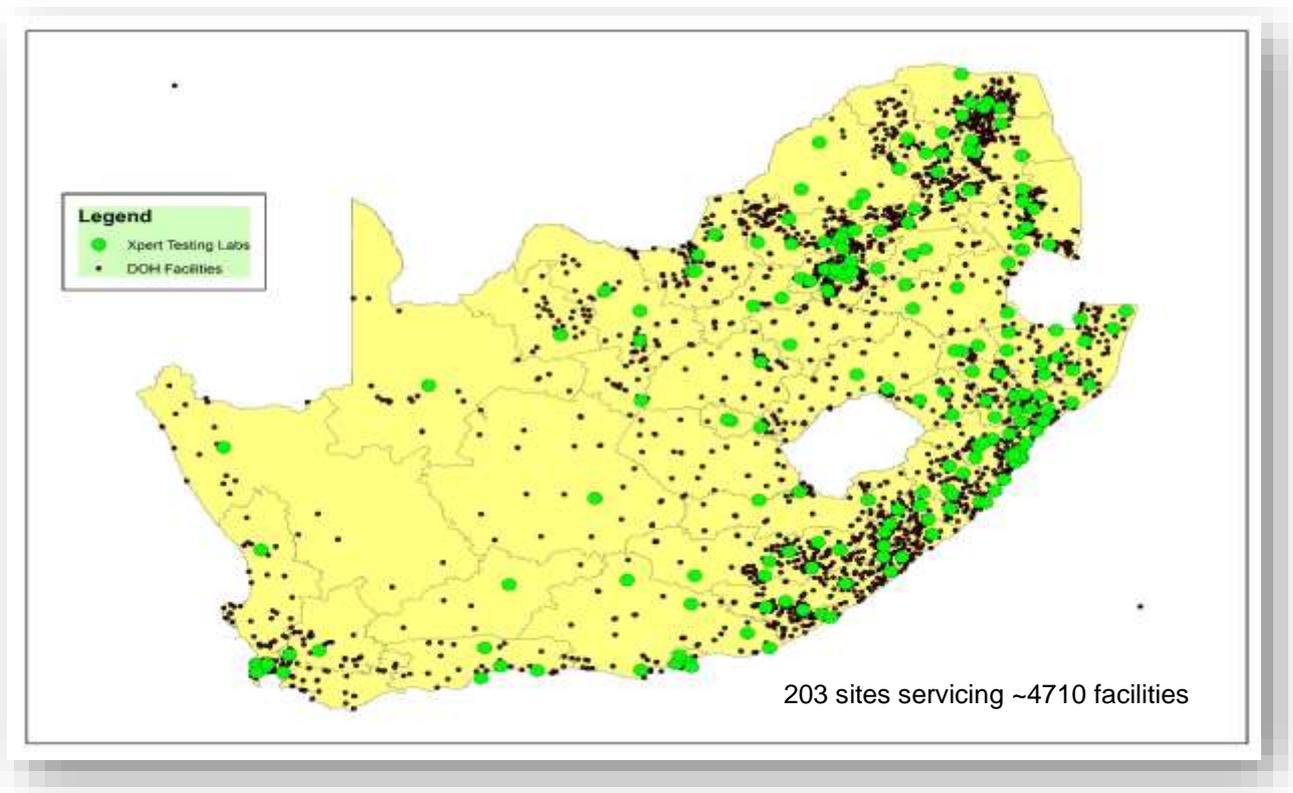
1. Background to Project

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 12,249,902 specimens have been processed to date (31 December 2017). In December 2017 a total 123,612 specimens were processed. The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 12.13% (14 992).



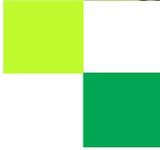


Table 1: National GeneXpert MTB Results (Cumulative)

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	207,101	1,499	1,938,804	32,948	2,180,352	9.50
Total	1,255,616	1,499	10,729,119	263,668	12,249,902	10.25

Table 2: National GeneXpert RIF Results (Cumulative)

Year	RIF Unsuccessful	Resistant	Sensitive	No RIF Result	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	2,192	11,908	192,886	115	207,101	5.75
Total	20,834	79,550	1,152,124	3,108	1,255,616	6.34

