NATIONAL HEALTH LABORATORY SERVICE

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 135,601 specimens have been processed to date (Oct 2011). The total % of MTB detected in this cohort amounted to 16.06% (21, 778 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)

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Table 1: GeneXpert MTB Results by province and by month

Province	MTB Result	March	April	May	June	July	August	September	October	Total
Eastern Cape	MTB Detected	6	143	229	250	278	394	393	381	2,074
	MTB Not Detected	147	688	1,063	1,242	1,285	1,903	2,036	1,642	10,006
	Test Unsuccessful	1	24	109	23	23	62	64	56	362
Total		154	855	1,401	1,515	1,586	2,359	2,493	2,079	12,442
% MTB Detected		4	17	16	17	18	17	16	18	17
Free State	MTB Detected		11	232	249	269	303	311	224	1,599
	MTB Not Detected		28	1,242	1,285	1,495	1,655	1,742	1,165	8,612
	Test Unsuccessful			11	6	7	1	12	5	42
Total		-	39	1,485	1,540	1,771	1,959	2,065	1,394	10,253
% MTB Detected		-	28	16	16	15	15	15	16	16
Gauteng	MTB Detected	49	66	316	228	225	342	336	312	1,874
	MTB Not Detected	436	315	1,483	1,201	1,519	2,358	2,258	1,997	11,567
	Test Unsuccessful	11	7	46	29	17	80	101	51	342
Total		496	388	1,845	1,458	1,761	2,780	2,695	2,360	13,783
% MTB Detected		10	17	17	16	13	12	12	13	14
Kwa-Zulu Natal	MTB Detected	474	1,574	848	888	1,190	1,124	1,157	732	7,987
	MTB Not Detected	1,458	5,650	3,182	3,654	4,754	4,718	5,209	4,058	32,683
	Test Unsuccessful	71	178	333	192	208	180	186	67	1,415
Total		2,003	7,402	4,363	4,734	6,152	6,022	6,552	4,857	42,085
% MTB Detected		24	21	19	19	19	19	18	15	19
Limpopo	MTB Detected	5	88	195	212	195	173	214	203	1,285
	MTB Not Detected	11	912	1,463	1,696	1,853	1,855	2,176	1,930	11,896
	Test Unsuccessful		18	29	32	13	18	20	20	150
Total		16	1,018	1,687	1,940	2,061	2,046	2,410	2,153	13,331
% MTB Detected		31	9	12	11	9	8	9	9	10
Mpumalanga	MTB Detected	68	210	287	256	346	300	277	249	1,993
	MTB Not Detected	306	1,028	1,377	1,579	1,499	1,273	1,401	1,205	9,668
	Test Unsuccessful	28	93	251	183	40	83	199	78	955
Total		402	1,331	1,915	2,018	1,885	1,656	1,877	1,532	12,616
% MTB Detected		17	16	15	13	18	18	15	16	16
North West	MTB Detected		74	222	206	254	340	378	248	1,722
	MTB Not Detected	2	523	1,180	1,064	1,201	1,641	1,843	1,540	8,994
	Test Unsuccessful		7	45	24	31	43	110	74	334
Total		2	604	1,447	1,294	1,486	2,024	2,331	1,862	11,050
% MTB Detected		-	12	15	16	17	17	16	13	16
Northern Cape	MTB Detected	36	125	308	359	433	501	468	333	2,563
	MTB Not Detected	281	685	1,156	1,696	2,371	2,578	2,457	1,579	12,803
	Test Unsuccessful	11	23	100	163	72	116	93	57	635
Total		328	833	1,564	2,218	2,876	3,195	3,018	1,969	16,001
% MTB Detected		11	15	20	16	15	16	16	17	16
Western Cape	MTB Detected	14	7		4	6	174	200	276	681
	MTB Not Detected	52	3		11	21	811	1,103	1,338	3,339
	Test Unsuccessful		1	1		1	6	5	6	20
Grand Total		3,467	12,481	15,708	16,732	19,606	23,032	24,749	19,826	135,601

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Table 2: Provincial GeneXpert RIF Results in MTB detected cases

