



NATIONAL HEALTH
LABORATORY SERVICE

GeneXpert MTB/RIF

Progress Report

February 2012





GeneXpert Implementation Report Update

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1. Background to Project

This project was initiated at the request of the Honorable Minister of Health in early 2011. A pilot study was proposed by the National Department of Health (NDoH) (particularly the TB cluster) while due diligence was being done with respect to project feasibility. This was further prompted by the World Health Organization's strong recommendation in December 2010 that "the new automated DNA test for TB be used as the initial diagnostic test in individuals suspected of MDR-TB or HIV/TB (i.e. all SA TB suspects).

The pilot phase was initiated in microscopy centres in high focus TB areas. The ministry requested that at least 1 instrument be placed in each province, preferably in a district that had a high burden of TB (Selections were made by TB cluster). Twenty-five microscopy centres were selected and a total of 30 instruments placed. The NDoH funded 9 GX16 and 14 GX4 instruments for the project. FIND donated 6 GX4 analysers and the Infinity or GX48 was supported by PEPFAR RTC. All instruments were placed by World TB day March 24th. 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.

2. Assays performed to date

In summary, a total of 271,666 specimens have been processed to date (Feb 2012). The total % of MTB detected in this cohort amounted to 17.24% (46,582 new TB cases). The percentage positivity has remained on average between 16-17% monthly nationally. To date KZN has performed the largest number of tests which is probably as a result of the throughput of the GX48 analyzer (Refer to table 1). Average Rifampicin resistance detection rates have remained around 7% since project inception (Refer to table 2). We have highlighted to CDW that some Health Districts are incorrect.



Table 1: GeneXpert MTB Results by province

Province	Month	Year	MTB Detected	MTB Not Detected	Test Unsuccessful	Grand Total	MTB % Detected
Eastern Cape	January	2012	1020	4243	149	5412	18.85
	February	2012	865	4150	108	5123	16.88
	March	2011	6	147		153	3.92
	April	2011	143	688	24	855	16.73
	May	2011	229	1063	106	1398	16.38
	June	2011	250	1242	22	1514	16.51
	July	2011	279	1285	21	1585	17.60
	August	2011	395	1903	62	2360	16.74
	September	2011	396	2050	78	2524	15.69
	October	2011	589	2782	100	3471	16.97
	November	2011	503	2335	71	2909	17.29
	December	2011	544	1974	75	2593	20.98
Eastern Cape Total			5219	23862	816	29897	17.46
Free State	January	2012	731	3559	10	4300	17.00
	February	2012	655	3985	18	4658	14.06
	April	2011	11	28		39	28.21
	May	2011	233	1240	1	1474	15.81
	June	2011	249	1285		1534	16.23
	July	2011	269	1495		1764	15.25
	August	2011	303	1655	1	1959	15.47
	September	2011	311	1742	2	2055	15.13
	October	2011	482	2169		2651	18.18
	November	2011	535	2778	17	3330	16.07
	December	2011	521	2439	5	2965	17.57
Free State Total			4300	22375	54	26729	16.09
Gauteng	January	2012	574	3351	58	3983	14.41
	February	2012	439	3012	61	3512	12.50
	March	2011	50	460	11	521	9.60
	April	2011	67	318	7	392	17.09
	May	2011	320	1492	46	1858	17.22
	June	2011	231	1219	28	1478	15.63
	July	2011	230	1640	17	1887	12.19
	August	2011	353	2436	59	2848	12.39
	September	2011	342	2330	100	2772	12.34
	October	2011	472	3121	77	3670	12.86
	November	2011	566	3733	51	4350	13.01
	December	2011	488	2542	35	3065	15.92
Gauteng Total			4132	25654	550	30336	13.62
Kwa-Zulu Natal	January	2012	1617	5974	133	7724	20.93
	February	2012	1577	6663	179	8419	18.73
	March	2011	483	1472	71	2026	23.84
	April	2011	1613	5728	171	7512	21.47
	May	2011	1020	3368	347	4735	21.54
	June	2011	1291	3938	202	5431	23.77
	July	2011	1297	3912	164	5373	24.14
	August	2011	1588	5237	196	7021	22.62
	September	2011	1614	5686	193	7493	21.54
	October	2011	1419	6550	113	8082	17.56
	November	2011	1522	7079	141	8742	17.41
	December	2011	1396	4629	132	6157	22.67
Kwa-Zulu Natal Total			16437	60236	2042	78715	20.88



