GeneXpert MTB/RIF

Progress Report

March 2017

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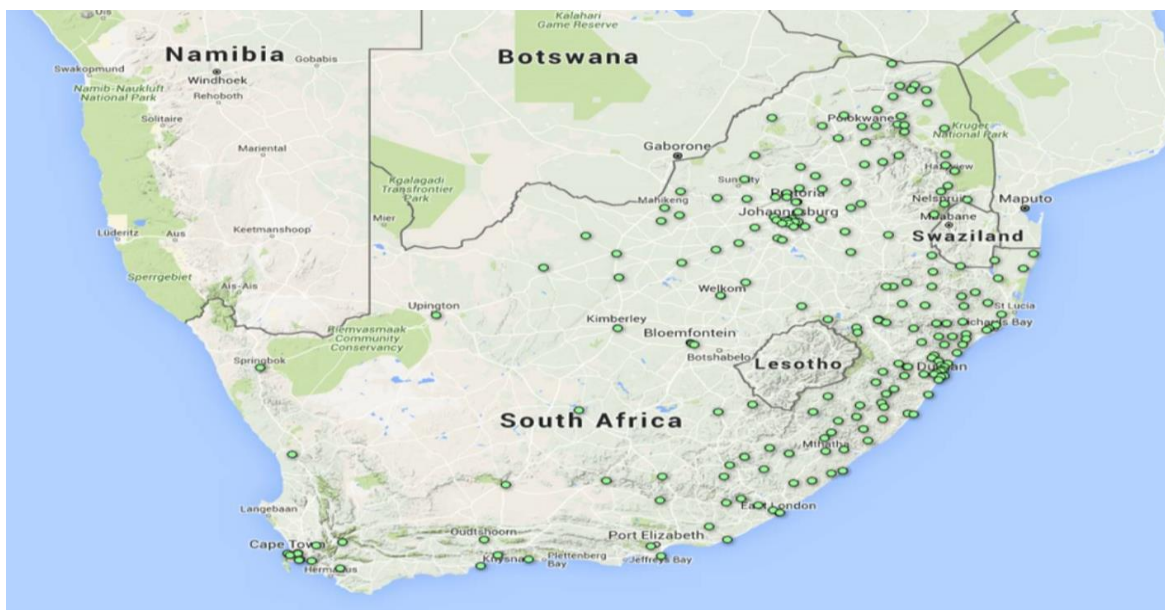
1. Background to Project

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 (207 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 10,566,489 specimens have been processed to date (31 March 2017). In March 2017 a total 226,220 specimens were processed. The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 7.96% (18 005).

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Table 1: National GeneXpert MTB Results (Cumulative)

Year	MTB Detected	MTB Not Detected	Test Unsuccessful	Total	% MTB Detected
2011	30 073	158 197	2 915	**191 185**	**15.73**
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	223 285	2 141 927	48 523	**2 413 735**	**9.25**
2017	52 007	494 665	10 581	**557 253**	**9.33**
Total	**1 095 224**	**9 221 315**	**249 950**	**10 566 489**	**10.37**

Table 2: National GeneXpert RIF Results (Cumulative)

Year	Inconclusive	Resistant	Sensitive	No RIF Result	Total	% RIF Resistant
2011	273	2 021	25 729	2 050	30 073	6.72
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	2 390	13 815	206 939	141	223 285	6.19
2017	544	3 181	48 256	26	52 007	6.12
Total	**18 973**	**71 632**	**999 872**	**4 747**	**1 095 224**	**6.54**

