



NATIONAL HEALTH
LABORATORY SERVICE

GeneXpert MTB/RIF

Progress Report

June 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 is being 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 6 246 446 specimens have been processed to date (31 May 2015). In June 225 062 specimens were processed. The total % of *Mycobacterium tuberculosis* complex (MTBC) detected in this cohort was 7.84% (17 639). 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	15 235	549	19 036	17,08
EASTERN CAPE	2012	15 880	84 755	2 862	103 497	15,34
EASTERN CAPE	2013	45 469	320 022	10 046	375 537	12,11
EASTERN CAPE	2014	48 900	382 950	11 369	443 219	11,03
EASTERN CAPE	2015	24 075	224 946	5 877	254 898	9,44
FREE STATE	2011	2 811	14 532	35	17 378	16,18
FREE STATE	2012	11 660	76 863	288	88 811	13,13
FREE STATE	2013	14 758	139 299	1 020	155 077	9,52
FREE STATE	2014	14 030	125 554	997	140 581	9,98
FREE STATE	2015	6 078	57 372	562	64 012	9,50
GAUTENG	2011	3 094	18 881	443	22 418	13,80
GAUTENG	2012	11 120	72 979	2 305	86 404	12,87
GAUTENG	2013	31 432	215 064	7 690	254 186	12,37
GAUTENG	2014	38 537	303 844	7 423	349 804	11,02
GAUTENG	2015	17 518	175 818	4 019	197 355	8,88
KWAZULU-NATAL	2011	7 546	30 575	896	39 017	19,34
KWAZULU-NATAL	2012	23 963	135 973	5 915	165 851	14,45
KWAZULU-NATAL	2013	42 294	293 200	15 003	350 497	12,07
KWAZULU-NATAL	2014	57 323	519 674	18 683	595 680	9,62
KWAZULU-NATAL	2015	27 256	293 395	9 665	330 316	8,25
LIMPOPO	2011	1 973	17 253	173	19 399	10,17
LIMPOPO	2012	4 004	30 924	689	35 617	11,24

5 Disclaimer: This is a dynamic specimen dataset requiring regular update and it should be noted that figures may change as linkages to individuals tested are updated.



LIMPOPO	2013	13 927	188 932	6 086	208 945	6,67
LIMPOPO	2014	14 376	211 956	7 688	234 020	6,14
LIMPOPO	2015	6 038	107 329	3 270	116 637	5,18
MPUMALANGA	2011	2 629	12 683	1 100	16 412	16,02
MPUMALANGA	2012	4 035	22 226	1 133	27 394	14,73
MPUMALANGA	2013	10 406	63 030	2 210	75 646	13,76
MPUMALANGA	2014	14 650	112 752	4 210	131 612	11,13
MPUMALANGA	2015	6 381	59 022	2 265	67 668	9,43
NORTH WEST	2011	3 429	14 557	644	18 630	18,41
NORTH WEST	2012	5 499	29 977	2 052	37 528	14,65
NORTH WEST	2013	13 301	100 512	4 926	118 739	11,20
NORTH WEST	2014	17 001	150 584	6 638	174 223	9,76
NORTH WEST	2015	7 552	80 349	2 693	90 594	8,34
NORTHERN CAPE	2011	2 727	15 527	712	18 966	14,38
NORTHERN CAPE	2012	3 830	21 728	1 038	26 596	14,40
NORTHERN CAPE	2013	7 912	53 728	2 529	64 169	12,33
NORTHERN CAPE	2014	8 685	63 062	2 891	74 638	11,64
NORTHERN CAPE	2015	4 013	31 912	1 132	37 057	10,83
WESTERN CAPE	2011	2 173	9 897	47	12 117	17,93
WESTERN CAPE	2012	13 206	68 045	689	81 940	16,12
WESTERN CAPE	2013	28 653	155 003	2 343	185 999	15,40
WESTERN CAPE	2014	33 717	180 294	1 992	216 003	15,61
WESTERN CAPE	2015	14 115	87 421	787	102 323	13,79
TOTAL		691 228	5 389 634	165 584	6 246 446	11,07