GeneXpert MTB Results by province continued:

Province	Month	Year	MTB Detected	MTB Not Detected	Test Unsuccessful	Grand Total	MTB % Detected
Limpopo	January	2012	259	1495	36	1790	14.47
	February	2012	221	1777	29	2027	10.90
	March	2011	5	11		16	31.25
	April	2011	88	912	12	1012	8.70
	May	2011	195	1463	19	1677	11.63
	June	2011	213	1695	31	1939	10.99
	July	2011	195	1853	9	2057	9.48
	August	2011	218	2195	16	2429	8.97
	September	2011	300	2750	20	3070	9.77
	October	2011	330	3019	31	3380	9.76
	November	2011	314	2356	16	2686	11.69
	December	2011	221	1447	17	1685	13.12
Limpopo Total			2559	20973	236	23768	10.77
Mpumalanga	January	2012	272	1307	87	1666	16.33
	February	2012	262	1258	87	1607	16.30
	March	2011	68	306	28	402	16.92
	April	2011	210	1028	92	1330	15.79
	May	2011	288	1376	251	1915	15.04
	June	2011	257	1578	181	2016	12.75
	July	2011	346	1499	40	1885	18.36
	August	2011	300	1273	83	1656	18.12
	September	2011	277	1401	189	1867	14.84
	October	2011	367	1732	107	2206	16.64
	November	2011	314	1659	93	2066	15.20
	December	2011	220	920	43	1183	18.60
Mpumalanga Total			3181	15337	1281	19799	16.07
North West	January	2012	283	1347	44	1674	16.91
	February	2012	286	1246	63	1595	17.93
	March	2011		2		2	-
	April	2011	74	523	7	604	12.25
	May	2011	222	1180	45	1447	15.34
	June	2011	206	1064	24	1294	15.92
	July	2011	254	1201	31	1486	17.09
	August	2011	340	1641	43	2024	16.80
	September	2011	379	1842	110	2331	16.26
	October	2011	358	2051	122	2531	14.14
	November	2011	340	1426	60	1826	18.62
	December	2011	249	1081	64	1394	17.86
North West Total			2991	14604	613	18208	16.43
Northern Cape	January	2012	174	561	7	742	23.45
	February	2012	277	1431	24	1732	15.99
	March	2011	36	281	11	328	10.98
	April	2011	131	679	21	831	15.76
	May	2011	309	1155	90	1554	19.88
	June	2011	359	1696	150	2205	16.28
	July	2011	434	2370	70	2874	15.10
	August	2011	501	2578	102	3181	15.75
	September	2011	467	2457	91	3015	15.49
	October	2011	500	2594	100	3194	15.65
	November	2011	326	1648	48	2022	16.12
	December	2011	156	506	5	667	23.39
Northern Cape Total			3670	17956	719	22345	16.42
Western Cape	January	2012	982	3448	17	4447	22.08
	February	2012	902	4156	29	5087	17.73
	March	2011	14	52		66	21.21
	April	2011	7	3	1	11	63.64
	May	2011			1	1	-
	June	2011	4	11		15	26.67
	July	2011	6	21		27	22.22
	August	2011	174	811	6	991	17.56
	September	2011	200	1103	3	1306	15.31
	October	2011	447	2146	3	2596	17.22
	November	2011	684	3237	6	3927	17.42
	December	2011	673	2711	11	3395	19.82
Western Cape Total			4093	17699	77	21869	18.72
Grand Total			46582	218696	6388	271666	17.15



