NATIONAL HEALTH LABORATORY SERVICE

# GeneXpert MTB/RIF

## Progress Report

August 2015

NATIONAL HEALTH LABORATORY SERVICE

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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.

## 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 242011. 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 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.

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### 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 6 732 849 specimens have been processed to date (31 August 2015). In August 233,731 specimens were processed. The total % of *Mycobacterium tuberculosis* complex (MTBC) detected in this cohort was 8.92% (20 832). 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 | 15,278 | 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 | 33,155 | 314,080 | 7,839 | **355,074** | **9.34** |
| 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 | 8,406 | 80,063 | 763 | **89,232** | **9.42** |
| 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 | 24,536 | 245,190 | 5,419 | **275,145** | **8.92** |
| 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 | 37,530 | 406,696 | 12,178 | **456,404** | **8.22** |
| 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** |


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| | | | | | | |
|---|---|---|---|---|---|---|
| LIMPOPO | 2014 | 14,412 | 212,466 | 7,694 | **234,572** | **6.14** |
| LIMPOPO | 2015 | 8,313 | 148,165 | 4,398 | **160,876** | **5.17** |
| 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 | 8,814 | 81,227 | 2,898 | **92,939** | **9.48** |
| 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 | 10,290 | 110,981 | 3,522 | **124,793** | **8.25** |
| 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 | 5,700 | 46,328 | 1,552 | **53,580** | **10.64** |
| 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 | 23,461 | 136,787 | 1,334 | **161,582** | **14.52** |
| **TOTAL** | | **738,569** | **5,818,222** | **176,058** | **6,732,849** | **10.97** |

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

| Province | MTB Detected | MTB Not Detected | Test Unsuccessful | Grand Total | % MTB Detected |
|---|---|---|---|---|---|
| Eastern Cape | 4490 | 46225 | 940 | 51655 | 8.69 |
| Free State | 1125 | 11030 | 87 | 12242 | 9.19 |
| Gauteng | 3298 | 31736 | 535 | 35569 | 9.27 |
| Kwa-Zulu Natal | 4690 | 51057 | 1159 | 56906 | 8.24 |
| Limpopo | 1037 | 19519 | 599 | 21155 | 4.90 |
| Mpumalanga | 1194 | 10831 | 336 | 12361 | 9.66 |
| North West | 1225 | 13650 | 379 | 15254 | 8.03 |
| Northern Cape | 774 | 6778 | 165 | 7717 | 10.03 |
| Western Cape | 3012 | 17690 | 170 | 20872 | 14.43 |
| **Grand Total** | **20845** | **208516** | **4370** | **233731** | 8.92 |



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

| Province | Inconclusive | Resistant | Sensitive | No RIF | Grand Total | % RIF Resistance |
|---|---|---|---|---|---|---|
| Eastern Cape | 63 | 232 | 4184 | 11 | 4490 | 5.17 |
| Free State | 17 | 79 | 1026 | 3 | 1125 | 7.02 |
| Gauteng | 53 | 214 | 3029 | 2 | 3298 | 6.49 |
| Kwa-Zulu Natal | 88 | 365 | 4227 | 10 | 4690 | 7.78 |
| Limpopo | 10 | 46 | 975 | 6 | 1037 | 4.44 |
| Mpumalanga | 21 | 106 | 1050 | 17 | 1194 | 8.88 |
| North West | 15 | 48 | 1161 | 1 | 1225 | 3.92 |
| Northern Cape | 13 | 41 | 720 | | 774 | 5.30 |
| Western Cape | 43 | 139 | 2828 | 2 | 3012 | 4.61 |
| **Grand Total** | **323** | **1270** | **19200** | **52** | **20845** | **6.09** |

