



NATIONAL HEALTH
LABORATORY SERVICE

GeneXpert MTB/RIF

Progress Report

October 2016





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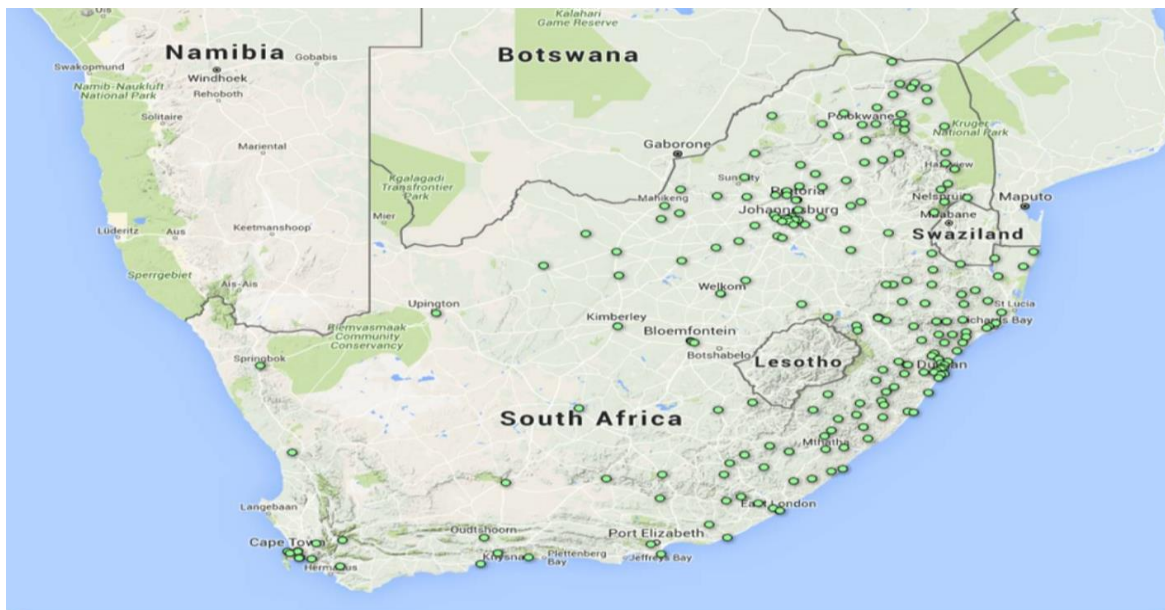
1. Background to Project

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 those with presumptive TB in South Africa.

The programme was further expanded to directly support the screening for TB and HIV in high risk populations in correctional centres and in peri-mining communities.

GeneXpert Placements

Figure 1: Current GeneXpert Placements (207 testing centers, 314 analysers, GX4: 115; GX16-8: 1; GX16: 189; GX48:1; GX80: 8)



2. Assays performed to date

In summary, a total of 9,695,971 specimens have been processed to date (31 October 2016). In October 2016 a total 210,339 specimens were processed. The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 9.30% (19 553).

Table 1: National GeneXpert MTB Results (Cumulative)

| Year | MTB Detected | MTB Not Detected | Test Unsuccessful | Total | % MTB Detected |
|--------------|------------------|------------------|-------------------|------------------|----------------|
| 2011 | 34 421 | 165 582 | 5 441 | 205 444 | 16.75 |
| 2012 | 93 248 | 544 109 | 16 903 | 654 260 | 14.25 |
| 2013 | 201 681 | 1 478 260 | 51 773 | 1 731 714 | 11.65 |
| 2014 | 249 014 | 2 060 754 | 62 038 | 2 371 806 | 10.50 |
| 2015 | 245 916 | 2 343 403 | 57 217 | 2 646 536 | 9.29 |
| 2016 | 188 842 | 1 856 080 | 41 289 | 2 086 211 | 9.05 |
| Total | 1 013 122 | 8 448 188 | 234 661 | 9 695 971 | 10.45 |