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

Province	MTB Detected	MTB Not Detected	Test Unsuccessful	Grand Total	% MTB Detected
Eastern Cape	4 030	43 911	871	48 812	8,26
Free State	979	10 712	86	11 777	8,31
Gauteng	2 743	33 607	678	37 028	7,41
Kwa-Zulu Natal	4 409	49 509	1 157	55 075	8,01
Limpopo	1 004	21 763	579	23 346	4,30
Mpumalanga	1 053	11 062	303	12 418	8,48
North West	1 087	12 618	397	14 102	7,71
Northern Cape	614	5 767	165	6 546	9,38
Western Cape	1 720	14 159	79	15 958	10,78
Grand Total	17 639	203 108	4 315	225 062	7,84



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

Province	Inconclusive	Resistant	Sensitive	No Rif Results	Grand Total	% Rif Resistance
Eastern Cape	45	254	3 712	19	4 030	6,30
Free State	9	47	922	1	979	4,80
Gauteng	32	146	2 562	3	2 743	5,32
Kwa-Zulu Natal	62	356	3 987	4	4 409	8,07
Limpopo	13	60	925	6	1 004	5,98
Mpumalanga	13	85	949	6	1 053	8,07
North West	18	56	1 013		1 087	5,15
Northern Cape	5	31	576	2	614	5,05
Western Cape	25	82	1 613		1 720	4,77
Grand Total	222	1 117	16 259	41	17 639	6,33

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	33	248	2 919	52	3 252	7,63
EASTERN CAPE	2012	213	1 077	14 456	134	15 880	6,78
EASTERN CAPE	2013	1 274	2 969	41 073	153	45 469	6,53
EASTERN CAPE	2014	1 248	2 983	44 620	49	48 900	6,10
EASTERN CAPE	2015	288	1431	22324	32	24 075	5,94
FREE STATE	2011	28	155	2 626	2	2 811	5,51
FREE STATE	2012	162	755	10 717	26	11 660	6,48
FREE STATE	2013	372	800	13 564	22	14 758	5,42
FREE STATE	2014	367	816	12 843	4	14 030	5,82
FREE STATE	2015	71	326	5677	4	6 078	5,36
GAUTENG	2011	25	179	2 889	1	3 094	5,79
GAUTENG	2012	136	766	10 142	76	11 120	6,89
GAUTENG	2013	921	2 008	28 433	70	31 432	6,39
GAUTENG	2014	818	2 293	35 399	27	38 537	5,95
GAUTENG	2015	207	1008	16295	8	17 518	5,75
KWAZULU-NATAL	2011	64	592	6 875	15	7 546	7,85
KWAZULU-NATAL	2012	417	2 166	21 128	252	23 963	9,04
KWAZULU-NATAL	2013	1 076	3 704	37 079	435	42 294	8,76
KWAZULU-NATAL	2014	1 512	4 962	50 646	203	57 323	8,66
KWAZULU-NATAL	2015	424	2133	24657	42	27 256	7,83
LIMPOPO	2011	25	148	1 775	25	1 973	7,50
LIMPOPO	2012	52	268	3 609	75	4 004	6,69



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LIMPOPO	2013	299	715	12 803	110	13 927	5,13
LIMPOPO	2014	328	706	13 294	48	14 376	4,91
LIMPOPO	2015	65	330	5620	23	6 038	5,47
MPUMALANGA	2011	30	207	2 386	6	2 629	7,87
MPUMALANGA	2012	57	401	3 501	76	4 035	9,94
MPUMALANGA	2013	238	1 024	9 116	28	10 406	9,84
MPUMALANGA	2014	380	1 281	12 969	20	14 650	8,74
MPUMALANGA	2015	85	511	5777	8	6 381	8,01
NORTH WEST	2011	39	303	3 083	4	3 429	8,84
NORTH WEST	2012	75	414	5 000	10	5 499	7,53
NORTH WEST	2013	325	730	12 219	27	13 301	5,49
NORTH WEST	2014	504	909	15 579	9	17 001	5,35
NORTH WEST	2015	116	389	7042	5	7 552	5,15
NORTHERN CAPE	2011	28	186	2 511	2	2 727	6,82
NORTHERN CAPE	2012	50	236	3 536	8	3 830	6,16
NORTHERN CAPE	2013	175	422	7 025	290	7 912	5,33
NORTHERN CAPE	2014	200	448	8 022	15	8 685	5,16
NORTHERN CAPE	2015	35	210	3766	2	4 013	5,23
WESTERN CAPE	2011	15	107	2 050	1	2 173	4,92
WESTERN CAPE	2012	153	653	12 397	3	13 206	4,94
WESTERN CAPE	2013	636	1 409	26 606	2	28 653	4,92
WESTERN CAPE	2014	678	1 766	31 272	1	33 717	5,24
WESTERN CAPE	2015	142	693	13278	2	14 115	4,91
Total		14 386	45 837	628 598	2 407	691 228	6,63

