Failing Xpert MTB/RIF modules: When? What warranty is needed from the customer's perspective? Experience in the DRC

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Background

Between 2012 and 2014, the Democratic Republic of Congo has gradually implemented 22 GeneXpert machines. The overall proportion of non-valid results (i.e. « error », « invalid » and « no result ») was 8%. Among the 68 analytical modules composing the 22 GeneXpert, 32% presented a significantly higher rate of non-valid results during the first 3 years of implementation, leading to unnecessary work and consumption of reagents as well as loss of diagnostic opportunities. The objective of this study was to determine whether it was possible to early identify modules presenting sub-optimal performance.

Methods

Data was collected from 8 GeneXpert (34 modules) located in the South-Kivu Province using the GenXchange (UCLouvain, Belgium; NTP, DRC) and XpertSMS (IRD, Pakistan) technology. We separated the modules in two groups: 11 modules identified with a high proportion of non-valid results, and 23 modules presenting normal figures. Figure 1 represents the activity (diameter of circles) and error rate (grayscale) for all GeneXpert analytical modules. Modules presenting an error rate superior to 10% are circled in red).

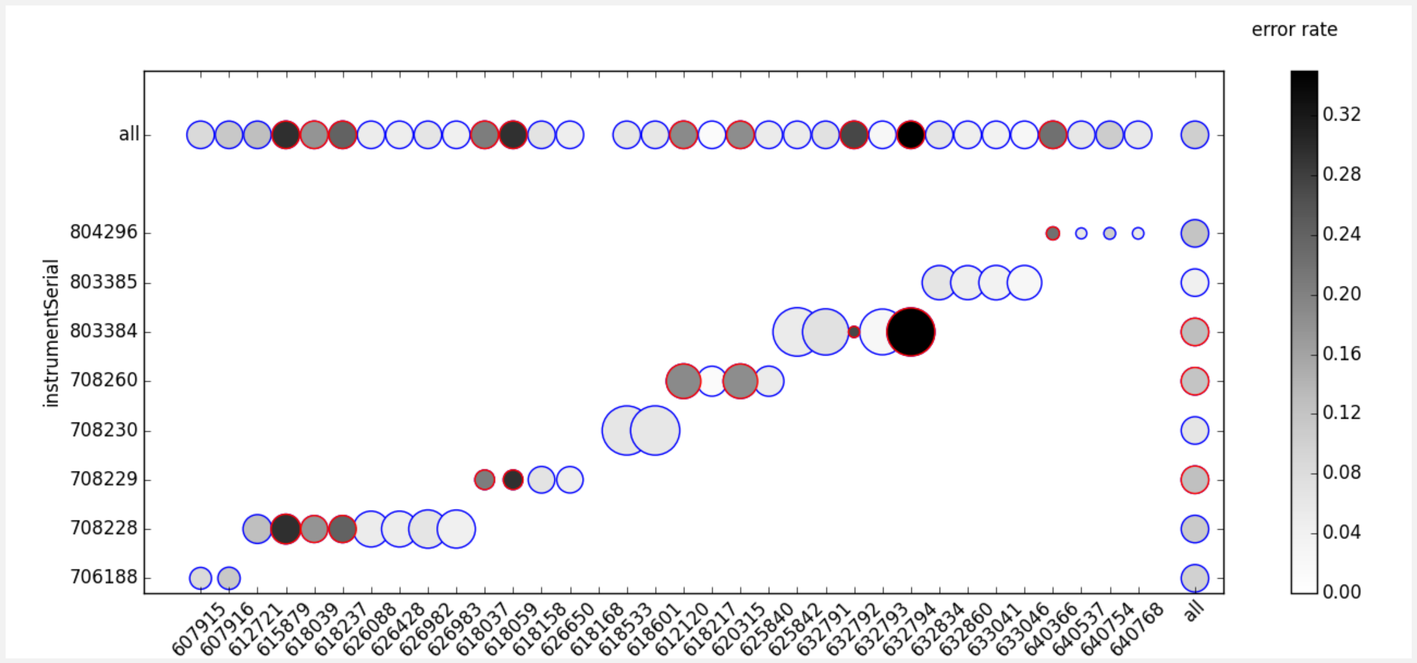

Figure 1

This first figure further shows that the main cause of invalid tests is linked with analytical modules rather than linked with other issues (GeneXpert instrument or local environment).

