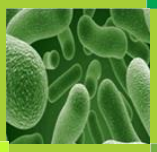
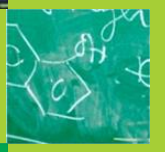
NATIONAL HEALTH LABORATORY SERVICE

National Priority Programmes





GeneXpert Xpert MTB/RIF
National report
March 2019

National Xpert MTB/RIF Programme

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.

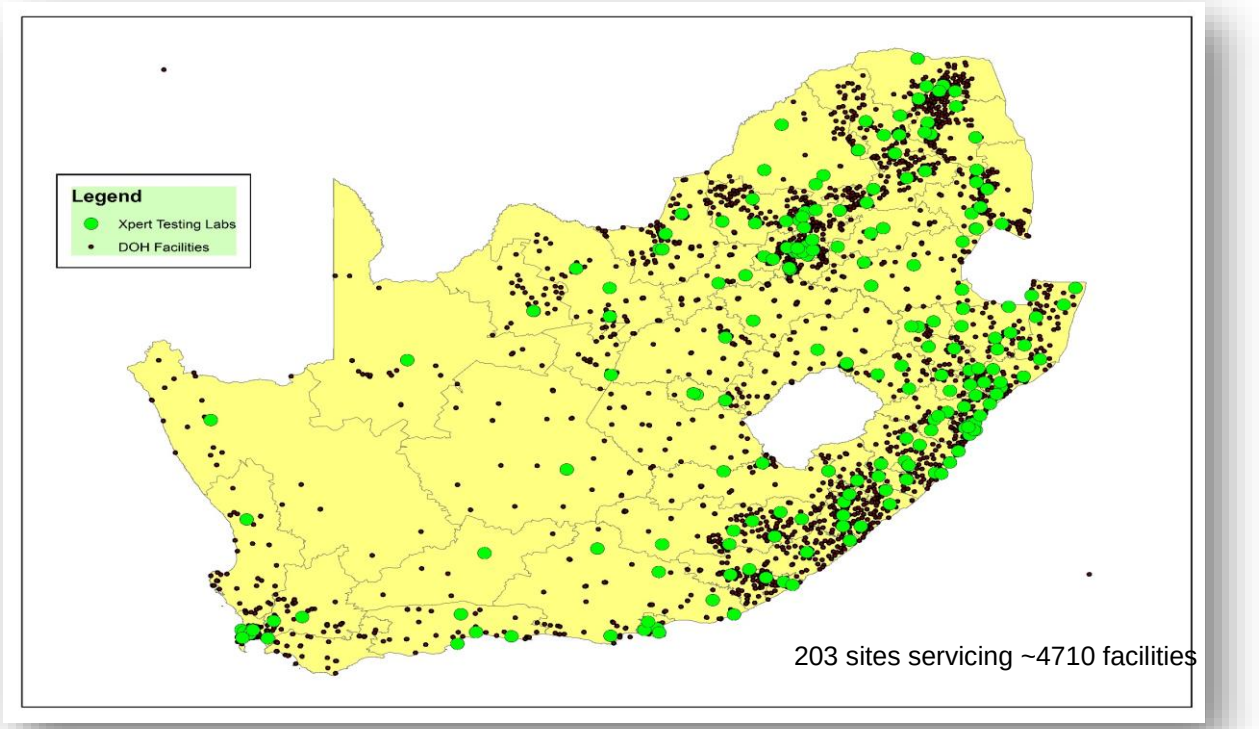
In 2014, the programme was further expanded to directly support the screening for TB and HIV in high risk populations in correctional centres and in peri-mining communities. Seven on-site laboratories at Correctional Services and six mobile laboratories were established.

The National rollout of the Xpert MTB/RIF Ultra was initiated in October 2017 and completed on the 31 March 2018. Xpert MTB/RIF Ultra test is designed to increase the detection of TB cases, particularly amongst patients living with HIV, and still detect resistance to rifampicin using the same volume of specimen, and the same GeneXpert instrumentation and test processing.

GeneXpert Placements

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

Page | 2



2. Assays performed to date

In summary, a total of 14,982,734 specimens have been processed to date (31 March 2019). In March 2019 a total 187,786 specimens were processed. The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 9.18% (14 989).

Table 1: National GeneXpert MTB Results (Cumulative)

Year	MTB Detected	Indeterminate *	Trace	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	208 764	1 634		1 952 030	33 441	2 195 869	9,51
2018	213 706	31 353	5 688	1 912 131	37 689	2 200 567	9,71
2019	49 550		8 752	447 343	11 103	516 748	9,59
TOTAL	**1 520 535**	**32 987**	**14 440**	**13 101 819**	**312 953**	**14 982 734**	**10,15**

*Reporting 'MTB trace detected' as Indeterminate ceased in October 2018, and was replaced with 'Trace'.