Table 2: National GeneXpert RIF Results (Cumulative)

| Year | Inconclusive | Resistant | Sensitive | No RIF Result | Total | % RIF Resistant |
|--------------|---------------|---------------|----------------|---------------|------------------|-----------------|
| 2011 | 311 | 5 634 | 28 171 | 305 | 34 421 | 16.37 |
| 2012 | 1 288 | 7 809 | 83 321 | 830 | 93 248 | 8.37 |
| 2013 | 5 122 | 13 451 | 182 015 | 1 093 | 201 681 | 6.67 |
| 2014 | 6 068 | 16 312 | 226 254 | 380 | 249 014 | 6.55 |
| 2015 | 3 288 | 15 043 | 227 358 | 227 | 245 916 | 6.12 |
| 2016 | 2 066 | 11 688 | 174 858 | 230 | 188 842 | 6.19 |
| Total | 18 143 | 69 937 | 921 977 | 3 065 | 1 013 122 | 6.90 |

Figure 2: MTB Positivity and RIF Resistant rates overtime

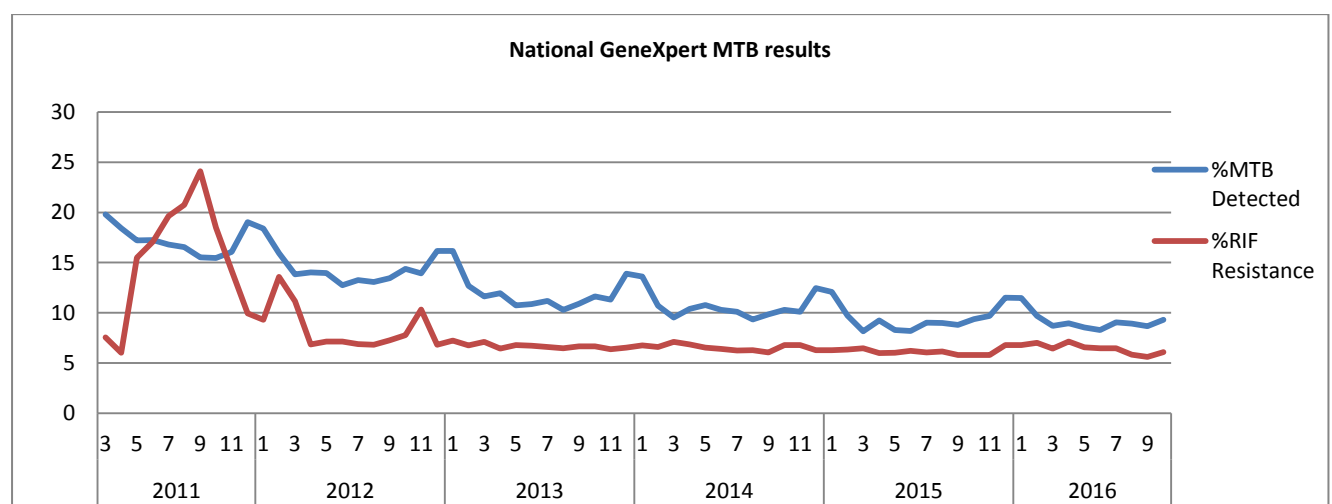
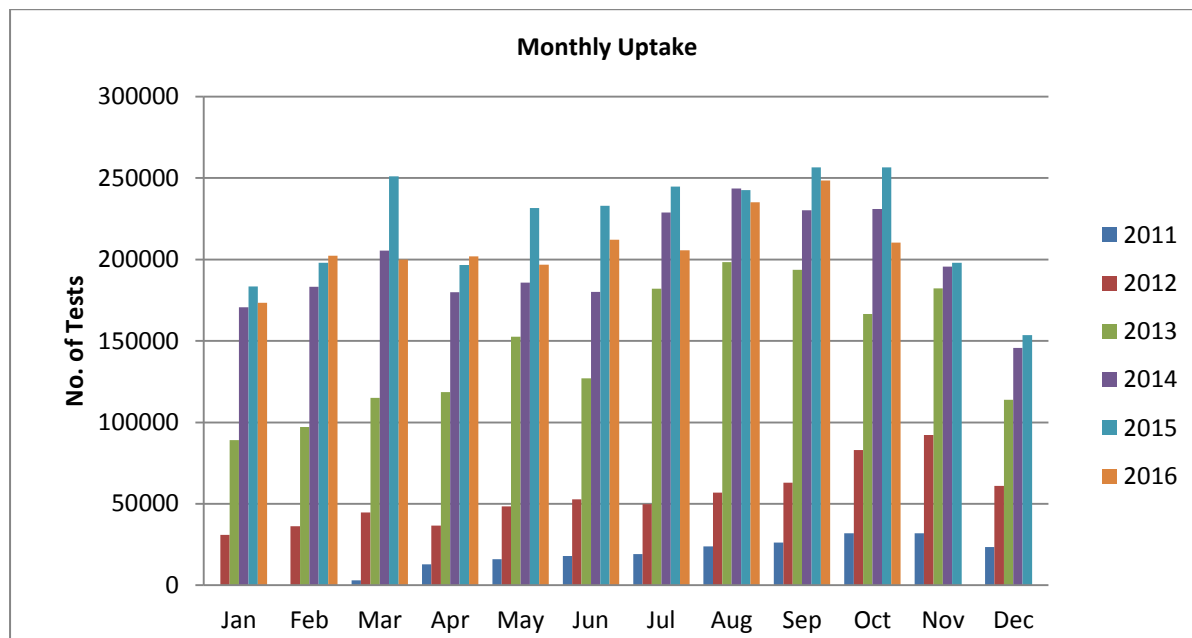