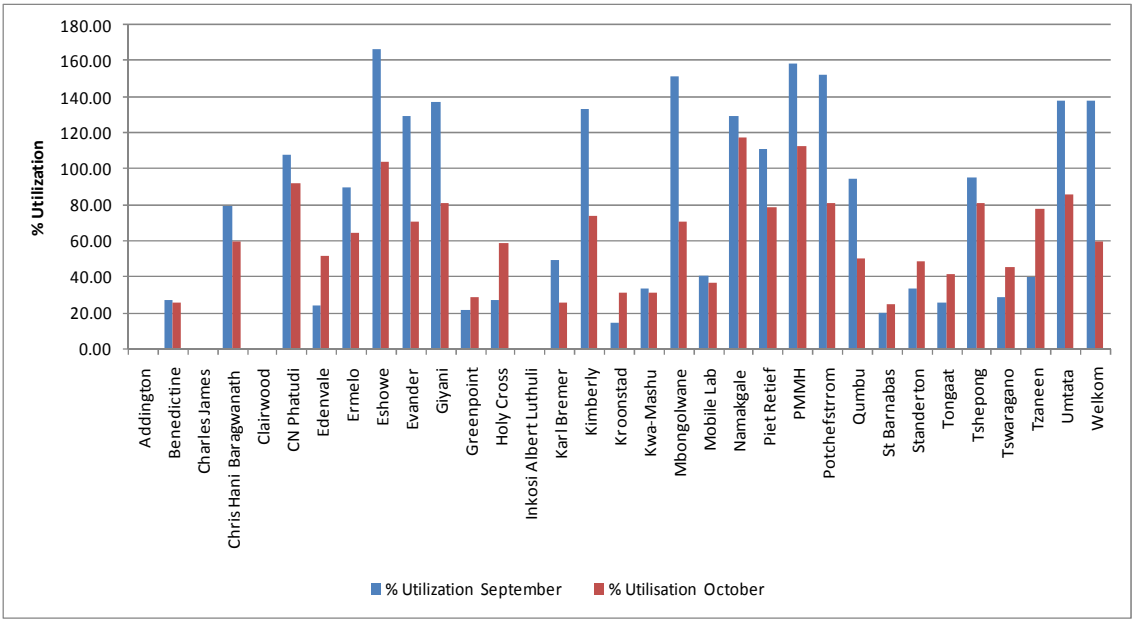
Province	MTB RIF Result	March	April	May	June	July	August	September	October	Total
Eastern Cape	Inconclusive	-	-	-	1	1	1	5	9	17
	Resistant	-	14	14	21	18	31	29	21	148
	Sensitive	6	129	213	226	245	333	353	340	1,845
	No Result			2	2	14	29	6	11	64
Total		**6**	**143**	**229**	**250**	**278**	**394**	**393**	**381**	**2,074**
% RIF Resistant		**0.00**	**9.79**	**6.11**	**8.40**	**6.47**	**7.87**	**7.38**	**5.51**	**7.14**
Free State	Inconclusive	-	-	2	2	2	5	6	2	19
	Resistant	-	-	15	11	16	14	18	13	87
	Sensitive	-	11	215	236	251	283	287	209	1,492
	No Result	-	-	-	-	-	1	-	-	1
Total		**-**	**11**	**232**	**249**	**269**	**303**	**311**	**224**	**1,599**
% RIF Resistant		**0.00**	**0.00**	**6.47**	**4.42**	**5.95**	**4.62**	**5.79**	**5.80**	**5.44**
Gauteng	Inconclusive	-	1		2	2	5	3	1	14
	Resistant	4	4	31	10	17	14	21	14	115
	Sensitive	45	61	285	216	206	323	312	296	1,744
	No Result	-	-	-	-	-	-	-	1	1
Total		**49**	**66**	**316**	**228**	**225**	**342**	**336**	**312**	**1,874**
% RIF Resistant		**8.16**	**6.06**	**9.81**	**4.39**	**7.56**	**4.09**	**6.25**	**4.49**	**6.14**
Kwa-Zulu Natal	Inconclusive	3	12	15	6	10	8	9	8	71
	Resistant	41	102	57	71	80	84	101	66	602
	Sensitive	428	1,425	764	809	1,098	1,032	1,044	658	7,258
	No Result	2	35	12	2	2	-	3		56
Total		**474**	**1,574**	**848**	**888**	**1,190**	**1,124**	**1,157**	**732**	**7,987**
% RIF Resistant		**8.65**	**6.48**	**6.72**	**8.00**	**6.72**	**7.47**	**8.73**	**9.02**	**7.54**
Limpopo	Inconclusive	-	-	2	1	1	-	8	2	14
	Resistant	1	9	9	23	14	13	16	12	97
	Sensitive	3	79	172	188	179	159	189	186	1,155
	No Result	1		12		1	1	1	3	19
Total		**5**	**88**	**195**	**212**	**195**	**173**	**214**	**203**	**1,285**
% RIF Resistant		**20.00**	**10.23**	**4.62**	**10.85**	**7.18**	**7.51**	**7.48**	**5.91**	**7.55**
Mpumalanga	Inconclusive	-	1	5	6	1	3	4	4	24
	Resistant	7	20	22	17	29	24	29	14	162
	Sensitive	60	189	260	233	316	273	244	231	1,806
	No Result	1								1
Total		**68**	**210**	**287**	**256**	**346**	**300**	**277**	**249**	**1,993**
% RIF Resistant		**10.29**	**9.52**	**7.67**	**6.64**	**8.38**	**8.00**	**10.47**	**5.62**	**8.13**
North West	Inconclusive	-	1	4	3	5	2	3	7	25
	Resistant	-	5	23	18	24	23	35	11	139
	Sensitive	-	68	195	185	225	315	340	230	1,558
Total		**-**	**74**	**222**	**206**	**254**	**340**	**378**	**248**	**1,722**
% RIF Resistant		**0.00**	**6.76**	**10.36**	**8.74**	**9.45**	**6.76**	**9.26**	**4.44**	**8.07**
Northern Cape	Inconclusive	-	-	2	2	5	4	7	1	21
	Resistant	5	5	14	29	49	28	24	14	168
	Sensitive	31	119	292	328	379	469	437	318	2,373
	No Result	-	1	-	-	-	-	-	-	1
Total		**36**	**125**	**308**	**359**	**433**	**501**	**468**	**333**	**2,563**
% RIF Resistant		**13.89**	**4.00**	**4.55**	**8.08**	**11.32**	**5.59**	**5.13**	**4.20**	**6.55**
Western Cape	Inconclusive	-	-	-	-	-	2	-	2	4
	Resistant	-	-	-	-	-	11	9	12	32
	Sensitive	14	7		2	6	161	191	262	643
	No Result	-	-	-	2	-	-	-	-	2
Total		**14**	**7**	**-**	**4**	**6**	**174**	**200**	**276**	**681**
% RIF Resistant		**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**6.32**	**4.50**	**4.35**	**4.70**
Grand Total		**652**	**2,298**	**2,637**	**2,652**	**3,196**	**3,651**	**3,734**	**2,958**	**21,778**

