



NATIONAL HEALTH
LABORATORY SERVICE

GeneXpert MTB/RIF

Progress Report

November 2016





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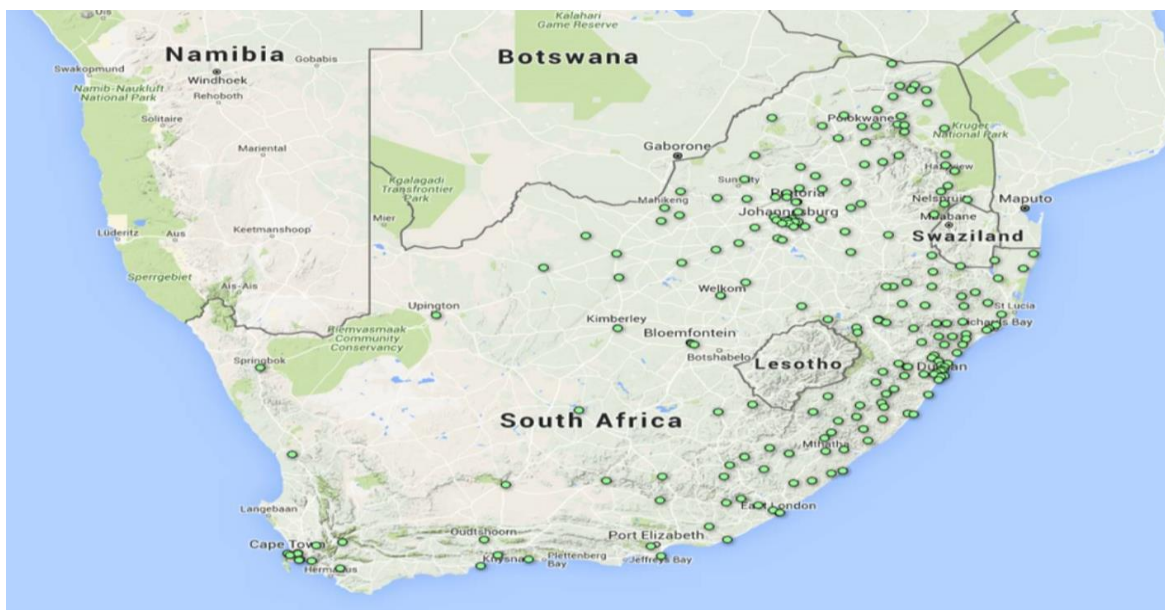
1. Background to Project

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 9,887,019 specimens have been processed to date (30 November 2016). In November 2016 a total 190,837 specimens were processed. The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 9.87% (18 831).

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 | 207 681 | 2 024 251 | 45 327 | 2 277 259 | 9.12 |
| Total | 1 031 961 | 8 616 359 | 238 699 | 9 887 019 | 10.44 |

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 | 2 251 | 12 849 | 192 433 | 148 | 207 681 | 6.19 |
| Total | 18 328 | 71 098 | 939 552 | 2 983 | 1 031 961 | 6.89 |

