



NATIONAL HEALTH
LABORATORY SERVICE

GeneXpert MTB/RIF

Progress Report

December 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 7 606 430 specimens have been processed to date (31 December 2015). In December 153,436 specimens were processed. The total % of *Mycobacterium tuberculosis* complex (MTBC) detected in this cohort was 11.51% (17 658). 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	50,454	467,410	10,885	528,749	9.54
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	13,107	121,843	1,186	136,136	9.63
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	37,952	366,465	8,013	412,430	9.20
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	56,886	607,266	17,300	681,452	8.35
LIMPOPO	2011	1,930	17,069	171	19,170	10.07
LIMPOPO	2012	3,984	30,848	690	35,522	11.22

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	13,417	181,744	6,013	201,174	6.67
LIMPOPO	2014	14,412	212,466	7,694	234,572	6.14
LIMPOPO	2015	12,850	215,490	6,542	234,882	5.47
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	13,437	118,670	3,871	135,978	9.88
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	15,699	164,384	4,749	184,832	8.49
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	8,882	72,475	2,372	83,729	10.61
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	35,996	206,943	2,079	245,018	14.69
Total		823,627	6,589,651	193,152	7,606,430	10.83

Table 2: GeneXpert MTB Results by province (01-31 December 2015)

Province	MTB Detected	MTB Not Detected	Test Unsuccessful	Grand Total	% MTB Detected
Eastern Cape	3572	22895	462	26929	13.26
Free State	935	6939	133	8007	11.68
Gauteng	2784	21866	404	25054	11.11
Kwa-Zulu Natal	4126	37744	1138	43008	9.59
Limpopo	1065	11425	426	12916	8.25
Mpumalanga	946	6584	200	7730	12.24
North West	1061	8158	205	9424	11.26
Northern Cape	605	4149	188	4942	12.24
Western Cape	2564	12723	139	15426	16.62
Grand Total	17658	132483	3295	153436	11.51

Table 3: Provincial GeneXpert RIF Results in MTB detected cases (01-31 December 2015)

Province	Inconclusive	Resistant	Sensitive	No RIF	Grand Total	% RIF Resistant
Eastern Cape	33	191	3348		3572	5.35
Free State	5	42	888		935	4.49
Gauteng	24	161	2598	1	2784	5.78
Kwa-Zulu Natal	39	319	3767	1	4126	7.73
Limpopo	8	53	1004		1065	4.98
Mpumalanga	9	88	844	5	946	9.30
North West	11	60	990		1061	5.66
Northern Cape	7	44	554		605	7.27
Western Cape	29	152	2382	1	2564	5.93
Grand Total	165	1110	16375	8	17658	6.29

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	682	2,883	46,839	50	50,454	5.71
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	154	713	12,236	4	13,107	5.44
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	487	2,240	35,215	10	37,952	5.90
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	870	4,410	51,536	70	56,886	7.75
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	159	666	11,997	28	12,850	5.18
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	182	1,047	12,186	22	13,437	7.79
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	255	758	14,678	8	15,699	4.83
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	103	469	8,303	7	8,882	5.28
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	388	1,792	33,809	7	35,996	4.98
Total		16,069	58,184	746,560	2,814	823,627	7.06

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 30 September 2015)

		GeneXpert Confirmation & Rif Concordance									
Province	Rif Resistant Cases	MGIT					LPA				
		Confirmed		Rif Concordance		Pre-analytical/No result	Confirmed		Rif Concordance		Indeterminate
		#	%	#	%		#	%	#	%	
Eastern Cape	8,663	348	4.0%	233	67.0%	3	2,823	32.6%	2,612	92.5%	11
Free State	2,701	217	8.0%	120	55.3%	0	852	31.5%	699	82.0%	187
Gauteng	6,297	219	3.5%	146	66.7%	4	1,604	25.5%	1,437	89.6%	29
Kwazulu-Natal	13,869	3,737	26.9%	3473	92.9%	0	3,630	26.2%	3,252	89.6%	166
Limpopo	2,101	94	4.5%	71	75.5%	2	508	24.2%	406	79.9%	21
Mpumalanga	3,333	679	20.4%	667	98.2%	0	1,258	37.7%	1,079	85.8%	3
North West	2,397	203	8.5%	139	68.5%	0	769	32.1%	621	80.8%	52
Northern Cape	1,341	283	21.1%	215	76.0%	3	566	42.2%	432	76.3%	34
Western Cape	4,784	185	3.9%	64	0.0%	0	3,753	78.4%	3,470	92.5%	3
National	45,486	5,965	13.1%	5,128	86.0%	12	15,763	34.7%	14,008	88.9%	506