Errors have ranged consistently below 3%, apart from May where a batch issue was identified with reagents. Details of invalid results, which likely represent sample issues is consistently below 1%. These are being monitored regularly and corrective action implemented where necessary.

Table 3: Number of Unsuccessful Tests and Reasons

MTB Result	Test Unsuccessful Reason	March	April	May	June	July	August	September	October	Total
MTB Detected		652	2,298	2,637	2,652	3,196	3,651	3,734	2,958	21,778
MTB Not Detected		2,693	9,832	12,146	13,428	15,998	18,792	20,225	16,454	109,568
Test Unsuccessful	Error	77	284	788	492	207	385	622	344	3,199
Test Unsuccessful	Invalid	35	31	88	129	180	156	133	63	815
Test Unsuccessful	No Result	8	16	12	7	8	7	8	2	68
Test Unsuccessful	Pre-Analytical Rejection	2	20	37	24	17	41	27	5	173
Total		**3,467**	**12,481**	**15,708**	**16,732**	**19,606**	**23,032**	**24,749**	**19,826**	**135,601**
% Error		2.22	2.28	5.02	2.94	1.06	1.67	2.51	1.74	2.36
% Invalid		1.01	0.25	0.56	0.77	0.92	0.68	0.54	0.32	0.60
% Pre-Analytical Rejection		0.06	0.16	0.24	0.14	0.09	0.18	0.11	0.03	0.13

3. **Utilization rates of instruments within the field**



Instrument utilization has decreased significantly from September to October due to the increase in the size or number of instruments in each facility.