Table 2: Provincial GeneXpert RIF Results in MTB detected cases

Province	Month	Year	Inconclusive	No Result	Resistant	Sensitive	Grand Total	RIF % Resistant
Eastern Cape	January	2012	12	20	74	914	1020	7.25
	February	2012	13	39	63	750	865	7.28
	March	2011		1		5	6	-
	April	2011			14	129	143	9.79
	May	2011		2	14	213	229	6.11
	June	2011	1	2	21	226	250	8.40
	July	2011	1	10	18	250	279	6.45
	August	2011	1	24	31	339	395	7.85
	September	2011	5	6	30	355	396	7.58
	October	2011	15	9	32	533	589	5.43
	November	2011	4		47	452	503	9.34
	December	2011	5	3	45	491	544	8.27
Eastern Cape Total			57	116	389	4657	5219	7.45
Free State	January	2012	13		47	671	731	6.43
	February	2012	12	2	34	607	655	5.19
	April	2011				11	11	-
	May	2011	2		15	216	233	6.44
	June	2011	2		11	236	249	4.42
	July	2011	2		16	251	269	5.95
	August	2011	5	1	14	283	303	4.62
	September	2011	6		18	287	311	5.79
	October	2011	4		33	445	482	6.85
	November	2011	5		23	507	535	4.30
	December	2011	3		27	491	521	5.18
Free State Total			54	3	238	4005	4300	5.53
Gauteng	January	2012	6		47	521	574	8.19
	February	2012	6		33	400	439	7.52
	March	2011			5	45	50	10.00
	April	2011	1		5	61	67	7.46
	May	2011			31	289	320	9.69
	June	2011	2		11	218	231	4.76
	July	2011	2		17	211	230	7.39
	August	2011	6		15	332	353	4.25
	September	2011	3		22	317	342	6.43
	October	2011	2	1	20	449	472	4.24
	November	2011	3		34	529	566	6.01
	December	2011	7		22	459	488	4.51
Gauteng Total			38	1	262	3831	4132	6.34
Kwa-Zulu Natal	January	2012	30	3	111	1473	1617	6.86
	February	2012	46	2	184	1345	1577	11.67
	March	2011	3	1	42	437	483	8.70
	April	2011	12	31	103	1467	1613	6.39
	May	2011	19	12	69	920	1020	6.76
	June	2011	9	1	101	1180	1291	7.82
	July	2011	10	1	76	1210	1297	5.86
	August	2011	14		109	1465	1588	6.86
	September	2011	14	4	125	1471	1614	7.74
	October	2011	14		110	1295	1419	7.75
	November	2011	13	3	125	1381	1522	8.21
	December	2011	5	5	113	1273	1396	8.09
Kwa-Zulu Natal Total			189	63	1268	14917	16437	7.71



Provincial GeneXpert RIF Results in MTB detected cases continued:

Province	Month	Year	Inconclusive	No Result	Resistant	Sensitive	Grand Total	RIF % Resistant
Limpopo	January	2012	2	1	14	242	259	5.41
	February	2012	4	1	18	198	221	8.14
	March	2011		1	1	3	5	20.00
	April	2011			9	79	88	10.23
	May	2011	2	11	9	173	195	4.62
	June	2011	1		24	188	213	11.27
	July	2011	1	1	14	179	195	7.18
	August	2011		1	14	203	218	6.42
	September	2011	15	2	20	263	300	6.67
	October	2011	3	4	22	301	330	6.67
	November	2011	2	2	19	291	314	6.05
	December	2011	3	1	19	198	221	8.60
Limpopo Total			33	25	183	2318	2559	7.15
Mpumalanga	January	2012	2	26	21	223	272	7.72
	February	2012	8		21	233	262	8.02
	March	2011		1	7	60	68	10.29
	April	2011	1		20	189	210	9.52
	May	2011	5		22	261	288	7.64
	June	2011	6		17	234	257	6.61
	July	2011	1		29	316	346	8.38
	August	2011	3		24	273	300	8.00
	September	2011	4		29	244	277	10.47
	October	2011	6		23	338	367	6.27
	November	2011	3	3	18	290	314	5.73
	December	2011	2	1	23	194	220	10.45
Mpumalanga Total			41	31	254	2855	3181	7.98
North West	January	2012	5		27	251	283	9.54
	February	2012	3		18	265	286	6.29
	April	2011	1	1	6	66	74	8.11
	May	2011	4		23	195	222	10.36
	June	2011	2	1	18	185	206	8.74
	July	2011	5		23	226	254	9.06
	August	2011	2		23	315	340	6.76
	September	2011	3		35	341	379	9.23
	October	2011	8		17	333	358	4.75
	November	2011	3		26	311	340	7.65
North West Total			36	2	241	2712	2991	8.06
Northern Cape	January	2012	3		11	160	174	6.32
	February	2012	3	2	13	259	277	4.69
	March	2011			5	31	36	13.89
	April	2011		1	7	123	131	5.34
	May	2011	2	1	14	292	309	4.53
	June	2011	1	1	29	328	359	8.08
	July	2011	5		50	379	434	11.52
	August	2011	4		28	469	501	5.59
	September	2011	7		24	436	467	5.14
	October	2011	4		28	468	500	5.60
	November	2011	4		14	308	326	4.29
	December	2011	1	1	4	150	156	2.56
Northern Cape Total			34	6	227	3403	3670	6.19
Western Cape	January	2012	5		45	932	982	4.58
	February	2012	6	1	35	860	902	3.88
	March	2011				14	14	-
	April	2011				7	7	-
	June	2011		1		3	4	-
	July	2011				6	6	-
	August	2011	2		11	161	174	6.32
	September	2011			9	191	200	4.50
	October	2011	4		17	426	447	3.80
	November	2011	7		35	642	684	5.12
	December	2011	3		34	636	673	5.05
Western Cape Total			27	2	186	3878	4093	4.54
Grand Total			509	249	3248	42576	46582	6.97