Page | 3

Table 2: National GeneXpert RIF Results (Cumulative)

Year	RIF Unsuccessful	RIF Resistant	RIF Sensitive	RIF Results Not Entered	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	2 277	12 173	194 230	84	208 764	5,83
2018	4 229	11 334	198 012	131	213 706	5,30
2019	1 368	2 612	45 565	5	49 550	5,27
Total	**26 516**	**93 761**	**1 397 045**	**3 213**	**1 520 535**	**6,17**

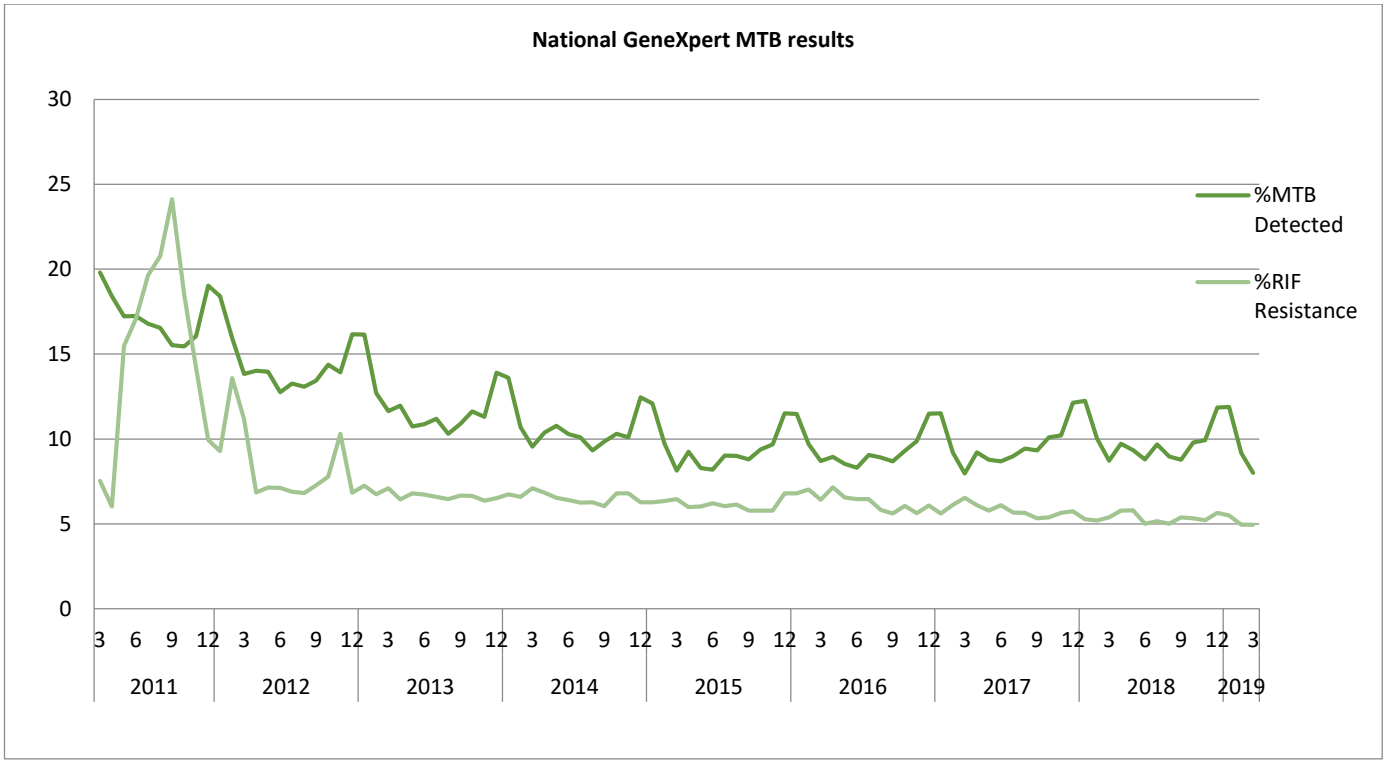


Figure 2: MTB Positivity and RIF Resistant rates overtime

Page | 4

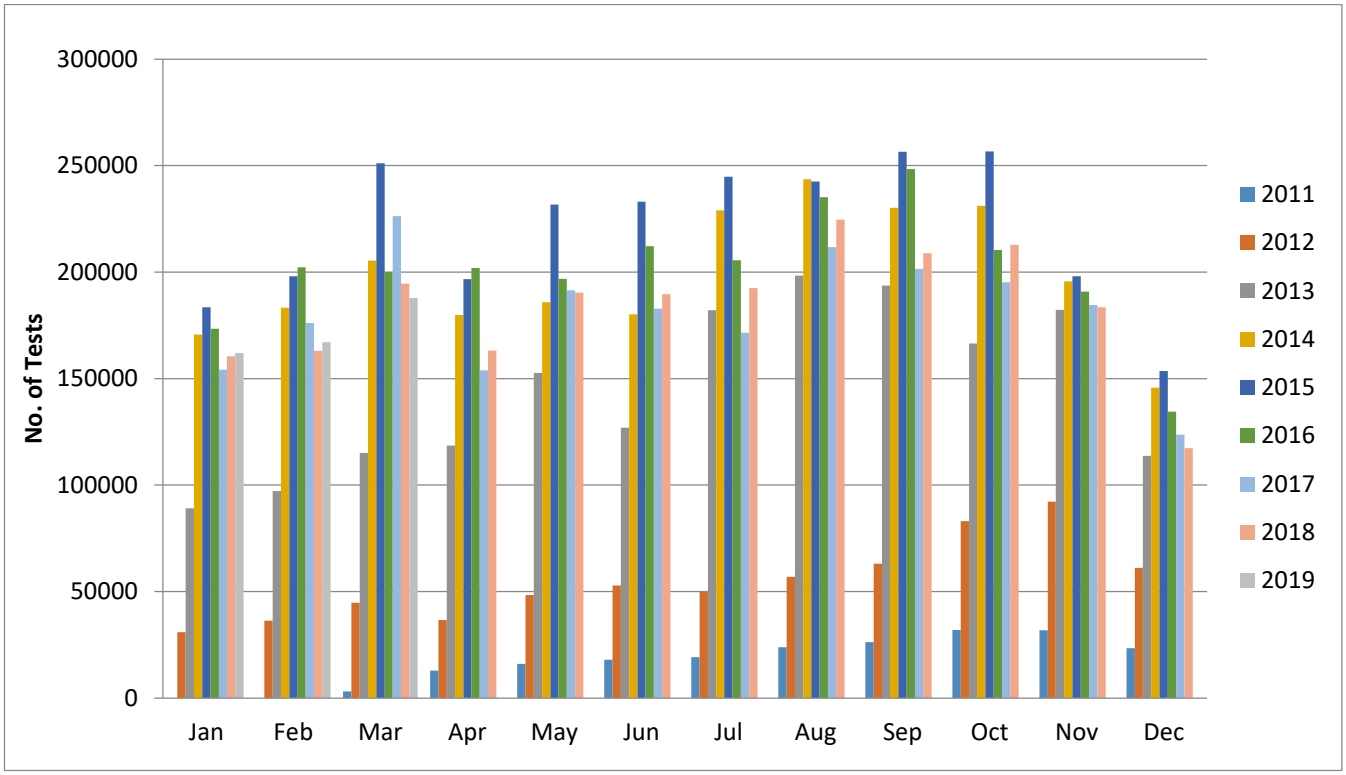


Figure 3: GeneXpert Monthly Uptake

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 400,166 specimens have been processed to date (31 March 2019). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 4.78% (19,135).

Table 3: Correctional Service GeneXpert MTB Results (Cumulative)

Page | 5

Year	MTB Detected	Indeterminate *	Trace	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 -Dec 2018	3 014	793	157	50 039	960	54 963	5,48
Jan -Mar 2019	633		197	9 921	182	10 933	5,79
Total	**19 135**	**813**	**354**	**373 297**	**6 567**	**400 166**	**4,78**

*Reporting 'MTB trace detected' as Indeterminate ceased in October 2018, and was replaced with 'Trace'.

Table 4: Correctional Service GeneXpert RIF Results (Cumulative)

Year	RIF Unsuccessful	RIF Resistant	RIF Sensitive	RIF Result Not Entered	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 -Dec 2018	27	124	2 861	2	3 014	4,11
Jan -Mar 2019	11	33	589		633	5,21
Total	**320**	**835**	**17 952**	**28**	**19 135**	**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 125, 207 specimens have been processed to date (31 March 2019). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 1.60% (1,999).