Figure 3: GeneXpert Monthly Uptake



3. 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 at either one of the 7 on-site labs, or at the nearest NHLS referral laboratory.

Total of 263,633 specimens have been processed to date (31 October 2016). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 4.53% (11,932).

Table 3: Correctional Service GeneXpert MTB Results (Cumulative)

| Year | MTB Detected | MTB Not Detected | Test Unsuccessful | Total | % MTB Detected |
|---------------|--------------|------------------|-------------------|---------------|----------------|
| Oct- Dec 2013 | 662 | 7236 | 142 | 8040 | 8.23 |
| Jan- Dec 2014 | 3620 | 55995 | 1004 | 60619 | 5.97 |
| Jan- Dec 2015 | 4831 | 124589 | 2216 | 131636 | 3.67 |
| Jan -Oct 2016 | 2819 | 59363 | 1156 | 63338 | 4.45 |
| Total | 11932 | 247183 | 4518 | 263633 | 4.53 |

Table 4: Correctional Service GeneXpert RIF Results (Cumulative)

| Year | Resistant | Inconclusive | Sensitive | No RIF Result | Total | % RIF Resistant |
|----------------|------------|--------------|--------------|---------------|--------------|-----------------|
| Oct- Dec 2013 | 27 | 7 | 626 | 2 | 662 | 4.08 |
| Jan - Dec 2014 | 188 | 107 | 3323 | 2 | 3620 | 5.19 |
| Jan - Dec 2015 | 190 | 99 | 4530 | 12 | 4831 | 3.93 |
| Jan -Oct 2016 | 121 | 31 | 2666 | 1 | 2819 | 4.29 |
| Total | 526 | 244 | 11145 | 17 | 11932 | 4.41 |

4. 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 undertake Xpert MTB/RIF testing for TB in these communities.

A total of 63,693 specimens have been processed to date (31 October 2016). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 1.10% (702).

