



NATIONAL HEALTH  
LABORATORY SERVICE

# GeneXpert MTB/RIF

Progress Report

August 2016





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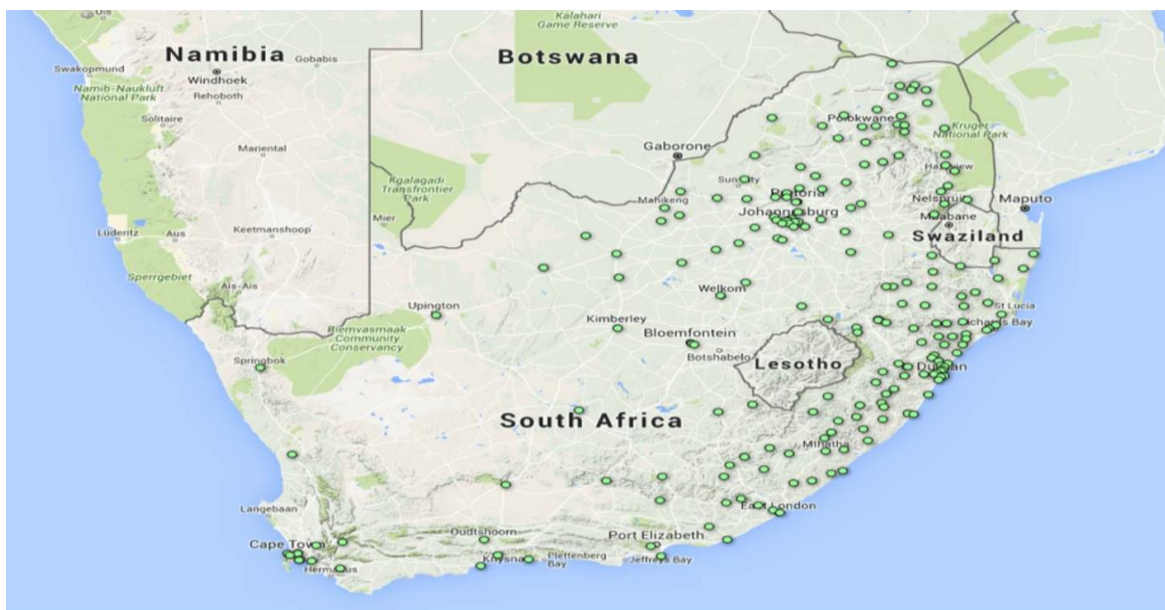
## 1. Background to Project

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 9,237,185 specimens have been processed to date (31 August 2016). In August 2016 a total 235,182 specimens were processed. The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 8.91% (20 958).

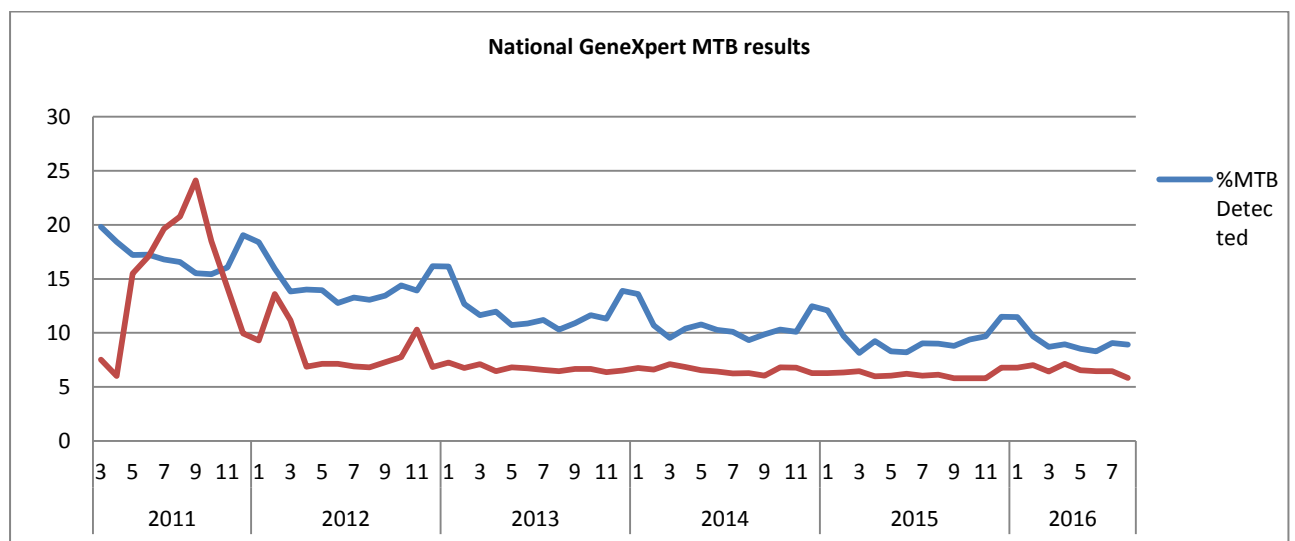
**Table 1: National GeneXpert MTB Results (Cumulative)**