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: Completion December 11/January 12

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

Instruments have all been placed at the end of phase 2a. A total of 17 GXVI instruments were installed. Fourteen instruments and 13,172 Xpert MTB/RIF kits were purchased in September 2011 through funding from CDC. The instruments were utilized to fully capacitate 14 laboratories in the high burden district. Installation, training, verification and interfacing to LIS of analyzers were completed in October 2011. Refer to table 1 for placement of instruments purchased through the CDC Funding.

Table 4: Placement of Phase 2a Instruments (CDC)

Province	Site	GX16
Eastern Cape	Holy Cross	1
Eastern Cape	St. Barnabas	1
Free State	Kroonstad	1
Free State	Kroonstad	1
Gauteng	Baragwanath	1
Gauteng	Edenvale	1
Kwazulu Natal	KwaMashu	1
Kwazulu Natal	Tongaat	1
Limpopo	Tzaneen	1
Mpumalanga	Standerton	1
North West	Tshepong	1
Northern Cape	Kimberley	1
Northern Cape	Tshwaragano	1
Western Cape	Greenpoint TB	1
TOTAL		14

Phase 2b, 3a and b

Further funding has been sourced from CDC through the NDoH and NHLS to rollout part of phase 2b. The combined budget will be sufficient to purchase a total of 8 GXIV and 5 GXVI analyzers and 6,620 Xpert MTB/RIF kits. Refer to table 5 for placement of instruments and progress.

20 GXVI analyzers are due for delivery in the third week of November for phase 3a and 3b.

- Two machines will be placed by December 2011 in Helen Joseph and Pretoria West or Bethlehem to pilot the study. Eight instruments will be placed in January 2012 at the following sites: ALL SAINTS, MARY THERESA, MT AYLIFF, ST PATRICK, , BOKSBURG BENONI, TEMBISA, , PRETORIA WEST or BETHLEHEM and WITBANK
- The remaining 10 machines should will be placed in July 2012 in the following laboratories: COFIMVABA, QUEENSTOWN, TAYLOR BEQUEST, UITENHAGE, MANAPO, NATALSPRUIT, CARLETONVILLE, JUBILEE, MAMELODI, NELSPRUI