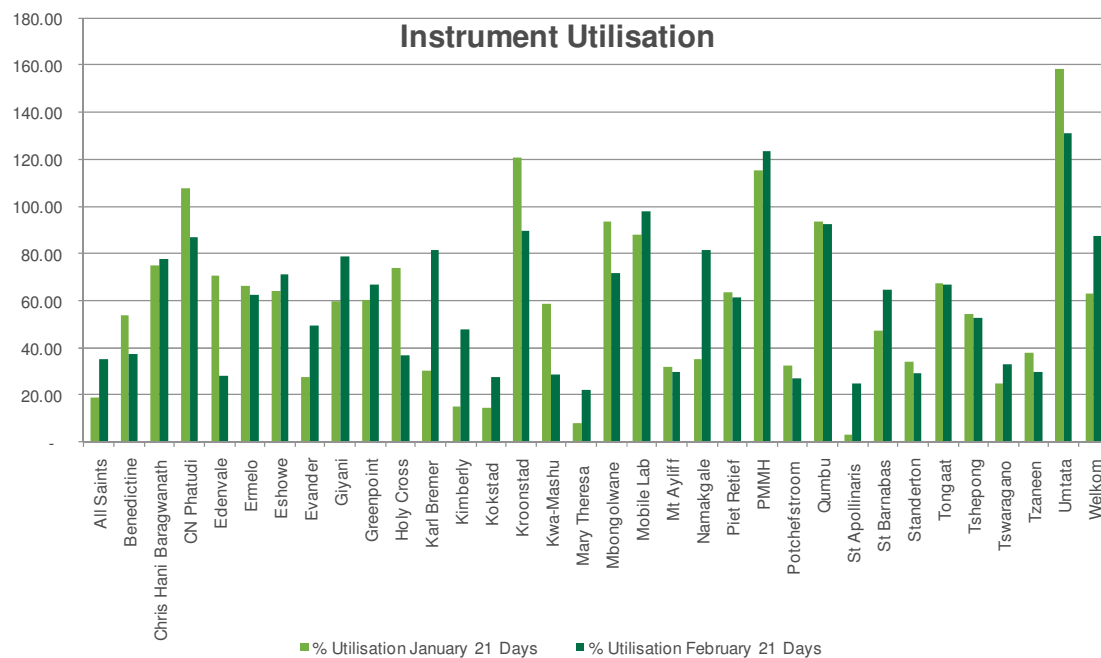


Errors have ranged consistently below 3%. Details of invalid results, which likely represent sample issues remains below 1%. These are being monitored regularly and corrective action implemented where necessary.