Figure 2: MTB Positivity and RIF Resistant rates overtime

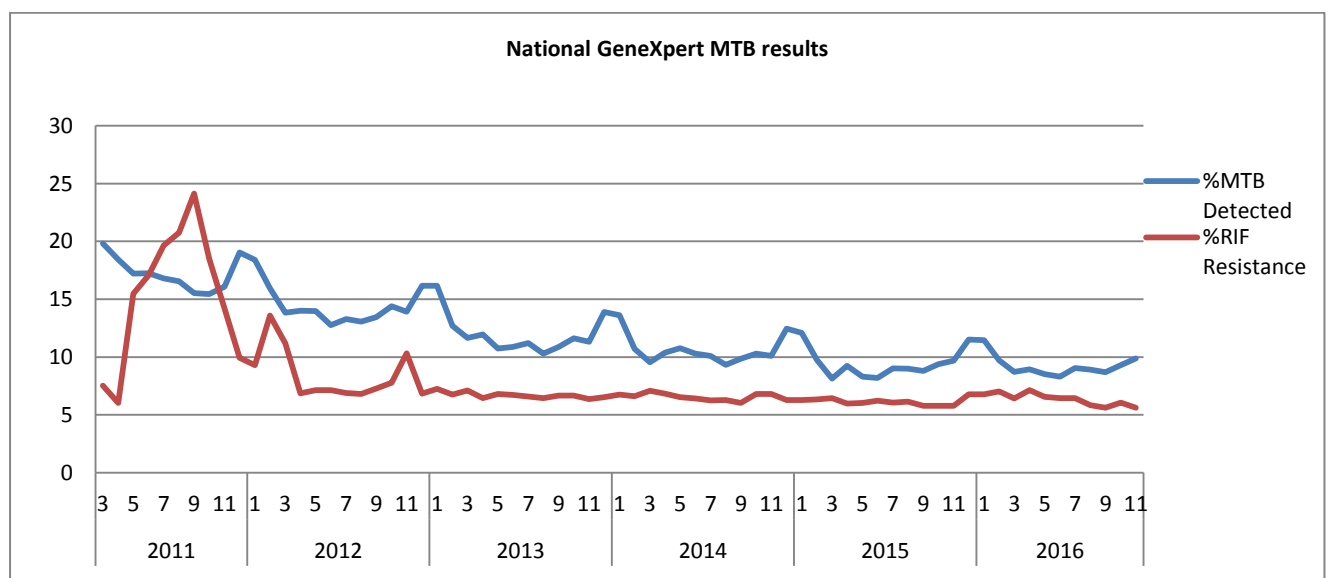
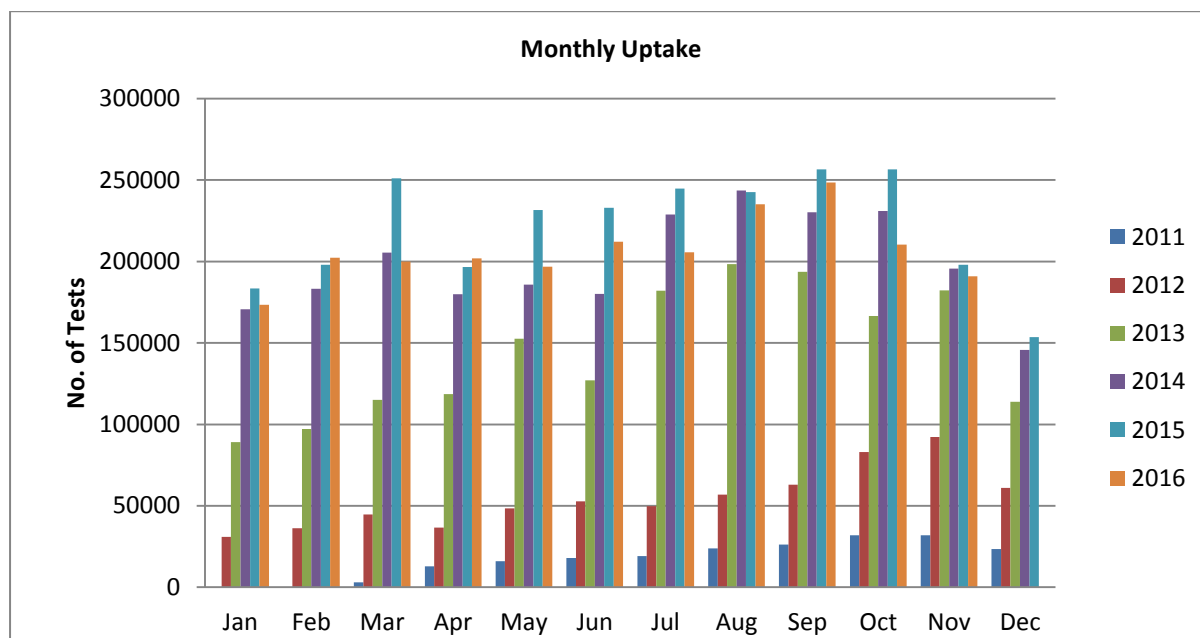


Figure 3: GeneXpert Monthly Uptake



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 269,202 specimens have been processed to date (30 November 2016). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 4.55% (12,242).