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

Table 5: Phase 2b

Province	District	Lab	GX4	GX16	GX48	Capacity Per Day	Status	Donor
EC	O.R. Tambo	ST ELIZABETH		1		64	Pending	CDC NHLS
EC	O.R. Tambo	ZITULELE		1		32	Pending	CDC NHLS
EC	O.R. Tambo	ST LUCY	1			16	Pending	From Pilot Phase
EC	Amathole	EAST LONDON TB			1	576	Pending	Global Fund Right to Care
EC	Nelson Mandela Bay Metro	PORT ELIZABETH TB	1	3		576	Pending	Global Fund Right to Care
GP	City of Johannesburg	CENTRAL TB	1	1		80	Pending	GX4 from Pilot Phase & GX16 CDC NHLS
GP	City of Johannesburg	NJH ROUTINE	1			16	Pending	From Pilot Phase
KZN	eThekwini	Mahatma Ghandi		1		48	Pending	CDC NHLS
KZN	eThekwini	PineTown MC		1		48	Pending	CDC NHLS
KZN	Sisonke	RIETVLEI		1		48	Pending	CDC DOH
KZN	Zululand	Benedictine		1		48	Pending	CDC DOH
KZN	eThekwini	Dbn Chest Clinic MC		1		64	Pending	CDC NHLS
KZN	eThekwini	RK Khan		1		64	Pending	CDC NHLS
KZN	Umzinyathi	COSH		1		64	Pending	CDC DOH
KZN	eThekwini	Addington		1		32	Pending	CDC NHLS
KZN	eThekwini	Inanda C MC		1		32	Pending	CDC NHLS
KZN	eThekwini	KwaDabeka MC		1		32	Pending	CDC NHLS
KZN	eThekwini	Wentworth		1		32	Pending	CDC DOH
KZN	Uthungulu	Eshowe	2			32	Completed	MSF & Pilot Phase
KZN	eThekwini	Clairwood	1			16	Pending	From Pilot Phase
KZN	eThekwini	Don Mackenzie MC	1			16	Pending	From Pilot Phase
KZN	eThekwini	FOSA MC	1			16	Pending	From Pilot Phase
KZN	eThekwini	Hlengisizwe MC	1			16	Pending	From Pilot Phase
KZN	eThekwini	Osindisweni	1			16	Pending	CDC NHLS
KZN	eThekwini	Verulam MC	1			16	Pending	CDC NHLS
KZN	Sisonke	Kokstad	2			32	Pending	TB/HIV Care and CDC DOH
KZN	Sisonke	Pholela HCC	1			16	Completed	TB/HIV Care
KZN	Sisonke	St. Appolinaris	1			16	Pending	TB/HIV Care
KZN	Uthungulu	Mbongolwana	1			16	Completed	MSF
LP	Mopani	KGAPANE		1		32	Pending	CDC DOH
LP	Mopani	PHALABORWA		1		32	Pending	
LP	Mopani	SEKORORO	1			16	Pending	From Pilot Phase
MP	Gert Sibande	EMBHULENI		1		32	Pending	
NC	Siyanda	UPINGTON		1		64	Pending	
NW	Dr Kenneth Kaunda (Southern)	POTCHEFSTROOM	2			48	Completed	From Pilot Phase
WC	City of Cape Town	GROOTE SCHUUR CLINICAL PATH		1		48	Pending	

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Table 5: Phase 3a

Serial	Province	District	Lab	GX4	GX16	GX48	Capacity Per Day	Status	Donor
4	EC	Alfred Nzo	MARY THERESA		1		64	Pending	Gates Foundation
5	EC	Alfred Nzo	MT AYLIFF		1		48	Pending	Gates Foundation
23	EC	Chris Hani	ALL SAINTS		1		64	Pending	Gates Foundation
56	FS	Thabo Mofutsanyane	BETHLEHEM		1		48	Pending	Gates Foundation
71	GP	City of Tshwane	PRETORIA WEST		1		48	Pending	Gates Foundation
74	GP	Ekurhuleni	BOKSBURG BENONI	1	1		80	Pending	Gates Foundation
79	GP	Ekurhuleni	TEMBISA		1		64	Pending	Gates Foundation
40	EC	O.R. Tambo	ST PATRICK		1		48	Pending	Gates Foundation
64	GP	City of Johannesburg	HELEN JOSEPH		1		48	Pending	Gates Foundation
148	MP	Nkangala	WITBANK		1		64	Pending	Gates Foundation

Table 6: Phase 3b

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

6. **Training: Laboratory and Clinical**

A total of 484 staff have been trained since July 2011 as summarized in table 8 and 9 below. Training was for both laboratory staff and health care professionals in all the nine provinces. This will be an ongoing process to support NDoH training on clinical algorithm. Laboratory staff will receive both clinical and technical training.

Table 8: Laboratory Training

Venue	DATE	Trainer	TOTAL # OF DELEGATES	Outcomes
Greenpoint	14-15 July	Tessa	8	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Eshowe	04 August	Floyd	10	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Mbongolwana	04 August	Floyd	5	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
CHB	26 & 30 August	Fimmie	10	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Benedictine	06 September	Veeresh	8	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Benedictine	14 September	Nico	5	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Benedictine	14 September	Nico	8	GeneXpert Overview and Algorithm
Siloah	15 September	Nico	11	GeneXpert Overview and Algorithm
Pholela	22 September	Veeresh	1	GeneXpert Operation, Maintenance, Troubleshooting and Data Entry
Pholela	30 September	Floyd, Sibulele	10	GeneXpert Overview and Algorithm