Table 3: Number of Unsuccessful Tests and Reasons

Province	Error	Invalid	No Result	GXP Result	Grand Total	% Error Total
Eastern Cape	730	71	15	29,081	29,897	2.44
Free State	48	6		26,675	26,729	0.18
Gauteng	474	67	9	29,786	30,336	1.56
Kwa-Zulu Natal	1,390	608	44	76,673	78,715	1.77
Limpopo	187	39	10	23,532	23,768	0.79
Mpumalanga	1,185	89	7	18,518	19,799	5.99
North West	575	34	4	17,595	18,208	3.16
Northern Cape	572	132	15	21,626	22,345	2.56
Western Cape	48	11	18	21,792	21,869	0.22
Grand Total	5,209	1,057	122	265,278	271,666	1.92

3. Utilization rates of instruments within the field



Instrument utilization seems to have decreased significantly at some few sites from December to January due to uptake.



4. Further project phases as defined in the NTCM model

Phase I has been completed and has been reported on in the section above.

Phase IIa involves full capacitation of existing labs: Completed October.

Phase IIb: Full capacitation of high burden districts.

Phase IIIa and b: Gates funded study (Gauteng, EC and Free State)

Phase IIIc: ensuring all districts have a minimum of 1 instrument per district

Phase IIId: Completion of all current microscopy and clinic sites

5. Specific GeneXpert Progress

- **Phase 2a:** Completed
- **Phase 2b:** Global Fund funding for phase 2b has been approved. Singing of contracts between the primary recipients and sub-recipients is underway. Phase 2b is projected to roll-out in April 2012. 19 Instruments have been installed at 12 sites. Training, verification and LIS interfacing of the instruments are underway.

Table 4: Phase 2b

Province	District	Lab	Capacity Per Day	Instruments			Donor
				GX4	GX16	GX48	
EC	Amathole	EAST LONDON TB	576	0	0	1	Global Fund RTC
EC	Nelson Mandela Bay Metro	PORT ELIZABETH TB	576	0	0	1	Global Fund RTC
EC	O.R. Tambo	ST ELIZABETH	64	0	1	0	Global Fund DOH
EC	O.R. Tambo	ST LUCY	16	1	0	0	Global Fund DOH
EC	O.R. Tambo	ZITULELE	32	0	1	0	Global Fund DOH
GP	City of Johannesburg	CENTRAL TB	80	1	1	0	Global Fund DOH
GP	City of Johannesburg	NJH ROUTINE	16	1	0	0	Global Fund DOH
KZN	eThekweni	Addington	32	0	1	0	Global Fund DOH
KZN	eThekweni	Charles James MC	32	0	1	0	Global Fund DOH
KZN	eThekweni	Clairwood	16	1	0	0	Global Fund DOH
KZN	eThekweni	Dbn Chest Clinic MC	64	0	1	0	Global Fund DOH
KZN	eThekweni	Don Mackenzie MC	16	1	0	0	Global Fund DOH
KZN	eThekweni	FOSA MC	16	1	0	0	Global Fund DOH
KZN	eThekweni	Hlengisizwe MC	16	1	0	0	Global Fund DOH
KZN	eThekweni	Inanda C MC	32	0	1	0	Global Fund DOH
KZN	eThekweni	KwaDabeka MC	32	0	1	0	Global Fund DOH
KZN	eThekweni	Mahatma Ghandi	48	0	1	0	Global Fund DOH
KZN	eThekweni	Osindisweni	16	1	0	0	Global Fund DOH
KZN	eThekweni	PineTown MC	48	0	1	0	Global Fund DOH
KZN	eThekweni	RK Khan	64	0	1	0	Global Fund DOH
KZN	eThekweni	Verulam MC	16	1	0	0	Global Fund DOH
KZN	eThekweni	Wentworth	32	0	1	0	Global Fund DOH
KZN	Sisonke	Kokstad	32	2	0	0	50% Global Fund DOH and TB/HIV Care
KZN	Sisonke	Pholela HCC	16	1	0	0	TB/HIV Care
KZN	Sisonke	Rietvlei	48	0	1	0	Global Fund DOH
KZN	Sisonke	St. Appolinaris	16	1	0	0	TB/HIV Care
KZN	Uthungulu	Eshowe	16	1	0	0	MSF
KZN	Uthungulu	Mbongolwana	16	1	0	0	MSF
KZN	Zululand	Benedictine	48	0	1	0	Global Fund DOH
LP	Mopani	KGAPANE	32	0	1	0	Global Fund DOH
LP	Mopani	PHALABORWA	32	0	1	0	Global Fund DOH
LP	Mopani	SEKORORO	16	1	0	0	Global Fund DOH
MP	Gert Sibande	EMBULENI	32	0	1	0	Global Fund DOH
NC	Siyanda	UPINGTON	64	0	1	0	Global Fund DOH
NW	Dr Kenneth Kaunda (Southern)	POTCHEFSTROOM	48	0	1	0	Global Fund DOH
WC	City of Cape Town	GROOTE SCHUUR CLINICAL PATH	48	0	1	0	Global Fund DOH



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Table 5: Phase 3a Progress

Installations, training and instrument verifications using dried culture spots completed.

