



NATIONAL HEALTH  
LABORATORY SERVICE

# GeneXpert MTB/RIF

## Progress Report

November 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, 314 GeneXpert instruments of varying sizes (GX4: 115; GX16:190; GX48: 1; GX80:8) have been placed in 211 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 7 427 506 specimens have been processed to date (30 November 2015). In November 188,659 specimens were processed. The total % of *Mycobacterium tuberculosis* complex (MTBC) detected in this cohort was 9.73% (18 355). 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 after introduction of Xpert® MTB/RIF assay (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	46,192	439,751	10,309	496,252	9.31
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	12,026	113,806	1,039	126,871	9.48
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	34,803	342,363	7,547	384,713	9.05
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	52,131	564,254	16,055	632,440	8.24
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	<b>234,572</b>	<b>6.14</b>
LIMPOPO	2015	11,702	202,669	6,087	<b>220,458</b>	<b>5.31</b>
MPUMALANGA	2011	2,647	12,813	1,105	<b>16,565</b>	<b>15.98</b>
MPUMALANGA	2012	4,034	22,218	1,133	<b>27,385</b>	<b>14.73</b>
MPUMALANGA	2013	9,908	59,950	2,311	<b>72,169</b>	<b>13.73</b>
MPUMALANGA	2014	14,623	112,311	4,202	<b>131,136</b>	<b>11.15</b>
MPUMALANGA	2015	12,295	110,512	3,615	<b>126,422</b>	<b>9.73</b>
NORTH WEST	2011	3,494	14,902	657	<b>19,053</b>	<b>18.34</b>
NORTH WEST	2012	5,499	29,974	2,051	<b>37,524</b>	<b>14.65</b>
NORTH WEST	2013	12,477	94,632	4,770	<b>111,879</b>	<b>11.15</b>
NORTH WEST	2014	17,009	150,702	6,631	<b>174,342</b>	<b>9.76</b>
NORTH WEST	2015	14,400	154,050	4,484	<b>172,934</b>	<b>8.33</b>
NORTHERN CAPE	2011	2,783	15,732	717	<b>19,232</b>	<b>14.47</b>
NORTHERN CAPE	2012	4,030	22,407	1,089	<b>27,526</b>	<b>14.64</b>
NORTHERN CAPE	2013	7,561	50,778	2,444	<b>60,783</b>	<b>12.44</b>
NORTHERN CAPE	2014	8,719	63,146	2,894	<b>74,759</b>	<b>11.66</b>
NORTHERN CAPE	2015	8,170	67,421	2,165	<b>77,756</b>	<b>10.51</b>
WESTERN CAPE	2011	2,195	10,089	28	<b>12,312</b>	<b>17.83</b>
WESTERN CAPE	2012	13,158	68,282	587	<b>82,027</b>	<b>16.04</b>
WESTERN CAPE	2013	30,163	162,869	2,785	<b>195,817</b>	<b>15.40</b>
WESTERN CAPE	2014	34,782	185,776	2,099	<b>222,657</b>	<b>15.62</b>
WESTERN CAPE	2015	33,092	192,245	1,099	<b>226,436</b>	<b>14.61</b>
<b>Total</b>		<b>803,175</b>	<b>6,435,776</b>	<b>188,555</b>	<b>7,427,506</b>	<b>10.81</b>

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

Province	MTB Detected	MTB Not Detected	Test Unsuccessful	Grand Total	% MTB Detected
Eastern Cape	3457	29894	571	33922	10.19
Free State	1013	8815	111	9939	10.19
Gauteng	2999	27566	670	31235	9.60
Kwa-Zulu Natal	4235	45990	1080	51305	8.25
Limpopo	967	14706	493	16166	5.98
Mpumalanga	1046	7794	205	9045	11.56
North West	1181	11100	199	12480	9.46
Northern Cape	687	5365	195	6247	11.00
Western Cape	2770	15328	222	18320	15.12
<b>Grand Total</b>	<b>18355</b>	<b>166558</b>	<b>3746</b>	<b>188659</b>	<b>9.73</b>