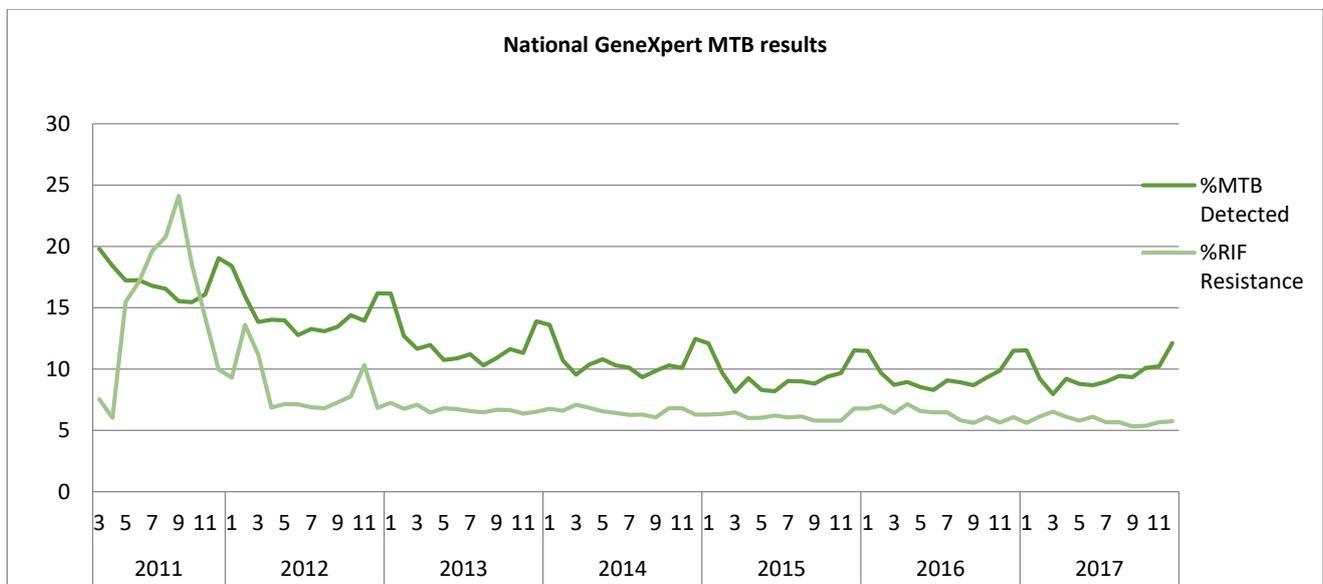


Figure 2: MTB Positivity and RIF Resistant rates overtime



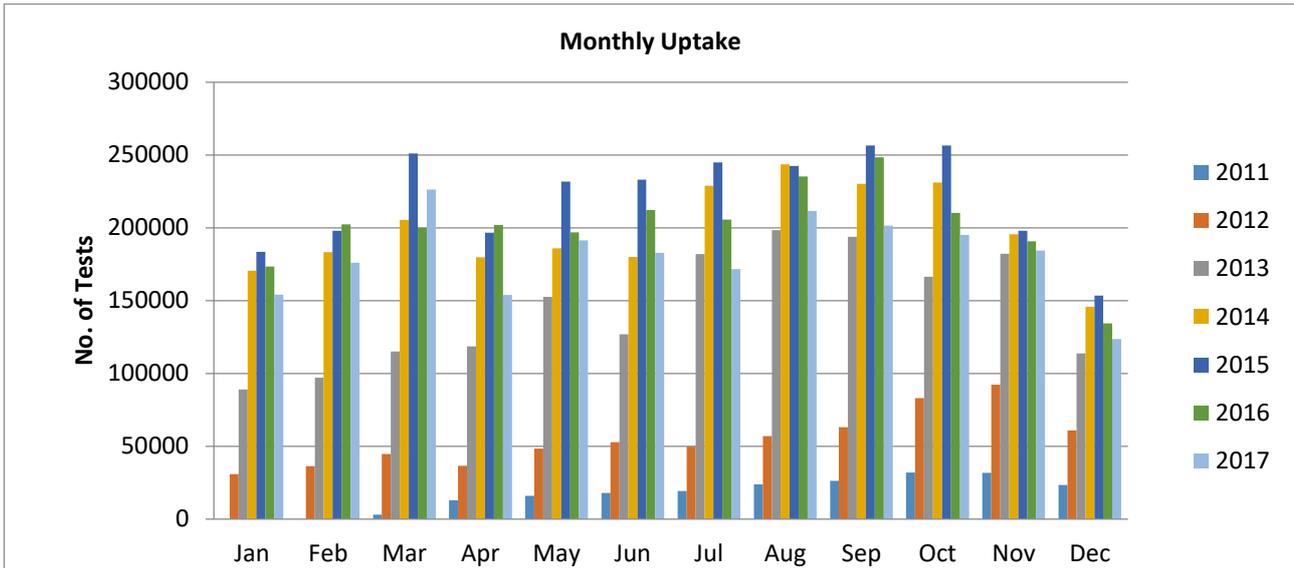


Figure 3: GeneXpert Monthly Uptake

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 334,270 specimens have been processed to date (31 December 2017). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 4.63% (15,488).

Table 3: Correctional Service GeneXpert MTB Results (Cumulative)

Year	MTB Detected	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
Total	15,488	20	31,3337	5,425	334,270	4.63

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
Total	282	678	14,502	26	15,488	4.38

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 95,134 specimens have been processed to date (31 December 2017). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 1.19% (1,136).

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

Year	MTB Detected	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
Total	1,136	21	92,192	1,785	95,134	1.19

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

Year	RIF Unsuccessful	Resistant	Sensitive	No RIF	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
Total	28	58	1,037	13	1,136	5.11





5. Training: Laboratory and Clinical

A total of 2,966 laboratory staff and 14,414 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 December 2017

Province	No of Participants
Eastern Cape	2
Northern Cape	9
Western Cape	39

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 December 2017, 6 473 (5.24%) specimens were rejected. On-going training remains a practical tool to guarantee improvement in specimen collection and labelling.