**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 | 2835 | 131 | **3252** | **7.84** |
| EASTERN CAPE | 2012 | 202 | 1489 | 13894 | 283 | **15868** | **9.38** |
| EASTERN CAPE | 2013 | 1199 | 2805 | 38646 | 148 | **42798** | **6.55** |
| EASTERN CAPE | 2014 | 1257 | 2993 | 44824 | 51 | **49125** | **6.09** |
| EASTERN CAPE | 2015 | 461 | 1931 | 30699 | 64 | **33155** | **5.82** |
| FREE STATE | 2011 | 9 | 1491 | 1346 | 3 | **2849** | **52.33** |
| FREE STATE | 2012 | 145 | 1357 | 10123 | 43 | **11668** | **11.63** |
| FREE STATE | 2013 | 361 | 793 | 13091 | 20 | **14265** | **5.56** |
| FREE STATE | 2014 | 367 | 824 | 12862 | 4 | **14057** | **5.86** |
| FREE STATE | 2015 | 101 | 473 | 7825 | 7 | **8406** | **5.63** |
| GAUTENG | 2011 | 25 | 179 | 2926 | 2 | **3132** | **5.72** |
| GAUTENG | 2012 | 136 | 763 | 10115 | 78 | **11092** | **6.88** |
| GAUTENG | 2013 | 852 | 1947 | 26855 | 68 | **29722** | **6.55** |
| GAUTENG | 2014 | 826 | 2320 | 35620 | 28 | **38794** | **5.98** |
| GAUTENG | 2015 | 327 | 1430 | 22768 | 11 | **24536** | **5.83** |
| KWAZULU-NATAL | 2011 | 107 | 916 | 11055 | 61 | **12139** | **7.55** |
| KWAZULU-NATAL | 2012 | 417 | 2166 | 21079 | 253 | **23915** | **9.06** |
| KWAZULU-NATAL | 2013 | 1054 | 3607 | 36306 | 403 | **41370** | **8.72** |
| KWAZULU-NATAL | 2014 | 1513 | 4965 | 50812 | 203 | **57493** | **8.64** |
| KWAZULU-NATAL | 2015 | 617 | 2966 | 33883 | 64 | **37530** | **7.90** |
| LIMPOPO | 2011 | 25 | 118 | 1742 | 45 | **1930** | **6.11** |
| LIMPOPO | 2012 | 52 | 264 | 3593 | 75 | **3984** | **6.63** |
| LIMPOPO | 2013 | 293 | 694 | 12322 | 108 | **13417** | **5.17** |
| LIMPOPO | 2014 | 328 | 713 | 13323 | 48 | **14412** | **4.95** |



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| | | | | | | | |
|---|---|---|---|---|---|---|---|
| LIMPOPO | 2015 | 107 | 461 | 7706 | 39 | **8313** | **5.55** |
| MPUMALANGA | 2011 | 31 | 189 | 2396 | 31 | **2647** | **7.14** |
| MPUMALANGA | 2012 | 57 | 402 | 3499 | 76 | **4034** | **9.97** |
| MPUMALANGA | 2013 | 221 | 989 | 8671 | 27 | **9908** | **9.98** |
| MPUMALANGA | 2014 | 378 | 1285 | 12940 | 20 | **14623** | **8.79** |
| MPUMALANGA | 2015 | 126 | 693 | 7961 | 34 | **8814** | **7.86** |
| NORTH WEST | 2011 | 40 | 2192 | 1258 | 4 | **3494** | **62.74** |
| NORTH WEST | 2012 | 75 | 471 | 4943 | 10 | **5499** | **8.57** |
| NORTH WEST | 2013 | 300 | 685 | 11465 | 27 | **12477** | **5.49** |
| NORTH WEST | 2014 | 504 | 909 | 15587 | 9 | **17009** | **5.34** |
| NORTH WEST | 2015 | 197 | 504 | 9583 | 6 | **10290** | **4.90** |
| NORTHERN CAPE | 2011 | 28 | 188 | 2540 | 27 | **2783** | **6.76** |
| NORTHERN CAPE | 2012 | 54 | 247 | 3720 | 9 | **4030** | **6.13** |
| NORTHERN CAPE | 2013 | 174 | 405 | 6694 | 288 | **7561** | **5.36** |
| NORTHERN CAPE | 2014 | 200 | 451 | 8053 | 15 | **8719** | **5.17** |
| NORTHERN CAPE | 2015 | 69 | 296 | 5333 | 2 | **5700** | **5.19** |
| WESTERN CAPE | 2011 | 15 | 106 | 2073 | 1 | **2195** | **4.83** |
| WESTERN CAPE | 2012 | 150 | 650 | 12355 | 3 | **13158** | **4.94** |
| WESTERN CAPE | 2013 | 668 | 1526 | 27965 | 4 | **30163** | **5.06** |
| WESTERN CAPE | 2014 | 695 | 1852 | 32233 | 2 | **34782** | **5.32** |
| WESTERN CAPE | 2015 | 250 | 1174 | 22024 | 13 | **23461** | **5.00** |
| **Total** | | **15044** | **53134** | **667543** | **2848** | **738569** | **7.19** |



