



NATIONAL HEALTH
LABORATORY SERVICE

GeneXpert MTB/RIF

Progress Report

September 2015



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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 TB suspects in South Africa. A pilot study was proposed by the TB Cluster within the National Department of Health (NDoH) while a project feasibility study was being performed with due diligence.

The pilot study was initiated in microscopy centres. The NDoH requested that at least 1 instrument be placed in each province, preferably in high burden districts. Selections were made by the TB cluster, with twenty-five microscopy centres being selected and a total of 30 instruments placed.

The NDoH funded 9 GX16 and 14 GX4 instruments for the project. FIND (The Foundation for Innovative New Diagnostics) donated 6 GX4 analysers and the Infinity or GX48 was supported by PEPFAR Right to Care funds. All instruments were placed by World TB day March 24 2011. This placement represented about 10% of national coverage. The basis for the calculations was an assumption that 2 smears at diagnosis would be replaced by 1 Xpert® MTB/RIF assay. All instruments were interfaced to the NHLS Laboratory Information System (LIS) allowing for troubleshooting and data collection.

Since then, 309 GeneXpert instruments of varying sizes (GX4: 110; GX16:190; GX48: 1; GX80:8) have been placed in 221 sites – both urban and rural settings, by the National Priority Programmes of the NHLS and the NDoH, the progress of which is described in point 6 below.

The programme was further expanded to directly support the annual screening for TB and HIV of a quarter of a million people in special risk populations in correctional centres and in peri-mining communities.

1.1. 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 either on-site, or at the nearest referral laboratory. During 2014, Xpert MTB/RIF testing facilities have been established on-site at the following Correctional Facilities:

- KgošiMampuru Management Area II
- Barberton Management Area
- Johannesburg Management Area
- Groenpunt Management Area
- Pollsmoor Management Area
- St Albans Management Area
- Durban-Westville Management Area

1.2. 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 will be provided within the communities to undertake Xpert MTB/RIF testing for TB. In addition, persons newly identified as HIV-infected through the clinical partner will be staged for HIV-treatment using CD4 tests provided by the closest NHLS lab in the district. The 6 districts with a high proportion of mines in South Africa that have been identified for focused attention are:

- Lejweleputswa (Free State),
- Dr K K Kaunda & Bojanala Districts (North West),
- West Rand (Gauteng)
- Waterberg & Sekhukhune (Limpopo)

2. Assays performed to date

In summary, a total of 6 977 512 specimens have been processed to date (30 September 2015). In September 256,370 specimens were processed. The total % of *Mycobacterium tuberculosis* complex (MTBC) detected in this cohort was 8.81% (22 585). As a reflection of Xpert MTB/RIF's superior sensitivity over microscopy, the average national TB positivity rate among suspects was found to be 8% using microscopy but up to 16-18% in the first year and 13-14% in the second year, 10-11% in the third and fourth years and has reduced to 9% in the 5th year, after introduction of Xpert® MTB/RIF assay. To date Kwa-Zulu Natal (KZN) has performed the greatest number of tests which is probably as a result of the number of instruments placed (refer to tables 1 & 2). Average Rifampicin resistance detection rates have remained around 7% since project inception (Refer to tables 3 & 4).

Table 1: GeneXpert MTB Results by province (cumulative)

