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A diagnostic evaluation of the Hardy MODS kit for the diagnosis of TB and MDR-TB from sputum samples.

Background

MODS is a rapid, inexpensive and reliable liquid culture method that detects *Mycobacterium tuberculosis* alongside rifampicin and isoniazid drug susceptibility. The assay is suited to resource-limited settings, but procurement of consumables from multiple providers may be complex. The Hardy MODS kit provides all materials & standardised reagents in a single box procured with a single order with culture plates that have a sealable silicone lid to minimise biosafety concerns.
The objective of this study was to compare the performance of Hardy MODS Kit (kMODS) to conventional MODS (cMODS) culture in a clinical setting.

Method

2,446 anonymised sputum samples sent to the regional TB reference laboratory from TB suspects were split equally and cultured by cMODS and kMODS. Technicians were blinded to the results of the parallel cultures. Data were analysed using Stata 10. The concordance of results for both TB & drug susceptibility detection was determined with the use of sensitivity and specificity (with 95% confidence intervals) as well as with kappa values. The z test for comparison of two proportions was used to compare contamination rates and Wilcoxon signed-rank test was used to compare the times to positive results between methods.

Results

kMODS has a high degree of agreement with cMODS for both TB & MDR-TB detection (agreement 97.5%, κ=0.94 & agreement 99.8%, κ=0.99 respectively). The relative sensitivity and specificity (including 95% confidence intervals) of kMODS compared to cMODS for TB detection was sensitivity 99.4% (98.5-99.8%) and specificity 98.4% (97.7-98.9%). For MDR-TB detection it was sensitivity 100% (95.0-100.0%) and specificity 99.8% (99.0-100.0%). Median time to culture positivity was significantly shorter for kMODS than cMODS (8.5 days [IQR, 7-11] vs. 10 days [IQR 9-13] respectively; P<0.001). Contamination rates were significantly higher (p<0.01) in kMODS compared to cMODS at 1.1% and 0.1% respectively, but this did not reduce kMODS sensitivity.

Conclusion

MODS kit performed well in comparison to conventional MODS culture. The use of quality-assured bacteriology as provided by the kit is likely to improve early case detection and diagnosis of TB & MDR-TB particularly for laboratories that would benefit from the simplification of culture methods and acquisition of materials.

Character (incl spaces) count (excluding title, authors & affiliations): 2,347