For each group of modules, we computed the proportion of non-valid results based on time after implementation of the GeneXpert. We used a moving average on 30 days.

Results

Figure 2 represent the percentage of non-valid results between the two groups of modules. In the group with a higher rate of non-valid results, all showed signs of dysfunction (proportion of not-valid results higher than 10%) from the first month after implementation. This separation between the two groups increased with the time, and was maximal after 6 months of activity.

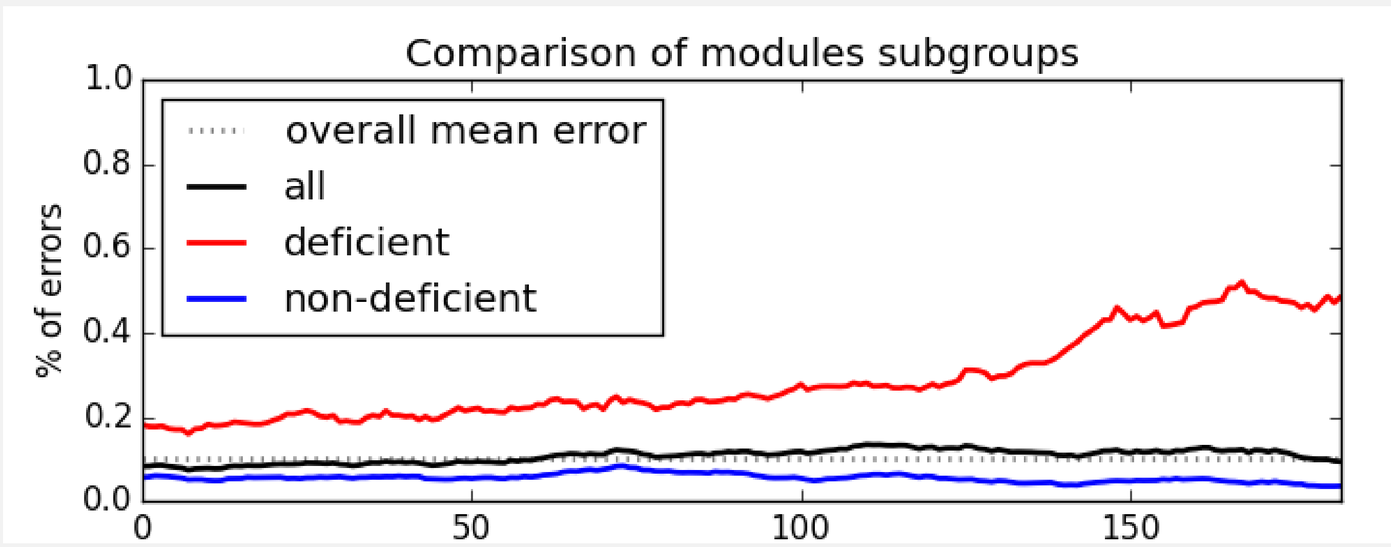

Figure 2

Conclusions

It had been previously reported that 32% of GeneXpert MTB/Rif modules presented signs of dysfunction during the first three years after implementation. We showed that failing modules present early signs of dysfunction which can be identified as early as the first month after implementation by using adequate automatic reporting systems. We conclude that the one-year free-of-charge warranty from the manufacturer will cover the vast majority of costs related to sub-optimal equipment delivered. Nevertheless, as failing modules can be difficult to identify, it is recommended to implement the adequate surveillance solutions in order to maximize the benefit that can be made from this warranty.