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	147 757	1 446 898	32 770	1 627 425	9.08
<b>TOTAL</b>	<b>972 037</b>	<b>8 039 006</b>	<b>226 142</b>	<b>9 237 185</b>	<b>10.52</b>

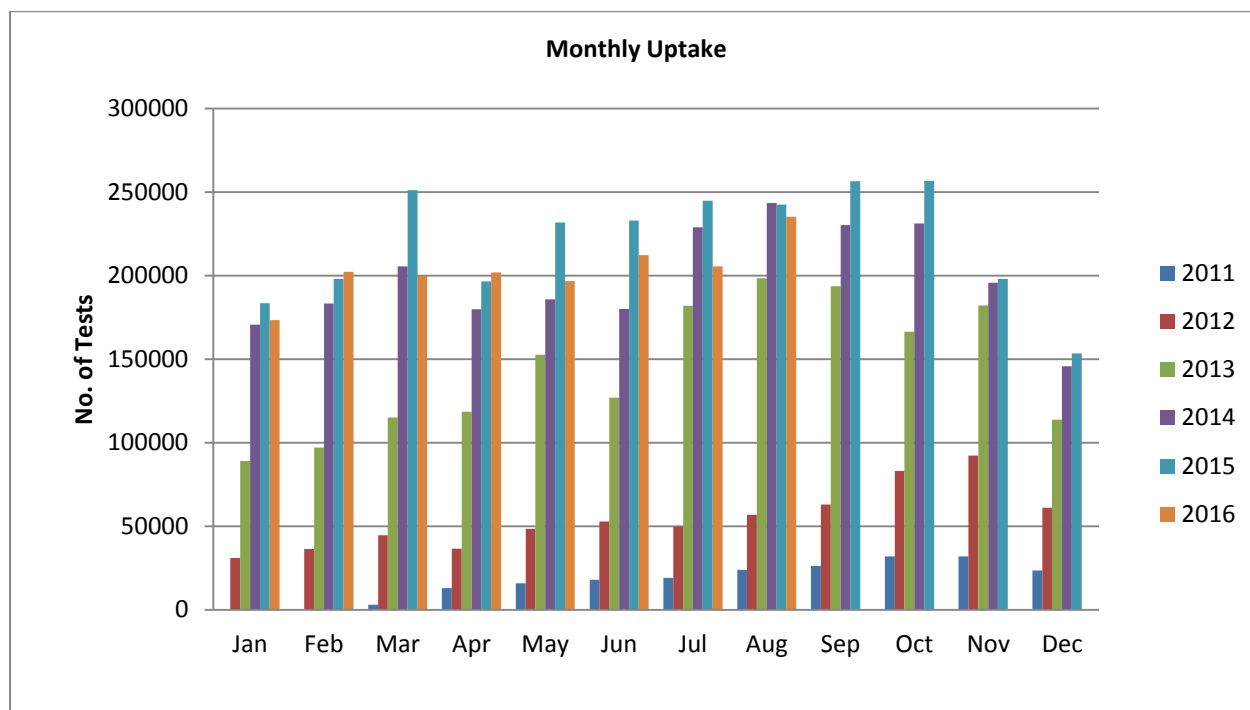
**Table 2: National GeneXpert RIF Results (Cumulative)**