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## 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)**

| | | GeneXpert Confirmation & Rif Concordance | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Province | Rif Resistant Cases | 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 August. 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 August 2015)**

| Province | Errors | Invalids | No Results | MTB Results | Grand Total | % Error |
|---|---|---|---|---|---|---|
| Eastern Cape | 757 | 110 | 73 | 50715 | 51655 | 1.47 |
| Free State | 67 | 13 | 7 | 12155 | 12242 | 0.55 |
| Gauteng | 395 | 79 | 61 | 35034 | 35569 | 1.11 |
| Kwa-Zulu Natal | 869 | 169 | 121 | 55747 | 56906 | 1.53 |
| Limpopo | 462 | 77 | 60 | 20556 | 21155 | 2.18 |
| Mpumalanga | 229 | 76 | 31 | 12025 | 12361 | 1.85 |
| North West | 300 | 44 | 35 | 14875 | 15254 | 1.97 |
| Northern Cape | 101 | 40 | 24 | 7552 | 7717 | 1.31 |
| Western Cape | 113 | 48 | 9 | 20702 | 20872 | 0.54 |
| **Grand Total** | **3293** | **656** | **421** | **229361** | **233731** | **1.41** |



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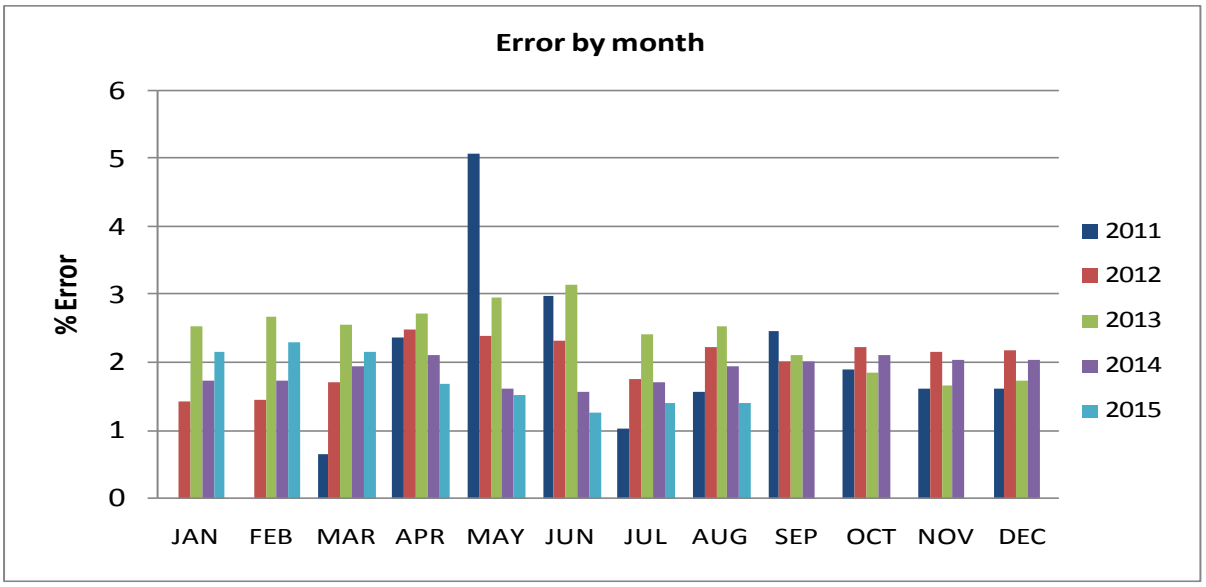
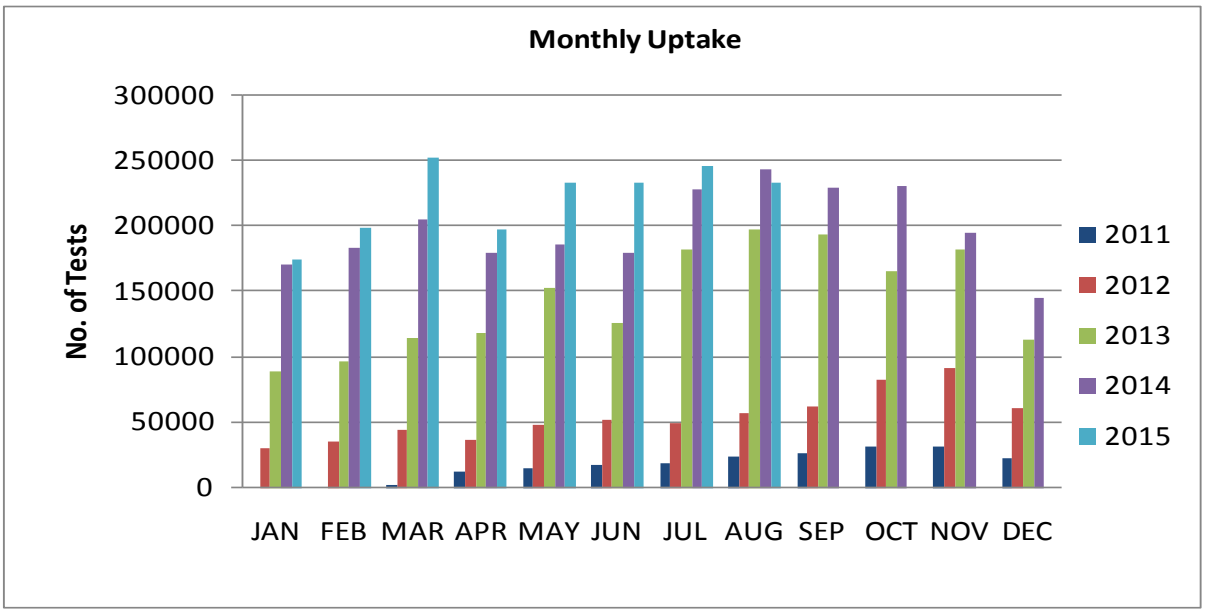
**Figure 1: GeneXpert Error by Month**