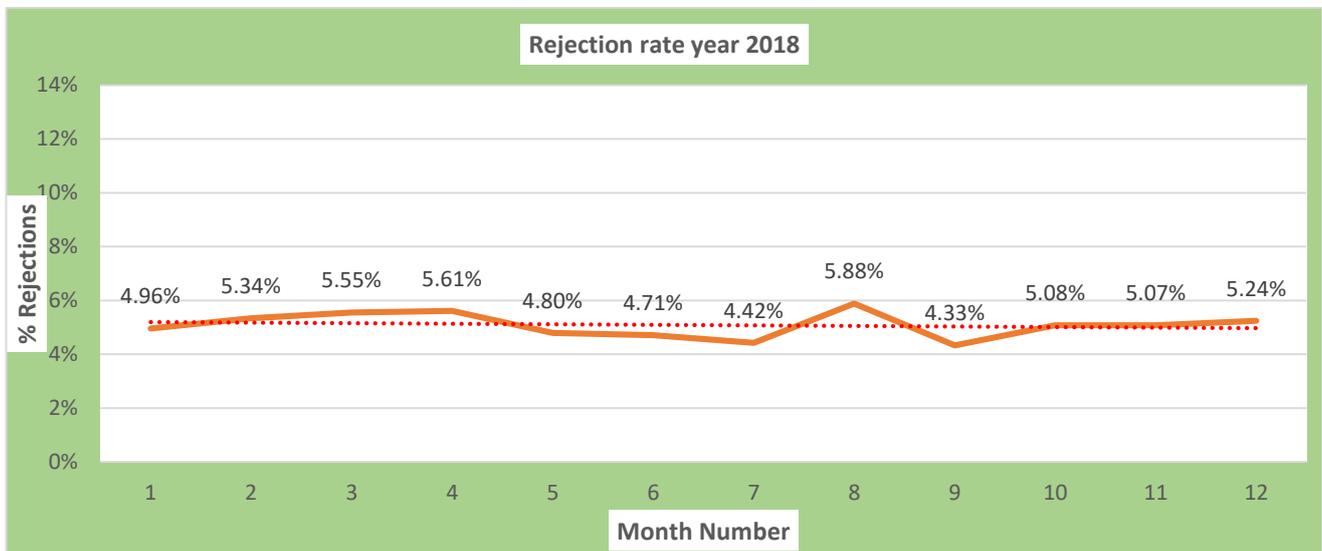


Figure 4: Rejections rate (January to December 2017)



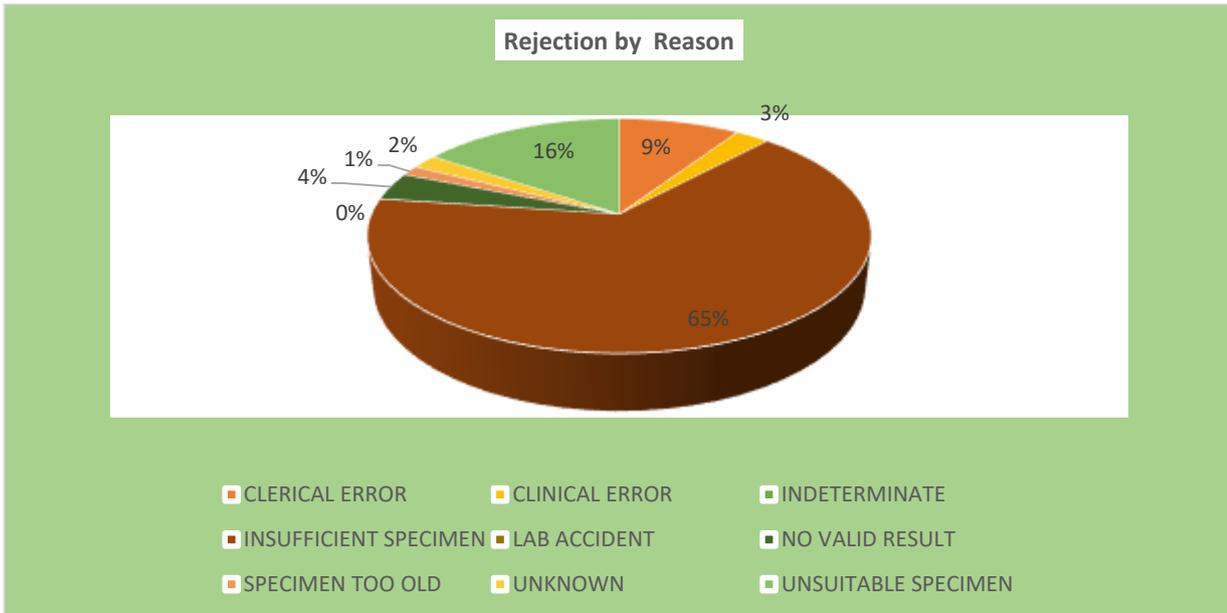


Figure 5: Rejections by reason

7. Challenges identified during the month of December 2017

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

8. 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.

9. Publications

- None