Province	Year	MTB Detected	MTB Not Detected	Test Unsuccessful	Total	% MTB Detected
EASTERN CAPE	2011	3,252	15,278	553	19,083	17.04
EASTERN CAPE	2012	15,868	84,658	2,862	103,388	15.35
EASTERN CAPE	2013	42,798	302,136	9,658	354,592	12.07
EASTERN CAPE	2014	49,125	383,571	11,381	444,077	11.06
EASTERN CAPE	2015	37,629	363,458	8,748	409,835	9.18
FREE STATE	2011	2,849	14,795	35	17,679	16.12
FREE STATE	2012	11,668	76,930	288	88,886	13.13
FREE STATE	2013	14,265	134,282	1,251	149,798	9.52
FREE STATE	2014	14,057	125,554	994	140,605	10.00
FREE STATE	2015	9,656	93,020	832	103,508	9.33
GAUTENG	2011	3,132	19,124	444	22,700	13.80
GAUTENG	2012	11,092	72,876	2,294	86,262	12.86
GAUTENG	2013	29,722	205,667	7,622	243,011	12.23
GAUTENG	2014	38,794	305,290	7,442	351,526	11.04
GAUTENG	2015	27,976	278,646	6,012	312,634	8.95
KWAZULU-NATAL	2011	12,139	45,780	1,731	59,650	20.35
KWAZULU-NATAL	2012	23,915	135,916	5,909	165,740	14.43
KWAZULU-NATAL	2013	41,370	286,202	14,919	342,491	12.08
KWAZULU-NATAL	2014	57,493	521,938	18,701	598,132	9.61
KWAZULU-NATAL	2015	42,299	456,620	13,443	512,362	8.26
LIMPOPO	2011	1,930	17,069	171	19,170	10.07
LIMPOPO	2012	3,984	30,848	690	35,522	11.22
LIMPOPO	2013	13,417	181,744	6,013	201,174	6.67



LIMPOPO	2014	14,412	212,466	7,694	234,572	6.14
LIMPOPO	2015	9,460	169,188	5,038	183,686	5.15
MPUMALANGA	2011	2,647	12,813	1,105	16,565	15.98
MPUMALANGA	2012	4,034	22,218	1,133	27,385	14.73
MPUMALANGA	2013	9,908	59,950	2,311	72,169	13.73
MPUMALANGA	2014	14,623	112,311	4,202	131,136	11.15
MPUMALANGA	2015	9,911	92,090	3,175	105,176	9.42
NORTH WEST	2011	3,494	14,902	657	19,053	18.34
NORTH WEST	2012	5,499	29,974	2,051	37,524	14.65
NORTH WEST	2013	12,477	94,632	4,770	111,879	11.15
NORTH WEST	2014	17,009	150,702	6,631	174,342	9.76
NORTH WEST	2015	11,701	126,977	3,828	142,506	8.21
NORTHERN CAPE	2011	2,783	15,732	717	19,232	14.47
NORTHERN CAPE	2012	4,030	22,407	1,089	27,526	14.64
NORTHERN CAPE	2013	7,561	50,778	2,444	60,783	12.44
NORTHERN CAPE	2014	8,719	63,146	2,894	74,759	11.66
NORTHERN CAPE	2015	6,563	54,141	1,845	62,549	10.49
WESTERN CAPE	2011	2,195	10,089	28	12,312	17.83
WESTERN CAPE	2012	13,158	68,282	587	82,027	16.04
WESTERN CAPE	2013	30,163	162,869	2,785	195,817	15.40
WESTERN CAPE	2014	34,782	185,776	2,099	222,657	15.62
WESTERN CAPE	2015	26,467	154,100	1,465	182,032	14.54
TOTAL		760,026	6,036,945	180,541	6,977,512	10.89

Table 2: GeneXpert MTB Results by province (01-30 September 2015)

Province	MTB Detected	MTB Not Detected	Test Unsuccessful	Grand Total	% MTB Detected
Eastern Cape	4679	49925	929	55533	8.43
Free State	1265	13006	68	14339	8.82
Gauteng	3518	34224	607	38349	9.17
Kwa-Zulu Natal	5104	56508	1409	63021	8.10
Limpopo	1155	20995	636	22786	5.07
Mpumalanga	1128	11100	287	12515	9.01
North West	1355	15058	276	16689	8.12
Northern Cape	853	7574	287	8714	9.79
Western Cape	3528	20730	166	24424	14.44
Grand Total	22585	229120	4665	256370	8.81

Table 3: Provincial GeneXpert RIF Results in MTB detected cases (01-30 September 2015)