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

Province	Inconclusive	Resistant	Sensitive	No RIF Results	Grand Total	% RIF Resistant
Eastern Cape	61	186	3210		3457	5.38
Free State	13	48	952		1013	4.74
Gauteng	36	191	2770	2	2999	6.37
Kwa-Zulu Natal	48	320	3858	9	4235	7.56
Limpopo	10	35	921	1	967	3.62
Mpumalanga	13	86	946	1	1046	8.22
North West	16	51	1113	1	1181	4.32
Northern Cape	8	44	635		687	6.40
Western Cape	32	123	2615		2770	4.44
<b>Grand Total</b>	<b>237</b>	<b>1084</b>	<b>17020</b>	<b>14</b>	<b>18355</b>	<b>5.91</b>

**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	641	2,661	42,827	63	46,192	5.76
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	148	663	11,208	7	12,026	5.51
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	457	2,050	32,282	14	34,803	5.89
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	824	4,055	47,170	82	52,131	7.78
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	151	607	10,900	44	11,702	5.19
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	170	944	11,146	35	12,295	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	242	677	13,474	7	14,400	4.70
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	96	418	7,649	7	8,170	5.12
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	356	1,631	31,099	6	33,092	4.93
<b>Total</b>		<b>15,874</b>	<b>56,912</b>	<b>727,516</b>	<b>2,873</b>	<b>803,175</b>	<b>7.09</b>

### 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
<b>National</b>	<b>41 522</b>	<b>5 208</b>	<b>12,5%</b>	<b>4 462</b>	<b>85,7%</b>	<b>12</b>	<b>14 030</b>	<b>33,8%</b>	<b>12 496</b>	<b>89,1%</b>	<b>432</b>

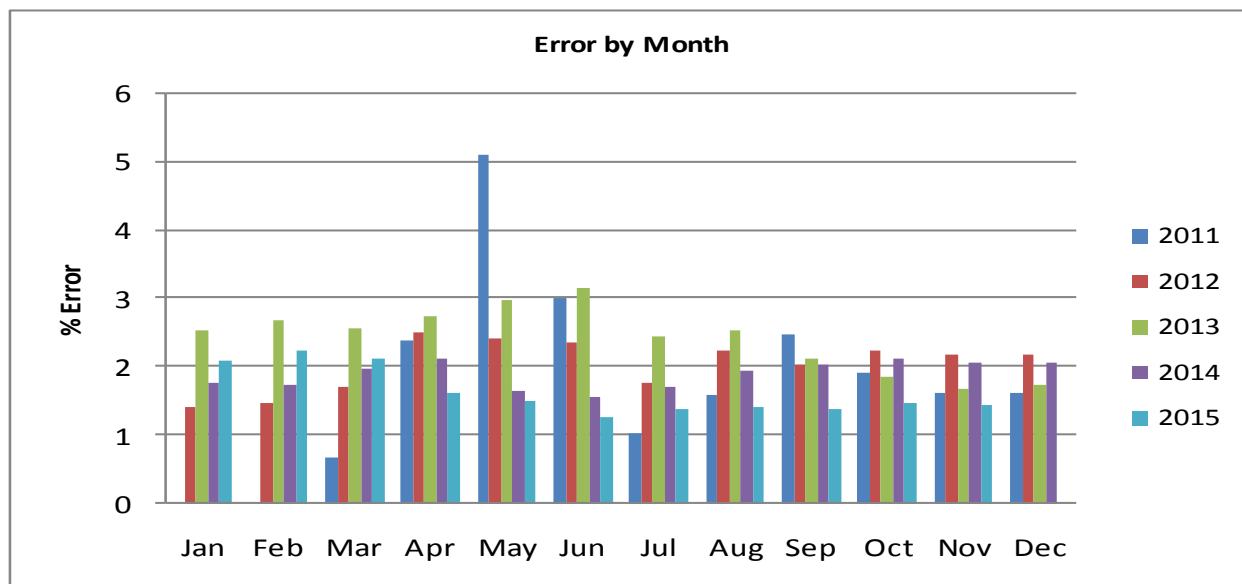
#### 4. Errors

Average error rate has ranged consistently below 3% in the month of November. 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 November 2015)**