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	1 699	9 287	136 581	190	147 757	6.29
<b>Total</b>	<b>17 776</b>	<b>67 536</b>	<b>883 700</b>	<b>3 025</b>	<b>972 037</b>	<b>6.95</b>

**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 252,025 specimens have been processed to date (31 August 2016). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 4.51% (11,359).

**Table 3: Correctional Service GeneXpert MTB Results (Cumulative)**

Year	MTB Detected	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 -Aug 2016	2 246	48 480	1 004	51 730	4.34
<b>Total</b>	<b>11 359</b>	<b>236 300</b>	<b>4 366</b>	<b>252 025</b>	<b>4.51</b>

**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	3 323	2	3 620	5.19
Jan - Dec 2015	190	99	4 530	12	4 831	3.93
Jan -Aug 2016	89	23	2 133	1	2 246	3.96
<b>Total</b>	<b>494</b>	<b>236</b>	<b>10 612</b>	<b>17</b>	<b>11 359</b>	<b>4.35</b>

#### 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 60,568 specimens have been processed to date (31 August 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 Aug 2016	205	19393	403	20001	1.02
<b>Total</b>	<b>666</b>	<b>58824</b>	<b>1078</b>	<b>60568</b>	<b>1.10</b>

**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 Aug 2016	8	14	176	7	205	6.83
<b>Total</b>	<b>21</b>	<b>43</b>	<b>591</b>	<b>11</b>	<b>666</b>	<b>6.46</b>

## 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
<b>National</b>	<b>54 225</b>	<b>7 167</b>	<b>13.2%</b>	<b>6 196</b>	<b>86.5%</b>	<b>12</b>	<b>19 555</b>	<b>36.1%</b>	<b>17 318</b>	<b>88.6%</b>	<b>543</b>

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

## 7. Training: Laboratory and Clinical

A total of 2,109 laboratory staff and 11,279 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 August 2016**

Date	District	Laboratory	No of Participants
29-Aug-16	Sedibeng	Kopanong	6
30-Aug-16	Sedibeng	Sebokeng	3
31-Aug-16	Ekhuruleni	Tembisa	4

**Table 9: Health Care workers trained for August 2016**

Date	District	Facility	No of Participants
05-Aug-16	Tshwane	ODI Hospital	18
16-Aug-16	Moqhaka	Grootvlei	10
17-Aug-16	Moqhaka	Bizza Makhathe	27
17-Aug-16	City of JHB	Helen Joseph Hospital	5
23-Aug-16	Ethekwini	Don Mackenzi	20
24-Aug-16	Ethekwini	Don Mackenzi	18
25-Aug-16	Ethekwini	Tropicana	80
26-Aug-16	Gert Sibande	Evander Hospital	13