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

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

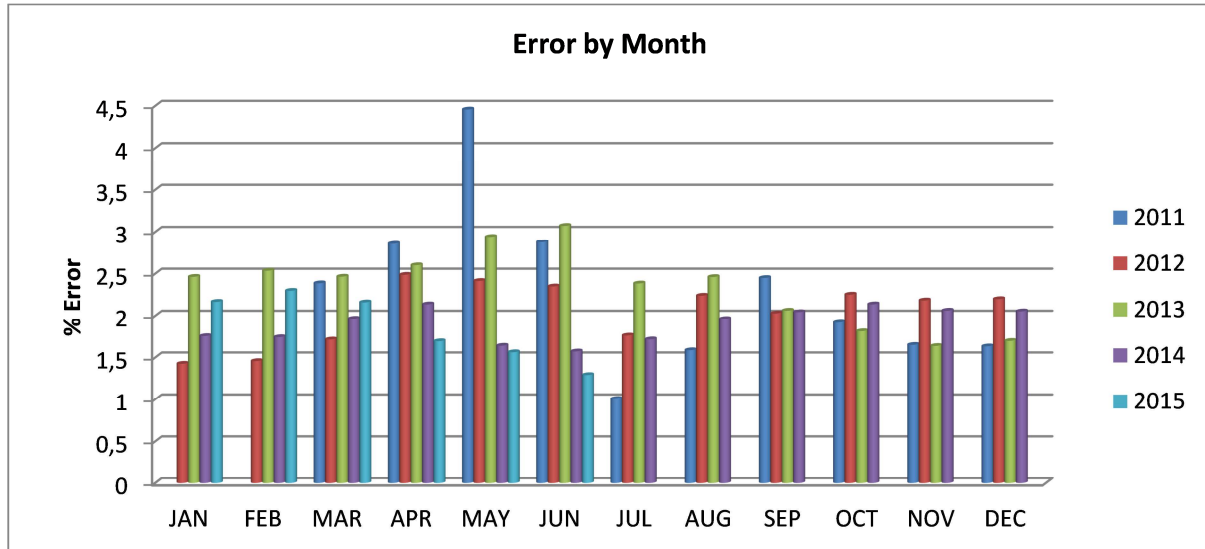
Average error rate has ranged consistently below 3% in the month of June. Details of the invalid results, which likely represent sample issues remains below 1%. These are being monitored regularly and corrective action implemented where necessary.

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

Province	Errors	Invalids	No Results	MTB Results	Grand Total	% Error
Eastern Cape	581	190	100	47 952	48 823	1,19
Free State	64	21	1	11 709	11 795	0,54
Gauteng	568	84	26	36 370	37 048	1,53
Kwa-Zulu Natal	644	334	179	54 608	55 765	1,15
Limpopo	463	99	17	22 790	23 369	1,98
Mpumalanga	202	71	30	12 124	12 427	1,63
North West	242	32	122	13 709	14 105	1,72
Northern Cape	101	61	3	6 386	6 551	1,54
Western Cape	50	23	6	15 924	16 003	0,31
Grand Total	2 915	915	484	221 572	225 886	1,29