Table 9: Clinical Training

Venue	DATE	Trainer	TOTAL # OF DELEGATES	Outcomes
Western Cape	23 September	Limenako	26	TB and DR-TB Management Update
Bloemfontein	14 September		51	TB Diagnosis and Algorithm
Forever Resort	27 September		45	TB Diagnosis and Algorithm
Kimberley	21 September	Pamela & Lessie	30	TB Management
Eastern Cape	14 September	T Kunene, O Mokgathle, Ms Mhlope, Dr Erasmus and Dr Mhlongo	65	TB and DR-TB Management Update
North West			37	TB and DR-TB Management Update
Clairwood Hospital	29 September	Lessie, T Kunene, O Mokgathle	60	TB and DR-TB Management Update
Turfontein Race Course	05 September		45	National Tb Guidelines
Mpumalanga	20 September	M Molefe, L Matsoso, T Kunene	49	TB and DR-TB Management Update

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

- Alignment of enthusiastic donors to support one plan
- Finalisation of the algorithm and the request forms: As expected, this took a significant amount of time and consultation.
- The development of a National TB costing model
- Clinical Algorithm: Understanding of the algorithm still poses a major challenge, however this is being addressed during the clinical training held in the different provinces.
- Error rates which have largely been resolved

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 6 below:

Table 8: Recent publications (GeneXpert for pulmonary TB and extrapulmonary TB)

Manuscript	Sample population and specimen type (n=…)	Results	
		Sensitivity	Specificity
Zeka et al, JCM 2011	253 pulmonary and 176 extrapulmonary specimens	Pulmonary specimens: 100% (27/27) and 68.6% (24/35) for smear positive and smear negative specimens respectively Extrapulmonary specimens: 100% for smear positive (4/4) and 47.7% for smear negative (21/44).	100%
Ioannidiset al, Int J Tub Lung Dis 2011	Microscopically negative and positive pulmonary and extrapulmonary	Pulmonary : 90.6%, Extrapulmonary samples: 100% For microscopically negative specimens: 86.3%	Pulmonary: 94.3% Extrapulmonary: 91.6% For microscopically negative specimens: 93%
Freidrich et al, JCM 2011	20 pleural effusions	25%	100%
Scott et al, JCM 2011	A pilot program using dried culture spots (DCS) of inactivated M.tb is described	Of 274 DCS results received, 2.19% generated errors; the remaining yielded 100% correct Mycobacterium tuberculosis detection	
Ligthelm et al, JCM 2011	Tuberculous lymphadenitis	96.7% And correctly identified 6/6 (100%) of the cytology smear-negative/culture-positive cases and 1 of 2 (50%) rifampin-resistant cases.	88.9%
Lawn et al, PloS Med, 2011	468 sputum	For culture-positive TB: 73.3%	For culture-positive TB: 99.2%
Teo et al, JCM 2011	Xpert MTB/RIF assay compared with Amplified Mycobacterium Tuberculosis Direct (MTD) assay using 162 respiratory and nonrespiratory specimens	Xpert: 90.9% MTD: 97.3%	Xpert: 89% MTD: 87.1%

9. Update on GeneXpert Research projects:

- An EQA program based on Dried Culture Spots has been developed
    - Other potential material is being investigated for an EQA program, including inactivated liquid culture
- Alternative specimen preparation protocols on the GeneXpert:
    - Protocols have been developed for Paediatric TB diagnosis and Extra-pulmonary TB diagnosis
    - Protocols are under development for GeneXpert testing on solid tissues, gastric aspirates etc.
- Sputum heat inactivation: a study to determine whether heat inactivation can be used prior to GeneXpert testing to render it safe for further manipulation, is underway
- A study to evaluate the new G4 Xpert cartridge is ongoing .

10. **Grants submitted**

The UNITAID proposal that was submitted on 20 September 2011 to source funding to fully capacitate the NHLS with the Xpert MTB/RIF test to provide full coverage of such TB diagnostic service for the national TB program in South Africa was not successful. The proposal did not meet UNITAID's eligibility criteria which require that at least 85% of UNITAID funds dedicated to purchase commodities be spent on low income countries (LICs). Though South Africa has a high disease prevalence it is classified as an upper middle income country (UMIC). The application was also from a single country.

11. **Funding issues**

- Urgency remains to conclude Global fund negotiations and release funds
- Recurrent assay cost price needs to be agreed upon before new financial year