Table 5: Peri-mining GeneXpert MTB Results (Cumulative)

| Year | MTB Detected | MTB Not Detected | Test Unsuccessful | Total | % MTB Detected |
|-----------------|--------------|------------------|-------------------|--------------|----------------|
| Jun to Dec 2014 | 55 | 2410 | 66 | 2531 | 2.17 |
| Jan to Dec 2015 | 406 | 37021 | 609 | 38036 | 1.07 |
| Jan to Oct 2016 | 241 | 22430 | 455 | 23126 | 1.04 |
| Total | 702 | 61861 | 1130 | 63693 | 1.10 |

Table 6: Peri-mining GeneXpert RIF Results (Cumulative)

| Year | Inconclusive | Resistant | Sensitive | No RIF | Total | % Resistant |
|-----------------|--------------|-----------|------------|-----------|------------|-------------|
| Jun to Dec 2014 | 3 | 2 | 51 | 0 | 56 | 3.57 |
| Jan to Dec 2015 | 10 | 27 | 364 | 4 | 405 | 6.67 |
| Jan to Oct 2016 | 8 | 14 | 211 | 8 | 241 | 5.81 |
| Total | 21 | 43 | 626 | 12 | 702 | 6.13 |

5. mHealth and Linkage-to-Care Programme for MDR-TB

Emocha (now called miLINC)

In 2015 a miLINC application was launched in South Africa to link thousands of patients afflicted with multi-drug resistant tuberculosis (MDR-TB) to specialised clinics for Care.

As of 31 March 2016, miLINC has screened over 7668 patients at 18 facilities. miLINC has linked 35/56 Rif Resistant patients into care in an average of 3 days and 8 hours.

Table 7: Summary from miLINC Dashboard (March 2015 to 10 February 2016)

| | |
|--------------------------------|-----------------|
| *Provinces initiated | KZN, EC |
| Number of facilities initiated | 28 |
| Number of patients screened | 8607 |
| Rifampicin Resistant (R-R) | 58(1%) |
| TB sensitive | 10% |
| TB Negative | 78% |
| R-R patients linked to care | 35 |
| Average time linked to care | 3 days, 8 hours |

Dashboard is currently only reporting on 18 facilities. The dashboard is still under construction. *Not all districts initiated.

6. RIF Concordance

A total of 54,225 Rif Resistant cases were reported between 1 March 2011 and 10 June 2016, 49% had a follow up confirmatory tests performed by either culture or LPA, of those there was a concordance of 86% for RIF resistance between GX and MGIT and 89% between GeneXpert and LPA.

Table 8: Rif Concordance by LPA or DST (from March 2011 to 10 June 2016)

| | | GeneXpert Confirmation & Rif Concordance | | | | | | | | | | |
|-----------------|---------------------|--|--------------|-----------------|--------------|--------------------------|---------------|--------------|-----------------|--------------|---------------|--|
| Province | Rif Resistant Cases | MGIT | | | | | LPA | | | | | |
| | | Confirmed | | Rif Concordance | | Pre-analytical/No result | Confirmed | | Rif Concordance | | Indeterminate | |
| | | # | % | # | % | | # | % | # | % | | |
| Eastern Cape | 10 399 | 390 | 3.8% | 257 | 65.9% | 3 | 3 565 | 34.3% | 3 285 | 92.1% | 18 | |
| Free State | 3 069 | 224 | 7.3% | 122 | 54.5% | 0 | 980 | 31.9% | 801 | 81.7% | 189 | |
| Gauteng | 7 583 | 267 | 3.5% | 183 | 68.5% | 4 | 1 939 | 25.6% | 1 733 | 89.4% | 31 | |
| Kwazulu-Natal | 16 423 | 4 575 | 27.9% | 4265 | 93.2% | 0 | 4 724 | 28.8% | 4 228 | 89.5% | 188 | |
| Limpopo | 2 449 | 93 | 3.8% | 70 | 75.3% | 2 | 624 | 25.5% | 495 | 79.3% | 20 | |
| Mpumalanga | 3 923 | 803 | 20.5% | 788 | 98.1% | 0 | 1 483 | 37.8% | 1 280 | 86.3% | 4 | |
| North West | 2 880 | 257 | 8.9% | 179 | 69.6% | 0 | 928 | 32.2% | 727 | 78.3% | 55 | |
| Northern Cape | 1 674 | 331 | 19.8% | 251 | 75.8% | 3 | 701 | 41.9% | 537 | 76.6% | 35 | |
| Western Cape | 5 825 | 227 | 3.9% | 81 | 0.0% | 0 | 4 611 | 79.2% | 4 232 | 91.8% | 3 | |
| National | 54 225 | 7 167 | 13.2% | 6 196 | 86.5% | 12 | 19 555 | 36.1% | 17 318 | 88.6% | 543 | |