Province	Error	Invalid	No Results	MTB Results	Grand Total	% Error
Eastern Cape	419	96	56	33353	33924	1.24
Free State	43	61	7	9828	9939	0.43
Gauteng	474	133	63	30565	31235	1.52
Kwa-Zulu Natal	829	154	97	50230	51310	1.62
Limpopo	354	113	25	15673	16166	2.19
Mpumalanga	152	24	29	8840	9045	1.68
North West	161	24	14	12281	12480	1.29
Northern Cape	112	58	25	6052	6247	1.79
Western Cape	175	28	19	18100	18322	0.96
<b>Grand Total</b>	<b>2719</b>	<b>691</b>	<b>335</b>	<b>184922</b>	<b>188668</b>	<b>1.44</b>

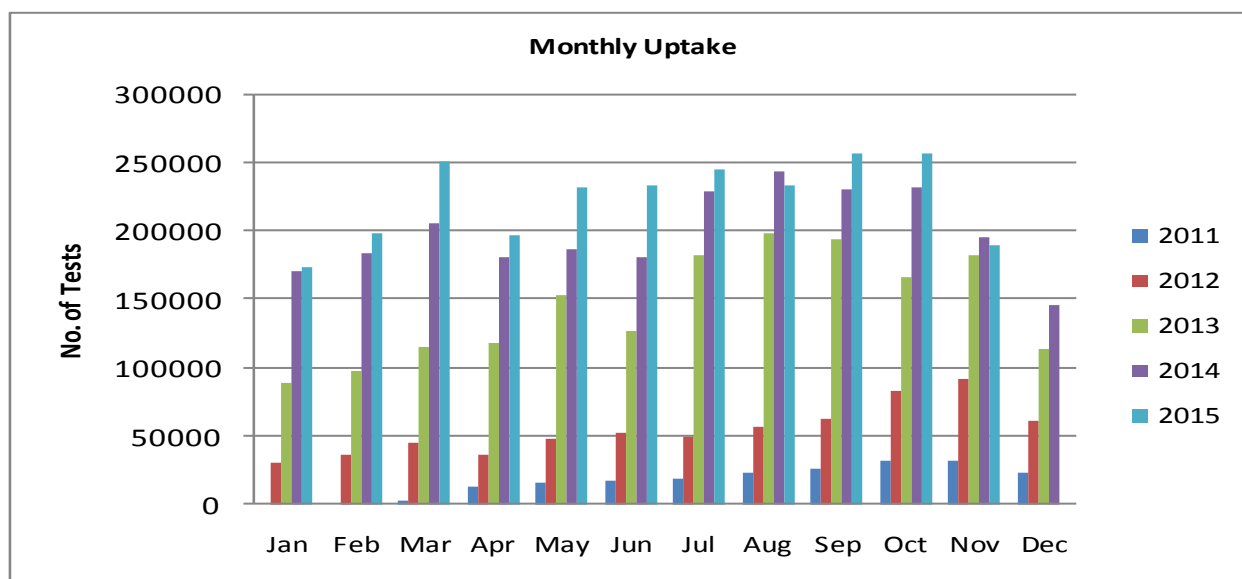
**Figure 1: GeneXpert Error by Month**



Average error rate has ranged consistently below 3%, except in May 2011-reagent lot problem