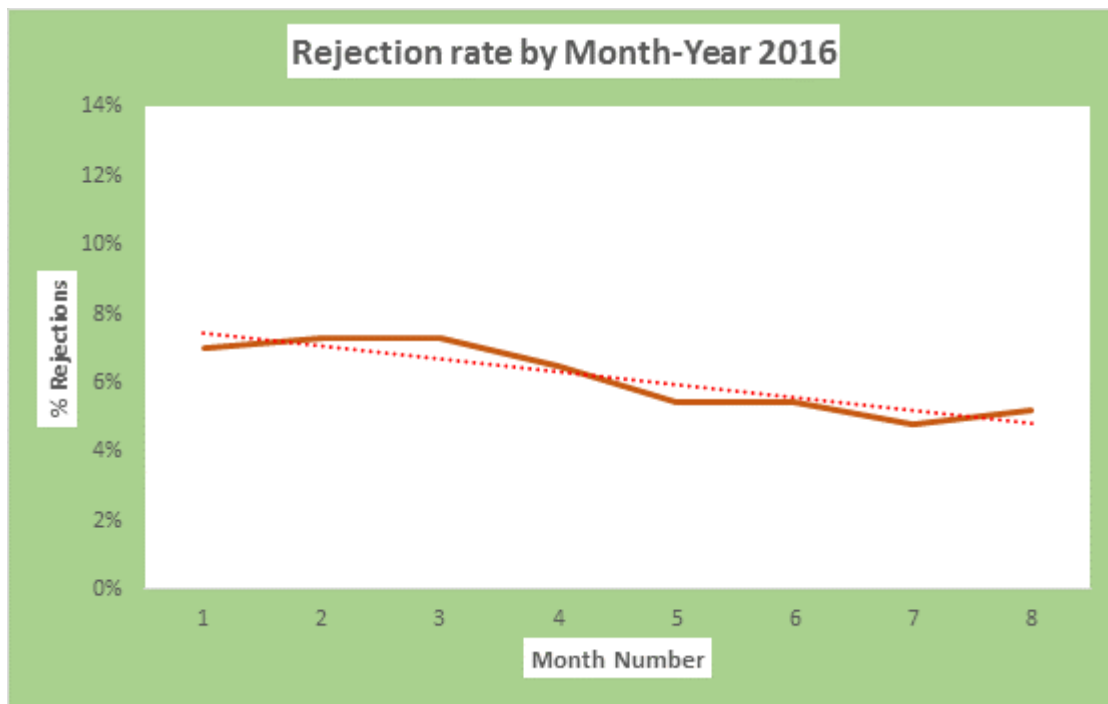




## 8. Rejected Specimens

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 August, 12 878 (5.18%) specimens were rejected. On-going training remains a practical tool to guarantee improvement in specimen collection and labelling.

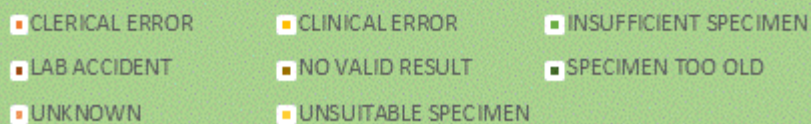
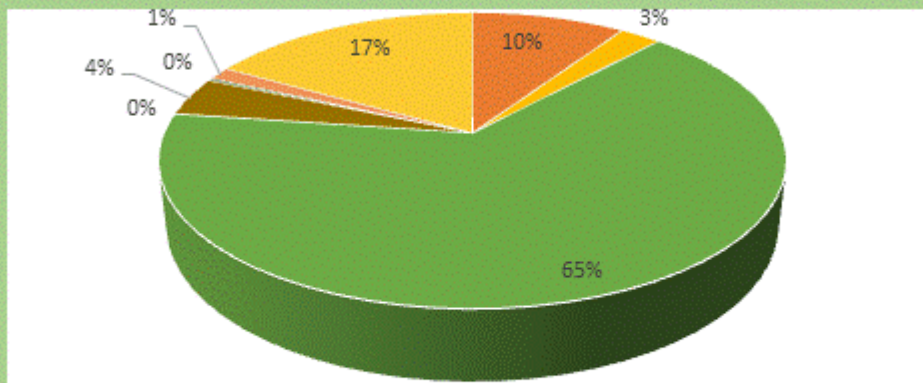
**Figure 4: Rejections rate (Jan to Aug 2016)**



**Figure 5: Rejections by reason (Jan to Aug 2016)**



Rejects Reason Jan to Aug 2016



#### 9. Challenges identified during the month of August 2016

- None

#### 10. Upcoming plans

- Roll out Roll out of Xpert MTB/RIF Ultra assay towards the end of 2016
- 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