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 -Nov 2016 | 3129 | 64550 | 1228 | 68907 | 4.54 |
| Total | 12242 | 252370 | 4590 | 269202 | 4.55 |

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 -Nov 2016 | 135 | 34 | 2958 | 2 | 3129 | 4.31 |
| Total | 540 | 247 | 11437 | 18 | 12242 | 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 65,128 specimens have been processed to date (30 November 2016). The total % of Mycobacterium tuberculosis complex (MTBC) detected in this cohort was 1.09% (711).

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 Nov 2016 | 250 | 23822 | 489 | 24561 | 1.02 |
| Total | 711 | 63253 | 1164 | 65128 | 1.09 |

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 Nov 2016 | 9 | 15 | 218 | 8 | 250 | 6.00 |
| Total | 22 | 44 | 633 | 12 | 711 | 6.19 |

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. Training: Laboratory and Clinical

A total of 2,186 laboratory staff and 11,938 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 November 2016

| Date | District | Laboratory | No of Participants |
|------------|-------------|--------------|--------------------|
| 1/11/2016 | City of JHB | Braamfontein | 4 |
| 10/11/2016 | Vhembe | Tshilidzi | 2 |

| | | | |
|------------|-------------------|-------------|---|
| 15/11/2016 | City of Cape Town | Tygerberg | 6 |
| 16/11/2016 | City of Cape Town | Karlbremmer | 1 |
| 16/11/2016 | City of Cape Town | Khayelitsha | 6 |

Table 9: Health Care workers trained for November 2016

| Date | Province | District | Facility | No of Trainees |
|------------|---------------|--------------|----------------------|----------------|
| 08/11/2016 | Mpumalanga | Enhlanzeni | Right to Care | 15 |
| 09/11/2016 | Mpumalanga | Enhlanzeni | Right to Care | 10 |
| 10/11/2016 | Mpumalanga | Enhlanzeni | Themba Hospita | 25 |
| 11/11/2016 | North west | Bojanala | Moses Kotane | 31 |
| 15/11/2016 | Kwazulu Natal | Zululand | Ulundi hospital | 30 |
| 16/11/2016 | Kwazulu Natal | Zululand | Vryheid Hospital | 23 |
| 17/11/2016 | Kwazulu Natal | Zululand | Benedictine hospital | 35 |
| 22/11/2016 | Kwazulu Natal | Umkhanyakude | Hlabisa Hospital | 13 |
| 23/11/2016 | Kwazulu Natal | Umkhanyakude | Bethesda Hospital | 10 |
| 24/11/2016 | Kwazulu Natal | Umkhanyakude | Mseleni Hospital | 12 |

7. 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 November, 10 276 (5.38%) specimens were rejected. On-going training remains a practical tool to guarantee improvement in specimen collection and labelling.

Figure 4: Rejections rate (Jan to Nov 2016)