Figure 2: MTB Positivity and RIF Resistant rates overtime

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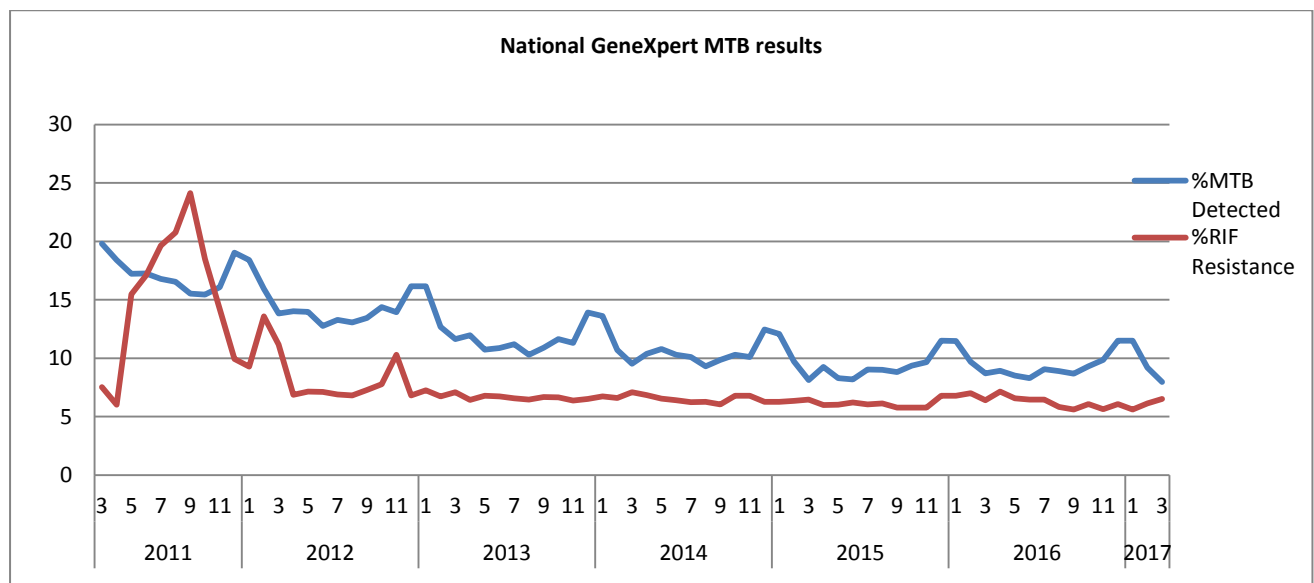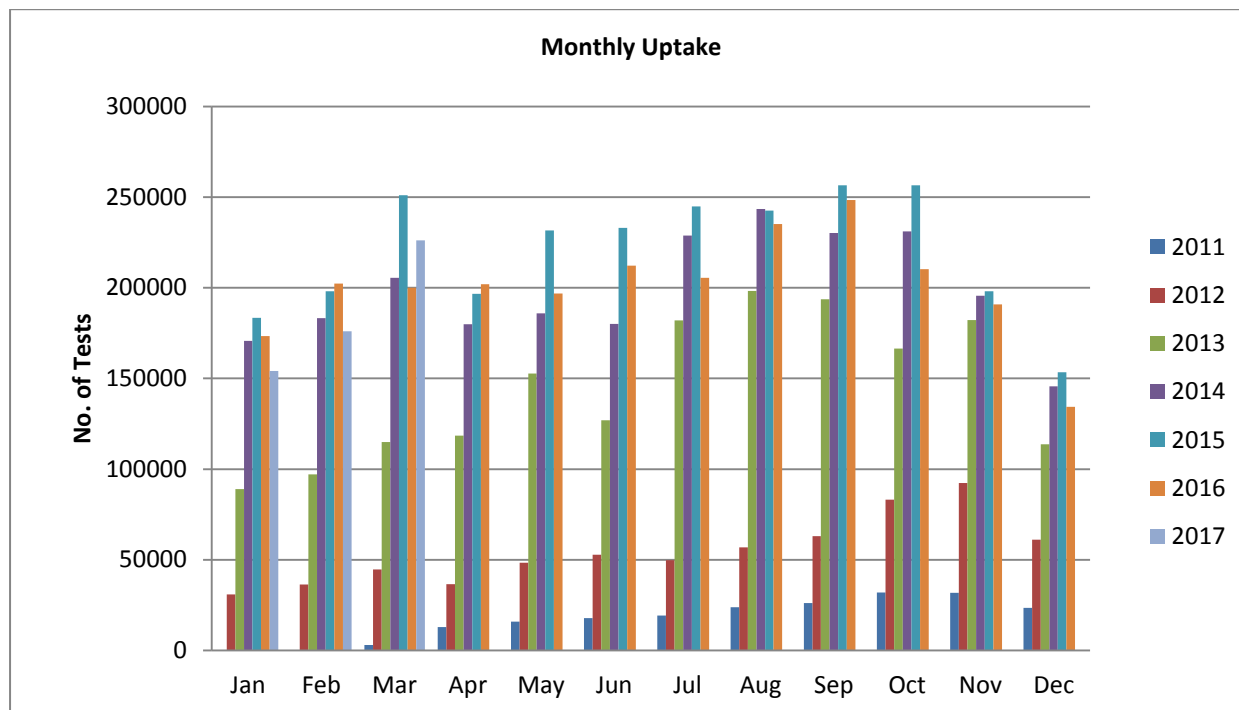
Figure 3: GeneXpert Monthly Uptake