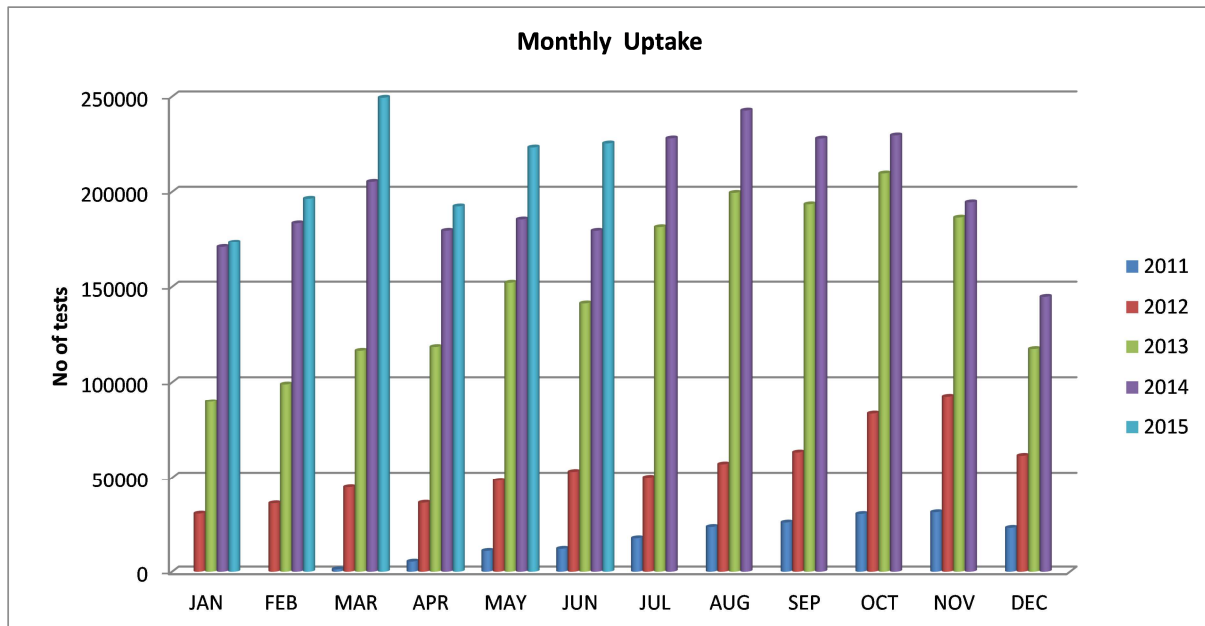


Figure 1: GeneXpert Error by Month



5. Monthly uptake since implementation started

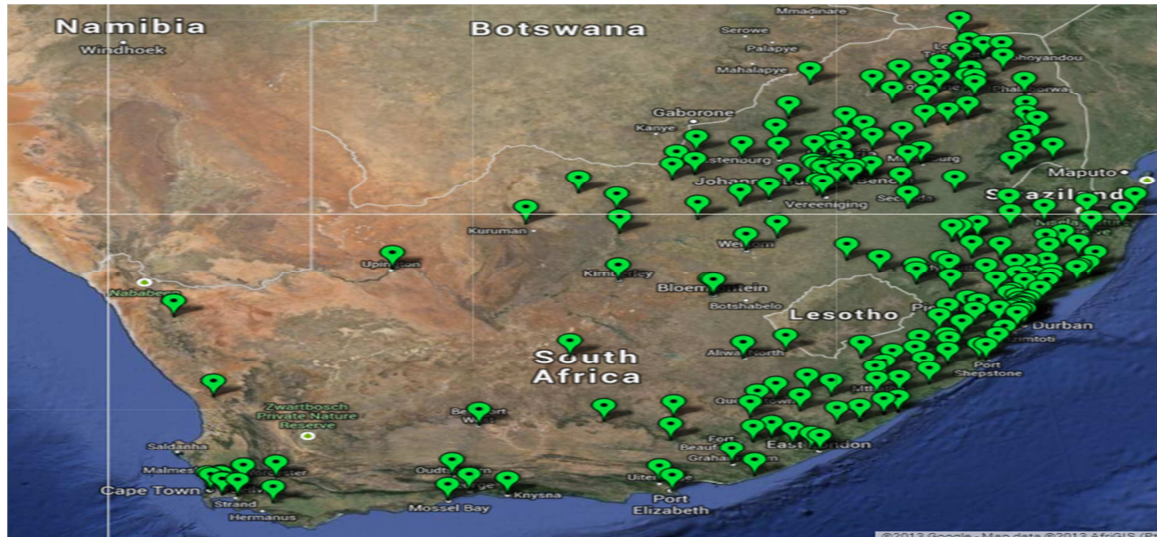
Figure 2: GeneXpert Monthly Uptake



Monthly uptake increased steadily since program inception. The main reason for interruptions is due to the variation in work practices which is expected during the December period.

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 1,747 laboratory staff and 8,745 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 to delay in 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 June