Table 6: Phase 3b

The remaining 10 machines will be placed in July 2012 in the following laboratories:

Serial	Province	District	Lab	GX4	GX16	GX48	Capacity Per Day	Status	Donor
25	EC	Chris Hani	COFIMVABA		1		64	Pending	Gates Foundation
29	EC	Chris Hani	QUEENSTOWN	1	1		80	Pending	Gates Foundation
33	EC	Nelson Mandela Bay Metro	UITENHAGE		1		64	Pending	Gates Foundation
57	FS	Thabo Mofutsanyane	MANAPO		1		48	Pending	Gates Foundation
68	GP	City of Tshwane	JUBILEE		1		48	Pending	Gates Foundation
69	GP	City of Tshwane	MAMELODI		1		64	Pending	Gates Foundation
77	GP	Ekurhuleni	NATALSPRUIT		1		64	Pending	Gates Foundation
85	GP	West Rand	CARLETONVILLE		1		64	Pending	Gates Foundation
46	EC	Ukhahlamba	TAYLOR BEQUEST	1	1		80	Pending	Gates Foundation
133	MP	Ehlanzeni	NELSPRUIT		2		128	Pending	Gates Foundation

Phase 3c and 3d remain on further release of funding

6. Training: Laboratory and Clinical

A total of 73 laboratory staff and 54 health care workers have been trained since December 2011 as summarized in table 7 and 8. This will be an ongoing process to support NDoH training on clinical algorithm. Laboratory staff will receive both clinical and technical training.

Table 7: Laboratory Training

Venue	DATE	Trainer	TOTAL # OF DELEGATES	Outcomes
Christ the King	12 December 11	Veeresh	2	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Kokstad	15 December 11	Trevor	2	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
St. Apollinaris	13 December 11	Veeresh	3	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Thembisa	15 December 11	Sebaka/Sheila	7	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Pretoria West	10 January 12	Sebaka/Sheila	4	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Mary Theresa	11-12 January 12	Pro-Gen	4	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Mt Ayliff	10 January 12	Pro-Gen	4	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
All Saints	11 January 12	Pro-Gen	4	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
St Patrick	13 January 12	Pro-Gen	3	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Bethlehem	23 January 12	Pro-Gen	3	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Helen Joseph	23 January 12	Sheila	11	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Witbank	16 January 12	Sheila	10	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Tembisa	20 January 12	Sheila	5	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Tambo Memorial	12 January 12	Sheila & Sebaka	11	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry



Table 8: Clinical Training

Venue	Date	Trainer	Total # of Delegates	Outcomes
Manapo Dept. of Social Services	08 & 09 Feb	Sebaka	28	
Siphosensimbi CHC	17 Feb	Linda	18	
Phola CHC	20 Feb	Linda	8	

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

- Implement fee for service from 1 February 2012 (R220.00)
- Finalization of request forms: Incorporate TB testing in the CCMT from if we are to bill using existing channels
- Finalization of signing of the Global Fund contract
- Delay in training health care workers on clinical algorithm
- Lengthy time between training and going live with testing,
 - Pretoria West and Helen Joseph due to shortage of staff
 - Tambo Memorial due to problems with power supply
- LIS downtime impacting on TAT(Witbank)

8. Literature Update For GeneXpert

There has been an expansion of the literature with respect to the assay performance. The highlights are summarized in table 9 below:



Table 9: Recent publications (GeneXpert for pulmonary TB and extrapulmonary TB)