Page | 6

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

Year	MTB Detected	Indeterminate *	Trace	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-Dec 2018	793	347	39	26 696	620	28 495	2,78
Jan-Mar 2019	70		15	1 459	34	1 578	4,44
Total	**1 999**	**368**	**54**	**120 347**	**2 439**	**125 207**	1,60

*Reporting 'MTB trace detected' as Indeterminate ceased in October 2018, and was replaced with 'Trace'.

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

Year	RIF Unsuccessful	RIF Resistant	RIF Sensitive	RIF Results Not Entered	Total	% RIF 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-Dec 2018	7	36	749	1	793	4,54
Jan-Mar 2019	1	2	67		70	2,86
Total	**36**	**96**	**1 853**	**14**	**1 999**	**4,80**

5. Training: Laboratory and Clinical

A total of 3,483 laboratory staff and 16,951 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 7: Laboratory staff trained in the month of March 2019

Month	Province	Number of Laboratories	Number of Participants
March 2019	Kwazulu Natal Training	1	2
Total		**1**	**2**

Table 8: Clinical staff trained in the month of March 2019

Month	Province	District	Sub-district	Number of Participants
March 2019	North west	Ngaka Modiri Molema	Mafikeng	36
Total				**36**

Page | 7

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 2019, 15 409(7.58%) specimens were rejected. On-going training remains a practical tool to guarantee improvement in specimen collection and labelling.

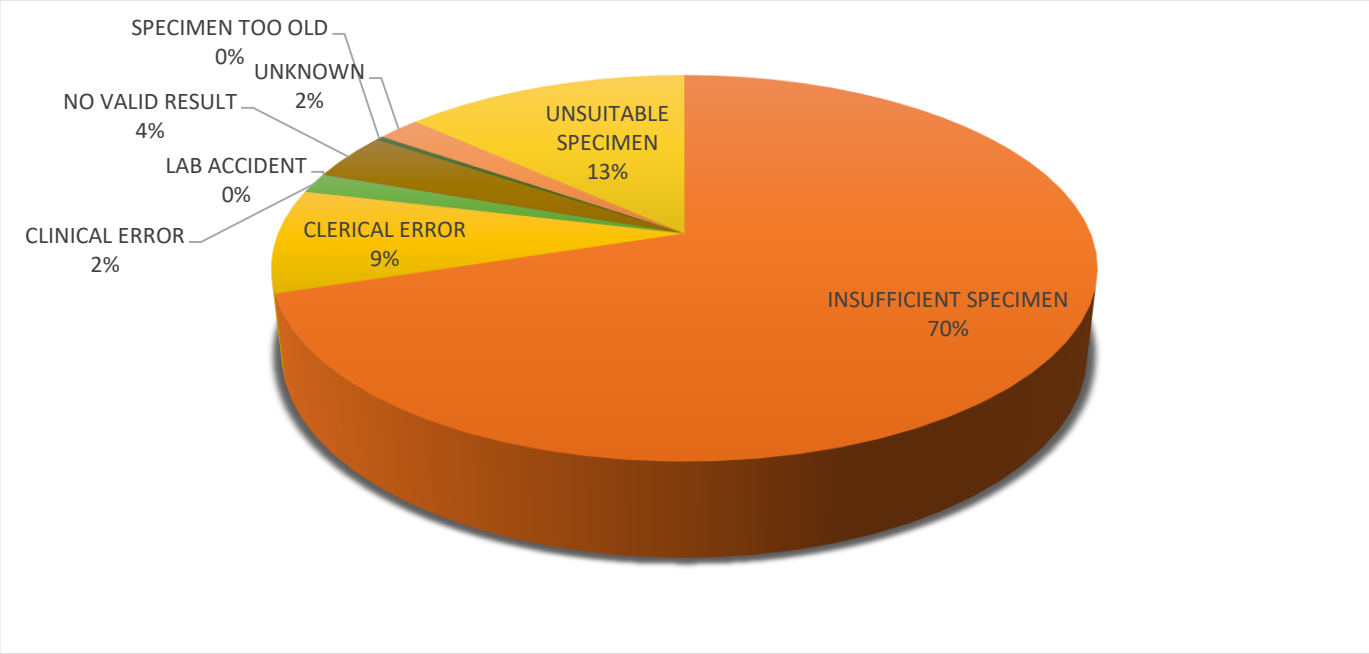


Figure 4: Rejections by reason for March 2019

7. Challenges identified during the month of March 2019

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

8. Upcoming and ongoing plans

- Continuous monitoring of sites through remote connectivity to improve program performance.
- Development of the GeneXpert dashboard to improve program performance.

Page | 8