Province	Inconclusive	Resistant	Sensitive	No RIF	Grand Total	% RIF Resistance
Eastern Cape	72	270	4334	3	4679	5.77
Free State	18	72	1175		1265	5.69
Gauteng	39	216	3261	2	3518	6.14
Kwa-Zulu Natal	94	382	4627	1	5104	7.48
Limpopo	16	54	1084	1	1155	4.68
Mpumalanga	23	74	1031		1128	6.56
North West	18	45	1292		1355	3.32
Northern Cape	11	34	807	1	853	3.99
Western Cape	40	162	3325	1	3528	4.59
Grand Total	331	1309	20936	9	22585	5.80

Table 4: Provincial GeneXpert RIF Results in MTB detected cases (cumulative)

Province	Year	Inconclusive	Resistant	Sensitive	No RIF Result	Total	% RIF Resistant
EASTERN CAPE	2011	31	255	2,835	131	3,252	7.84
EASTERN CAPE	2012	202	1,489	13,894	283	15,868	9.38
EASTERN CAPE	2013	1,199	2,805	38,646	148	42,798	6.55
EASTERN CAPE	2014	1,257	2,993	44,824	51	49,125	6.09
EASTERN CAPE	2015	534	2,184	34,858	53	37,629	5.80
FREE STATE	2011	9	1,491	1,346	3	2,849	52.33
FREE STATE	2012	145	1,357	10,123	43	11,668	11.63
FREE STATE	2013	361	793	13,091	20	14,265	5.56
FREE STATE	2014	367	824	12,862	4	14,057	5.86
FREE STATE	2015	119	541	8,989	7	9,656	5.60
GAUTENG	2011	25	179	2,926	2	3,132	5.72
GAUTENG	2012	136	763	10,115	78	11,092	6.88
GAUTENG	2013	852	1,947	26,855	68	29,722	6.55
GAUTENG	2014	826	2,320	35,620	28	38,794	5.98
GAUTENG	2015	365	1,637	25,961	13	27,976	5.85
KWAZULU-NATAL	2011	107	916	11,055	61	12,139	7.55
KWAZULU-NATAL	2012	417	2,166	21,079	253	23,915	9.06
KWAZULU-NATAL	2013	1,054	3,607	36,306	403	41,370	8.72
KWAZULU-NATAL	2014	1,513	4,965	50,812	203	57,493	8.64
KWAZULU-NATAL	2015	705	3,323	38,205	66	42,299	7.86
LIMPOPO	2011	25	118	1,742	45	1,930	6.11
LIMPOPO	2012	52	264	3,593	75	3,984	6.63
LIMPOPO	2013	293	694	12,322	108	13,417	5.17
LIMPOPO	2014	328	713	13,323	48	14,412	4.95



LIMPOPO	2015	125	515	8,782	38	9,460	5.44
MPUMALANGA	2011	31	189	2,396	31	2,647	7.14
MPUMALANGA	2012	57	402	3,499	76	4,034	9.97
MPUMALANGA	2013	221	989	8,671	27	9,908	9.98
MPUMALANGA	2014	378	1,285	12,940	20	14,623	8.79
MPUMALANGA	2015	150	761	8,982	18	9,911	7.68
NORTH WEST	2011	40	2,192	1,258	4	3,494	62.74
NORTH WEST	2012	75	471	4,943	10	5,499	8.57
NORTH WEST	2013	300	685	11,465	27	12,477	5.49
NORTH WEST	2014	504	909	15,587	9	17,009	5.34
NORTH WEST	2015	216	555	10,924	6	11,701	4.74
NORTHERN CAPE	2011	28	188	2,540	27	2,783	6.76
NORTHERN CAPE	2012	54	247	3,720	9	4,030	6.13
NORTHERN CAPE	2013	174	405	6,694	288	7,561	5.36
NORTHERN CAPE	2014	200	451	8,053	15	8,719	5.17
NORTHERN CAPE	2015	80	327	6,153	3	6,563	4.98
WESTERN CAPE	2011	15	106	2,073	1	2,195	4.83
WESTERN CAPE	2012	150	650	12,355	3	13,158	4.94
WESTERN CAPE	2013	668	1,526	27,965	4	30,163	5.06
WESTERN CAPE	2014	695	1,852	32,233	2	34,782	5.32
WESTERN CAPE	2015	290	1,290	24,882	5	26,467	4.87
Total		15,373	54,339	687,497	2,817	760,026	7.15

3. Rif Concordance

Rifampicin concordance is good for both LPA and culture. The data is skewed by reporting the GeneXpert immediately, but still have to wait for MGIT and LPA results.