*table generated quarterly in order match GX RESULTS with follow up confirmatory tests

7. Training: Laboratory and Clinical

A total of 2,167 laboratory staff and 11,734 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.

Table 9: Laboratory staff trained for October 2016

| Date | District | Laboratory | No of Participants |
|----------------|--------------------------------------|---------------|--------------------|
| 06-07-Oct-2016 | Westrand | Carletonville | 9 |
| 11-Oct-16 | Ekhuruleni | Bertha Gxowa | 2 |
| 06-07-Oct-2016 | Advanced GeneXpert Training EC sites | | 15 |

Table 9: Health Care workers trained for October 2016

| Date | District | Facility | No of Participants |
|-----------|------------|--------------------|--------------------|
| 04-Oct-16 | Enhlanzeni | Sabie Hospital | 23 |
| 07-Oct-16 | Tshwane | Mamelodi Hospital | 10 |
| 12-Oct-16 | Enhlanzeni | Tonga Hospital | 24 |
| 13-Oct-16 | Enhlanzeni | Shongwe Hospital | 31 |
| 18-Oct-16 | Enhlanzeni | Barberton Hospital | 24 |
| 19-Oct-16 | Nkangala | Allemansdrift CHC | 14 |



| | | | |
|-----------|------------|---------------------|----|
| 21-Oct-16 | Nkangala | Kwamhlanga CHC | 22 |
| 25-Oct-16 | Enhlanzeni | Matikwane Hospital | 21 |
| 26-Oct-16 | Ekhuruleni | Mapulaneng Hospital | 26 |
| 27-Oct-16 | Enhlanzeni | Tintswalo Hospital | 25 |

8. Rejected Specimens

Rejections of GeneXpert specimens mostly occur as a result of Clerical errors (incorrect labelling and or incomplete request forms), cancellations (clinical errors), unsuitable specimens and insufficient volumes. In October, 11 273 (5.35%) specimens were rejected. On-going training remains a practical tool to guarantee improvement in specimen collection and labelling.

Figure 4: Rejections rate (Jan to Oct 2016)