## 5. Monthly uptake since implementation started

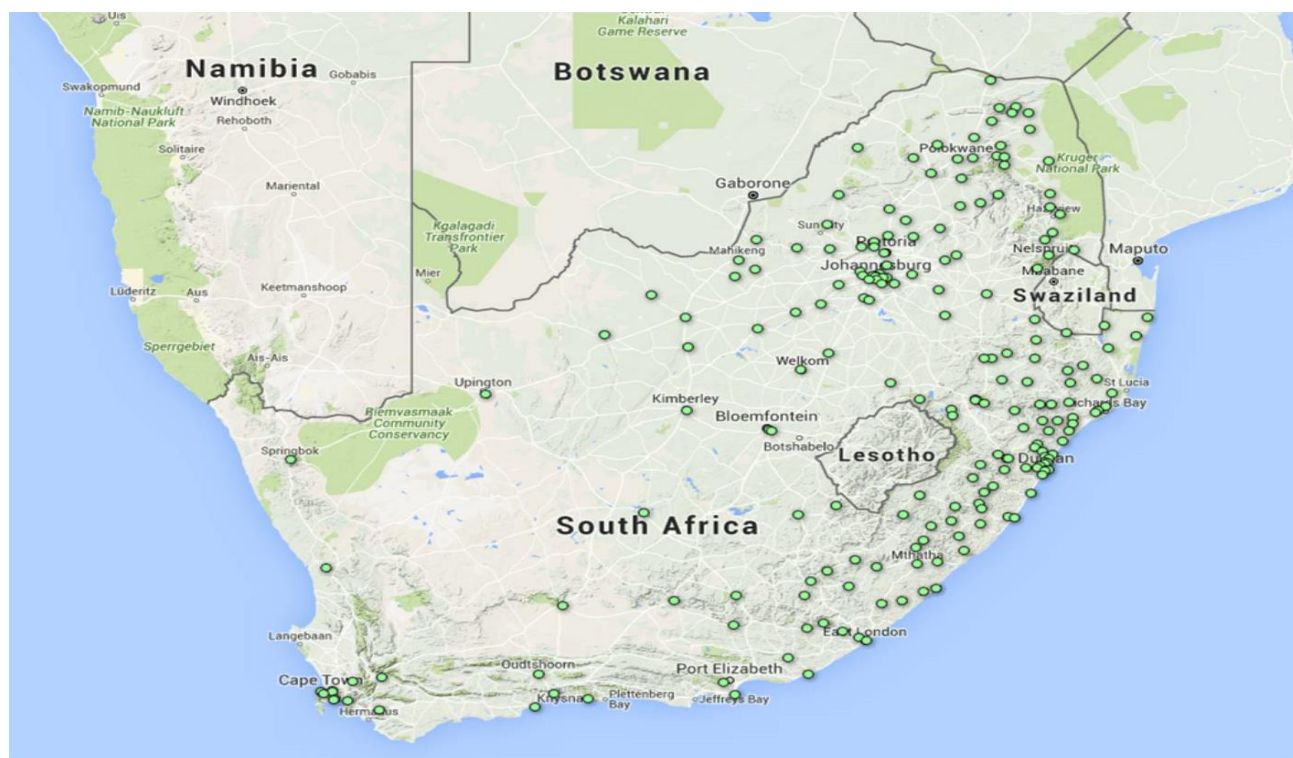
**Figure 2: GeneXpert Monthly Uptake**



Monthly uptake increased steadily since program inception.

## 6. Phased Implementation Progress

**Figure 3:** Current GeneXpert Placements (211 testing centers, 314 analysers, GX4: 115; GX16-8: 1; GX16: 189; GX48:1; GX80: 8) \*281 hospital placements \*20 clinic placements \*7 Correctional Facilities \*6 Mobile Vans



## 7. Training: Laboratory and Clinical

A total of 1,965 laboratory staff and 9,935 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
<b>Subtotal</b>	<b>100</b>

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

## 10. Recent Campaigns

- The NHLS National priority program (NPP) supported an HCT campaign in Khayelitsha on 30 November that was attended by parliamentarians. A mobile lab was present at the event.
- The NHLS NPP supported an HCT campaign at Parliament on 3 November for an address by the Minister of Health to parliamentarians.