Table 5: Rif Concordance by LPA or DST (from March 2011 to 16 June 2015)

Province	Rif Resistant Cases	GeneXpert Confirmation & Rif Concordance									
		DST					LPA				
		Confirmed		Rif Concordance		Pre-analytical/ No result	Confirmed		Rif Concordance		Indeterminate
		#	%	#	%		#	%	#	%	
EC	7 914	310	3,9%	209	67,4%	3	2 386	30,1%	2 209	92,6%	7
FS	2 501	203	8,1%	112	55,2%	0	943	37,7%	805	85,4%	179
GP	5 668	207	3,7%	135	65,2%	4	1 428	25,2%	1 279	89,6%	26
KZN	12 664	3 129	24,7%	2 914	93,1%	0	3 100	24,5%	2 773	89,5%	119
LP	1 907	94	4,9%	70	74,5%	2	456	23,9%	364	79,8%	15
MP	3 090	660	21,4%	651	98,6%	0	1 132	36,6%	974	86,0%	3
NW	2 230	171	7,7%	113	66,1%	0	730	32,7%	604	82,7%	47
NC	1 243	268	21,6%	201	75,0%	3	527	42,4%	407	77,2%	34
WC	4 305	166	3,9%	57	0,0%	0	3 328	77,3%	3 081	92,6%	2
National	41 522	5 208	12,5%	4 462	85,7%	12	14 030	33,8%	12 496	89,1%	432