## 5. Monthly uptake since implementation started

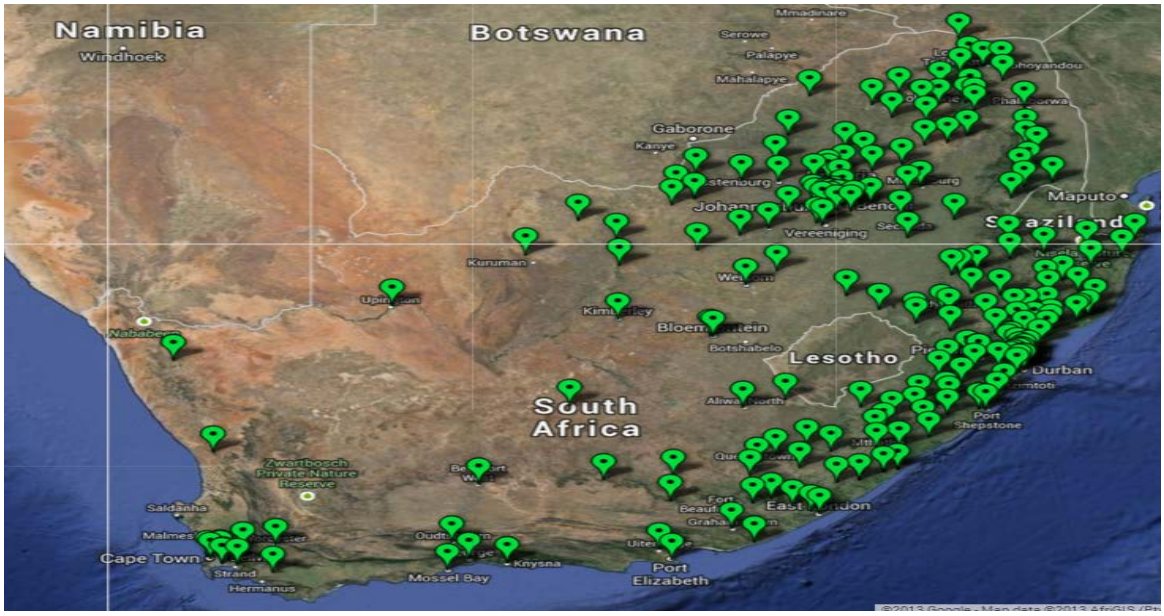
**Figure 2: GeneXpert Monthly Uptake**




Monthly uptake increased steadily since program inception.

## 6. Phased Implementation Progress

**Figure 3:** Current GeneXpert 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 1,800 laboratory staff and 9,259 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

None in August