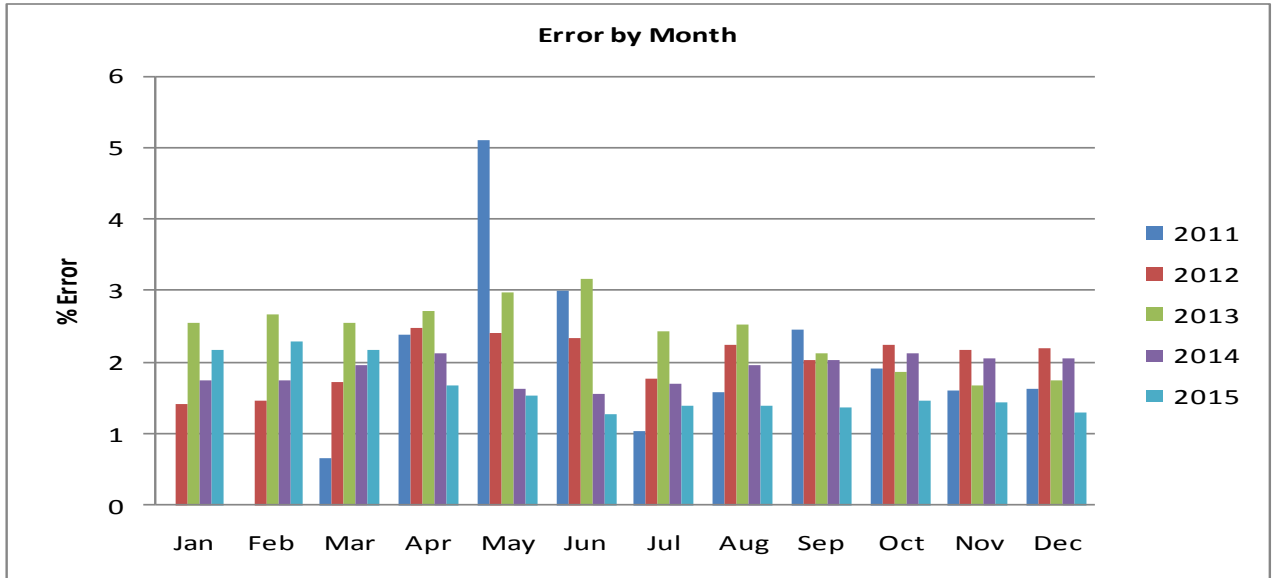
4. Errors

Average error rate has ranged consistently below 3% in the month of December. 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 (1-31 December 2015)

Province	Error	Invalid	No Results	MTB Results	Grand Total	% Error
Eastern Cape	291	127	44	26467	26929	1.08
Free State	43	88	2	7878	8011	0.54
Gauteng	204	182	18	24661	25065	0.81
Kwa-Zulu Natal	775	248	115	41884	43022	1.80
Limpopo	251	130	45	12496	12922	1.94
Mpumalanga	126	51	23	7532	7732	1.63
North West	142	59	4	9221	9426	1.51
Northern Cape	67	104	17	4755	4943	1.36
Western Cape	96	29	14	15289	15428	0.62
Grand Total	1995	1018	282	150183	153478	1.30