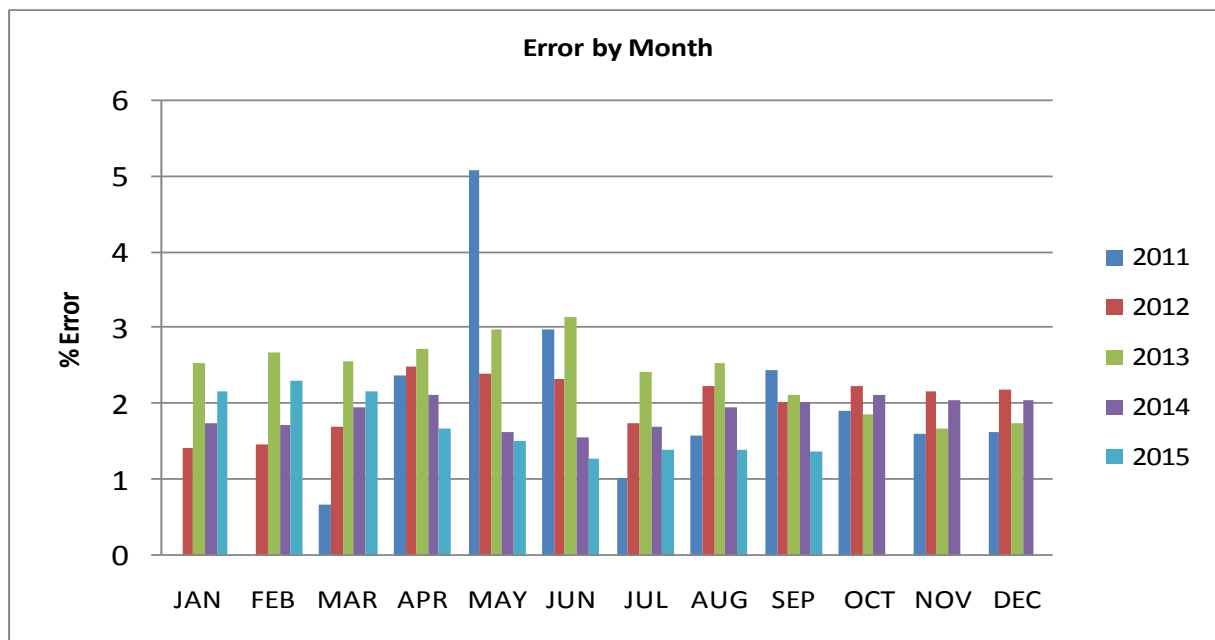
4. Errors

Average error rate has ranged consistently below 3% in the month of September. Details of the invalid results, which likely represent sample issues remains below 1%. These are being monitored regularly and corrective action implemented where necessary.

Table 6: Number of Unsuccessful Tests and Reasons (1-30 September 2015)

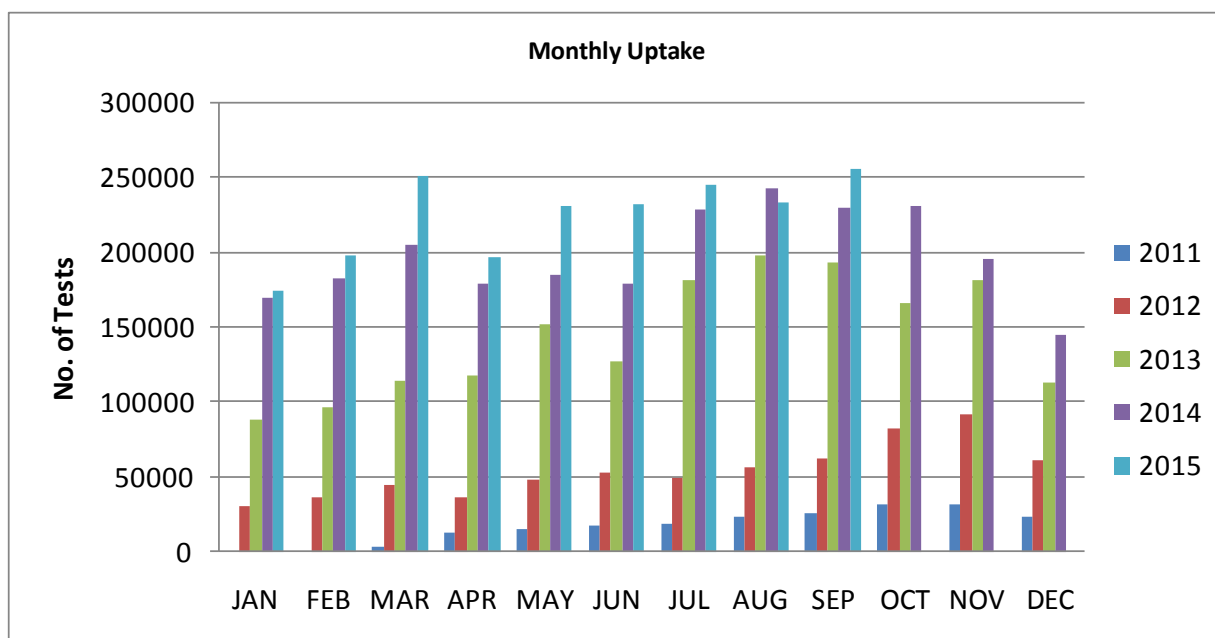
Province	Error	Invalids	No Results	MTB Results	Grand Total	% Error
Eastern Cape	720	108	101	54605	55534	1.30
Free State	43	24	1	14271	14339	0.30
Gauteng	506	67	34	37746	38353	1.32
Kwa-Zulu Natal	1093	143	173	61617	63026	1.73
Limpopo	498	92	46	22157	22793	2.18
Mpumalanga	191	77	19	12228	12515	1.53
North West	219	39	18	16413	16689	1.31
Northern Cape	143	132	12	8427	8714	1.64
Western Cape	114	30	22	24263	24429	0.47
Grand Total	3527	712	426	251727	256392	1.38