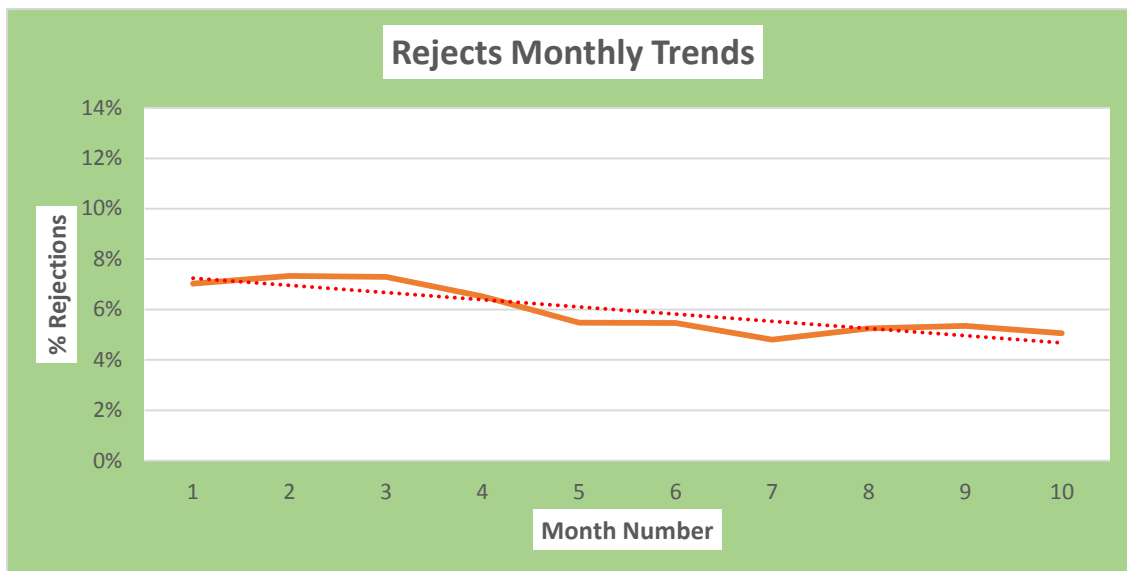
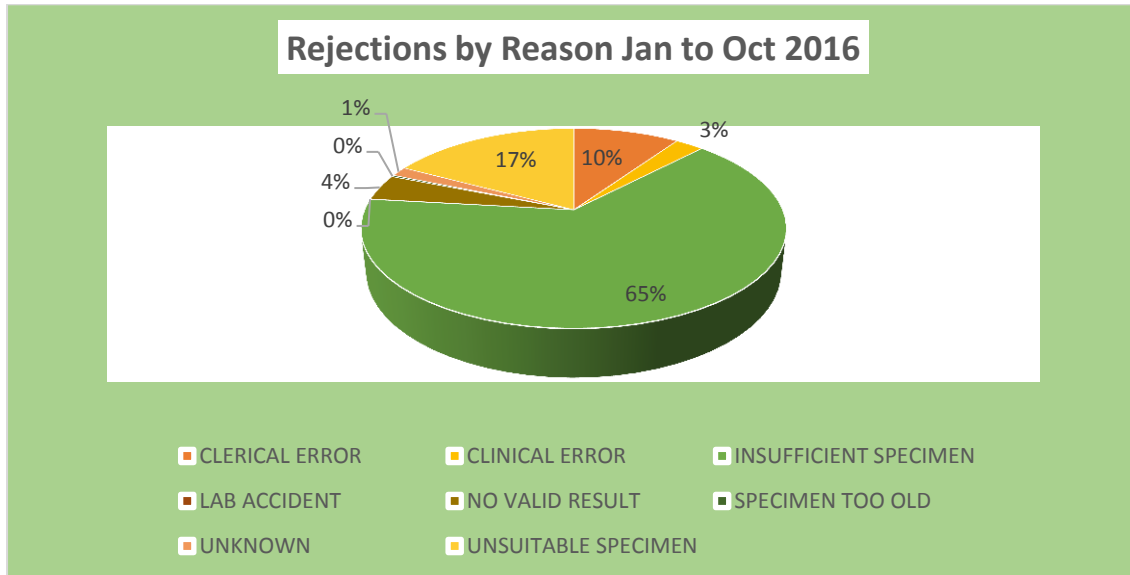




Figure 5: Rejections by reason



9. Challenges identified during the month of October 2016

- None

10. Upcoming plans

- Roll out Roll out of Xpert MTB/RIF Ultra assay.
- Continuous monitoring of sites through remote connectivity to improve program performance.
- Development of the GeneXpert dashboard to improve program performance.
- Recruitment of additional trainers to maximize service provided for NHLS labs and NDoH.

11. Publications

- None