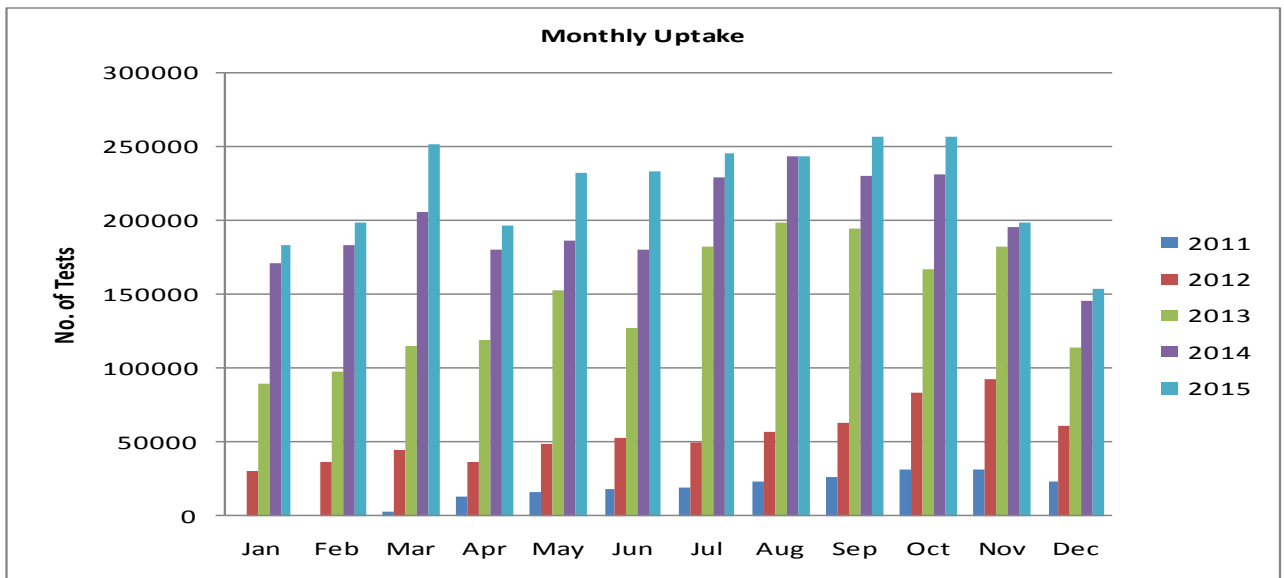
Figure 1: GeneXpert Error by Month



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

5. Monthly uptake since implementation started

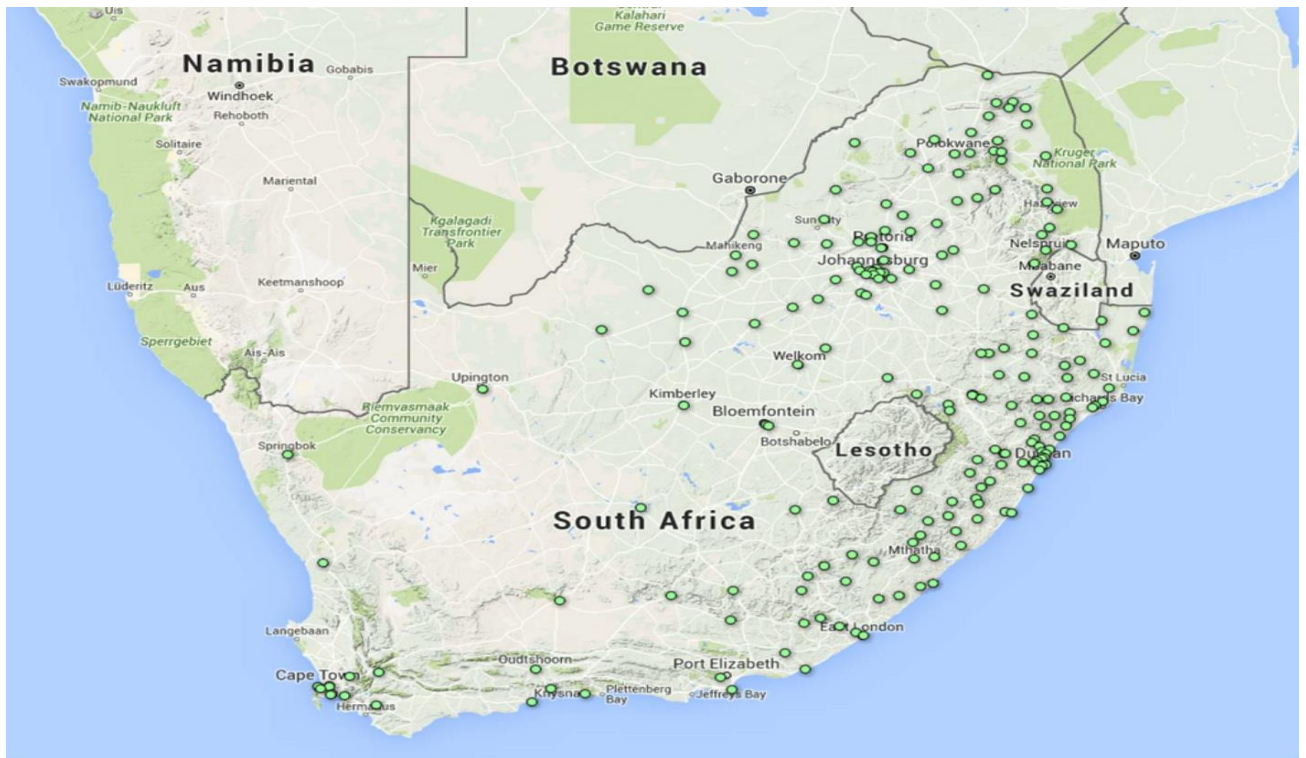
Figure 2: GeneXpert Monthly Uptake



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 1,984 laboratory staff and 9,953 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

- a. The NHLS supported the World Union Conference from 1-5 December offering on-site testing in a mobile lab to delegates and community attendees. A total of 16 GeneXpert were tested on site at the conference.
- b. The NHLS NPP team presented oral presentations at the World Union Conference.
- c. The NHLS supported the World Aids day event at Port Shepstone Kwazulu Natal on the 1st December. No testing performed on site.



Picture: NHLS NPP Team and the KZN management staff on World aids day event in Port Shepstone KwaZulu Natal