Figure 1: GeneXpert Error by Month



5. Monthly uptake since implementation started

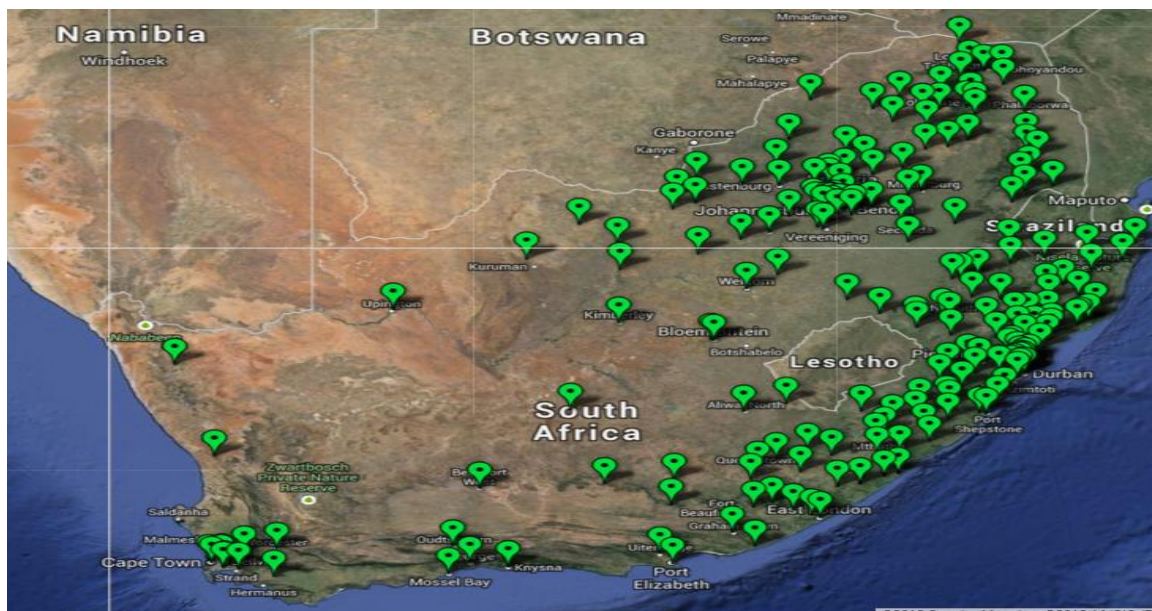
Figure 2: GeneXpert Monthly Uptake



Monthly uptake increased steadily since program inception.

6. Phased Implementation Progress

Figure 3: Current GeneXpert Placement (221 testing centers, 309 **analysers**, **Gx4:** 110; Gx16-8: 1; **Gx16:** 189; GX48:1; GX80-80: 8) *20 clinic placements *7 Correctional Facilities *6 Mobile Vans



7. Training: Laboratory and Clinical

A total of 1,903 laboratory staff and 9,514 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

8. Challenges identified during the course of the project to date

- Rollout of EGK to avoid duplications
- Implementing WHO recommended guidelines for Xpert testing on EPTB and paediatric samples: being addressed
- EPTB training to be expanded to correctional facilities to ensure compliance
- Hospital staff not complying to the GXP testing algorithm because trainings has not been conducted in most of the hospitals- being addressed
- Staff rotation in hospital wards posing a challenge in the implementation and compliance to the TB algorithms resulting in delay to initiating patients on TB Treatment

9. Funding

Table 9: Total and Percentage Contribution to date by Donor

Donor	% Contribution
NDoH	24.04
Bill & Melinda Gates Foundation	7.20
TB Reach	1.42
MSF	0.90
FIND	0.45
USAID	2.45
CDC NHLS 2010/11	14.78
CDC NDoH	0.72
CDC NHLS 2011/12	1.39
Dr. Niebauer	0.20
Gobal Fund NDOH	40.91
Global Fund RTC	2.78
CDC NDoH	2.77
Subtotal	100

CDC has contributed 19, 65% towards the program to date.

10. Recent Campaigns

None in September