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 289,403 specimens have been processed to date (31 March 2017). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 4.56% (13,204).

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 -Dec 2016	3333	68003	1308	72644	4.59

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Jan -Mar 2017	758	15475	231	16464	4.60
Total	**13204**	**271298**	**4901**	**289403**	**4.56**

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 -Dec 2016	149	35	3146	3	3333	4.47
Jan -Mar 2017	33	10	714	1	758	4.35
Total	**587**	**258**	**12339**	**20**	**13204**	**4.45**

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 70,149 specimens have been processed to date (31 March 2017). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 1.11% (780).

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 Dec 2016	257	24289	510	25056	1.03
Jan to Mar 2017	62	4313	151	4526	1.37
Total	**780**	**68033**	**1336**	**70149**	**1.11**

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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 Dec 2016	9	15	225	8	257	5.84
Jan to Mar 2017	1	1	59	1	62	1.61
Total	**23**	**45**	**699**	**13**	**780**	**5.77**

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.

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6. Training: Laboratory and Clinical

A total of 2,297 laboratory staff and 13,127 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

Date	District	Laboratory	No of Participants
02/03/2017	Ukhahlamba	Taylor Bequest	1
08/03/2017	Cape Winelands	Worcester	3
09/03/2017	Cape Winelands	Paarl	2
10/03/2017	City of Capetown	Mitchells plain	3
23/03/2017	Greater Sekhukhune	St Rita	1
24/03/2017	Tshwane	Tshwane Academic	6
28-31/03/2017	National	Advanced Infinity Training	18

Table 10: Health Care workers trained in the month of March 2017

Date	District	Facility	No of Participants
01/03/2017	Francis Baard	Kimberely	36
02/03/2017	Francis Baard	De Aar	18
14/03/2017	Harry Gwala	E.G. Usher Hospital	12
15/03/2017	Harry Gwala	Rietvlei	27
16/03/2017	Harry Gwala	St appolinaris	12
17/03/2017	Harry Gwala	Christ the Church	14
22/03/2017	Francis Baard	Kimberely	15

7. 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 2017, 13 334 (5.60%) specimens were rejected. On-going training remains a practical tool to guarantee improvement in specimen collection and labelling.