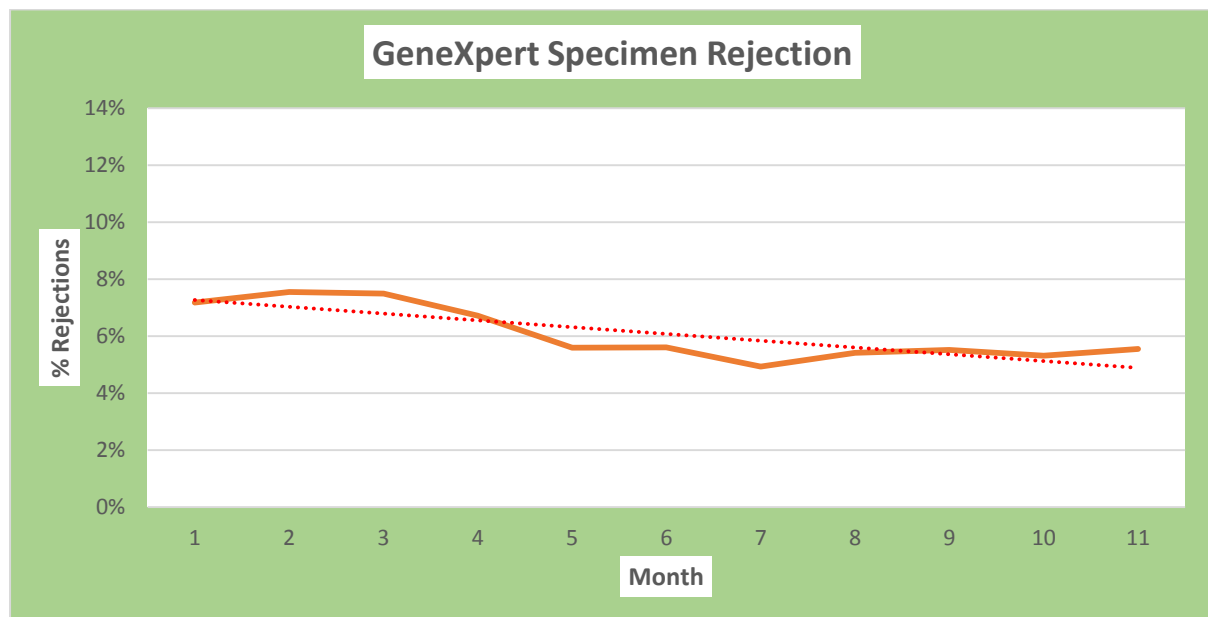
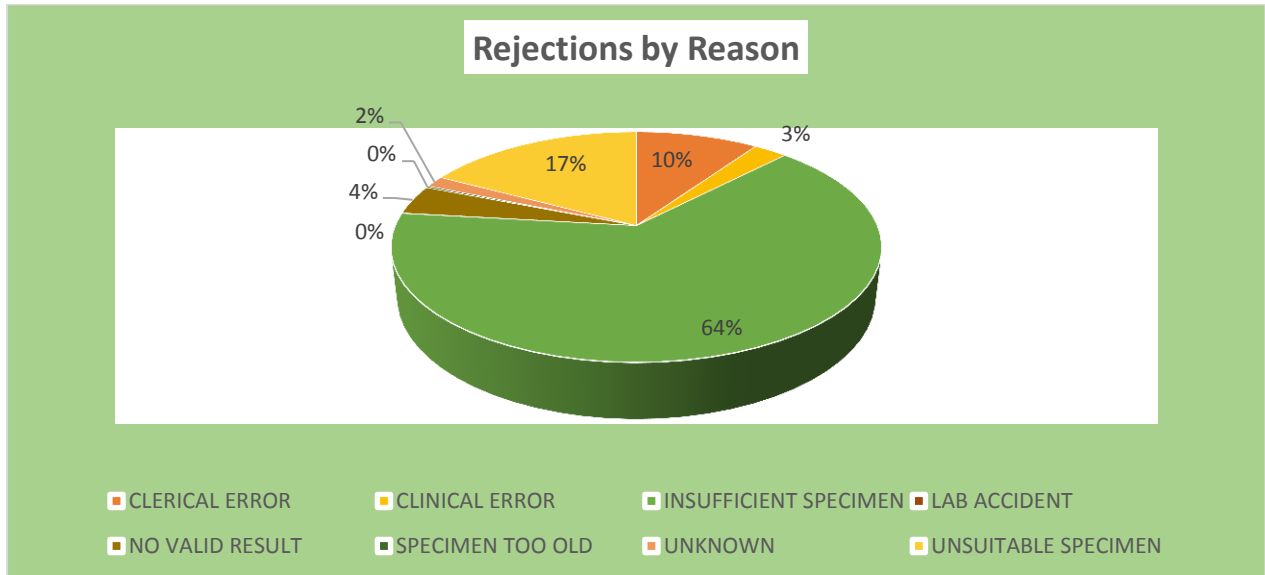




Figure 5: Rejections by reason



8. Challenges identified during the month of November 2016

- None

9. 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.

10. Publications

- None