Manuscript	Sample population and specimen type (n=...)	Results	
		Sensitivity	Specificity
Chang et al, J Infect 2012	Comprehensive searches of the Pubmed and Embase, we identified outcome data from all articles estimating diagnostic accuracy with Xpert MTB/RIF assay = meta-analysis included 18 studies (10,224 suspected specimens)	Summary estimate was 90.4% (95%CI 89.2%-91.4%) for sensitivity	98.4% (95%CI 98.0%-98.7%) for specificity
Wood et al, BMC Infect Dis, 2012	199 urine specimens tested by LAM and positives tested by Xpert MTB/RIF	15/15 Xpert positive patients were also LAM positive patients.	
Andrews et al, AIDS 2012	Used a microsimulation model to evaluate the clinical impact and cost-effectiveness of alternative TB screening modalities -in all patients or only symptomatic patients - for hypothetical cohorts of individuals initiating ART in South Africa (mean CD4 171/ μ L; tuberculosis prevalence 22%)	Compared with no screening, life expectancy in tuberculosis-infected patients increased by 1.6 months using smear in symptomatic patients and by 6.6 months with 2 Xpert samples in all patients. At 22% tuberculosis prevalence, the incremental cost-effectiveness ratios for Xpert (2 samples) for all patients was \$5,100/YLS. Strategies involving one Xpert sample or symptom screening were less efficient	
Lawn SD et al, Clin Infect Dis. 2012	N=602 HIV+ patients screened for TB to determine the characteristics and early ART program outcomes of such Xpert negative patients	523 had ≥ 1 Xpert and culture result, yielding 89 culture-positive tuberculosis diagnoses. Of these, 37 (42%) of the patients with TB were Xpert-negative when a single sputum sample was tested, compared with 25 (28%) when 2 samples were tested. Those with Xpert-negative TB had substantially higher CD4 cell counts, lower plasma viral loads, higher hemoglobin concentrations, and higher BMI	
		Conclusion: Demonstrated less advanced immunosuppression and less advanced tuberculosis and no adverse outcomes despite substantial delays in starting tuberculosis treatment in Xpert negative TB patients.	
Lawn SD et al, Lancet Infect Dis. 2011	Developed a decision-analytic model to estimate the incremental cost, deaths averted, and cost-effectiveness of three TB diagnostic algorithms. Compared current practice with WHO-recommended practice with culture and	The cost per patient was: ✓ \$850 for current practice, ✓ \$809 for the algorithm with Xpert test, and ✓ \$879 for the algorithm with culture.	



	WHO-recommended practice with the Xpert MTB/RIF test and considered relevant medical costs from a health system perspective using the timeframe of the first six months of ART.	The results show that both WHO-recommended algorithms avert more deaths among TB cases than does current practice.
		Conclusion: The algorithm with Xpert test was least costly at reducing early mortality compared with current practice.

9. Update on GeneXpert Research projects:

- DCS Verification – all phase 2a instruments verified.
- Cepheid Liquid EQA pilot prepared for 20 sites with questionnaire.
- DCS EQA & verification program development - ACTG (3 sites) and MSF included in program.
- Flow cytometry on raw/processed sputum still under development
- Alternative specimen preparation protocols:
 - i. Protocols developed for Pediatric TB diagnosis and Extra-pulmonary TB diagnosis
 - ii. Protocols under development for solid tissue, gastric aspirates etc
 - iii. Sputum heat inactivation: to determine whether heat inactivation can be used prior to Xpert testing to render it safe for further manipulation – ongoing
- Evaluation of G4 cartridge:
 - i. 500 samples processed at Baragwanath. No significant performance differences between G3 and G4.
 - ii. Further evaluation ongoing using MGIT concentrates.
- Connectivity: Collaboration with Cepheid ongoing
 - i. Remote connectivity – System demo (5 Jan)

10. TB/HIV Integration

- Grand Challenges Canada: Multiple POC HIV/TB integration project
 - Phase I complete



- Phase II: Evaluation of nurse operated POC versus routine lab completed at HJH Themba Lethu clinic (n=326).
 - Site visits completed (n=12) and selection being finalized.
 - Finalization of RCT protocol.
- Connectivity:
 - Conworx (POCcelerator) and LDS (AegisPOC) to be trialed in 2 sites during RCT
 - Awaiting NHLS feedback for HemoCue project at CMJAH

11. Grants submitted

None

12. Funding issues

None