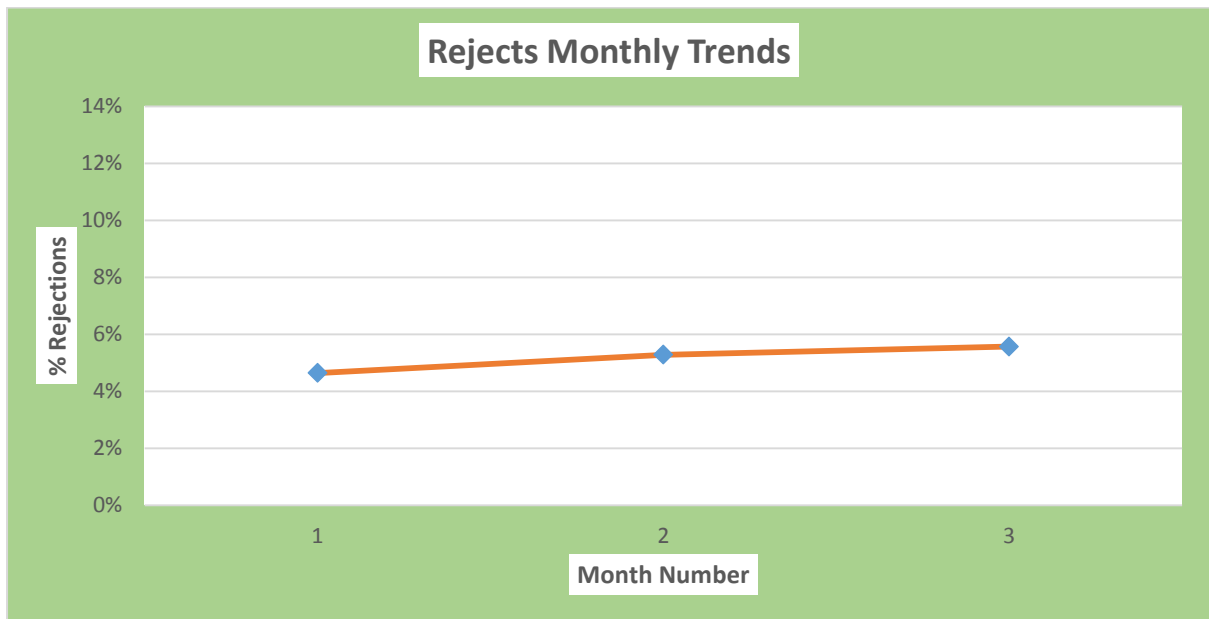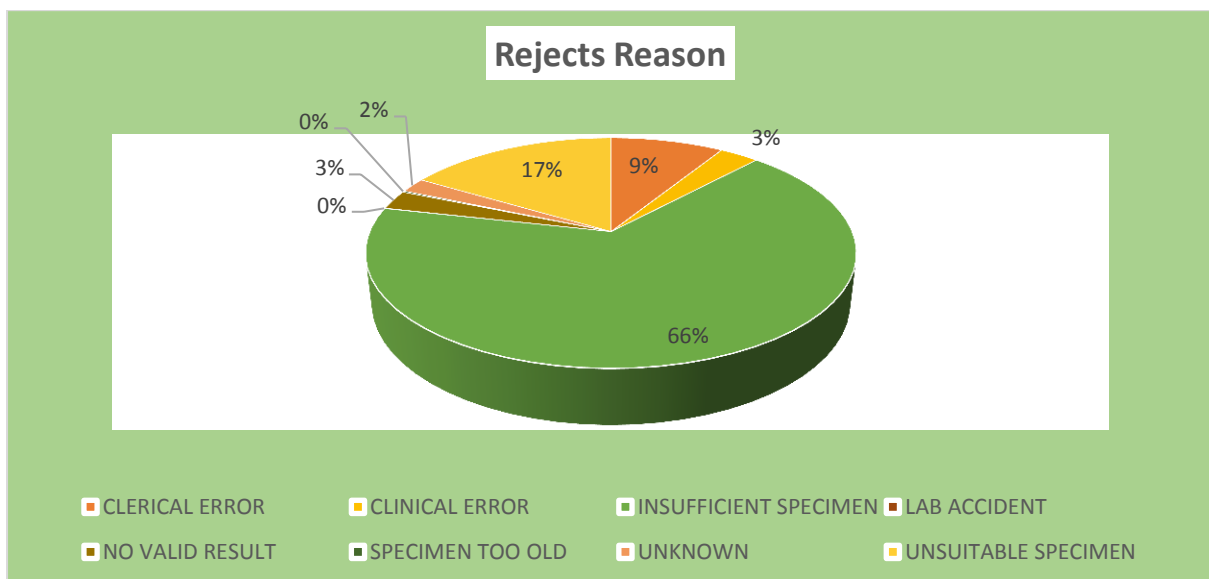**Figure 4: Rejections rate (Jan to March 2017)**

Rejects Monthly Trends

Figure 5: Rejections by reason

8. **Challenges identified during the month of March 2017**

   - None

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9. 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.

10. Publications

- None

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