

Comparing Diagnostic Performance of Pronto Dry Rapid Urease® and Culture to Histopathology among Endoscopy Patients at the Aga Khan University Hospital, Nairobi-Kenya.

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ABSTRACT

Aim: This study sought to evaluate Pronto dry rapid urease® diagnostic test and compare its performance with culture. Study Design: Cross-sectional study. Place and Duration: From September 2017 to July 2018, across-sectional study was conducted at the Aga Khan University Hospital.

Methodology: Patients attending endoscopy unit at the hospital were randomly sampled to provide gastric biopsy specimen. One specimen was tested for presence or absence of *H. pylori* using Pronto dry rapid urease® test and another specimen subjected to in vitro culture test which were then compared with histology reference results. Test validity and reliability was determined using Graph Pad Prism v5.01.

Results: Of 274 study specimens, 121(44%) were positive for histology. Ninety-one (33%) of the study specimen were positive for culture compared to 147(54%) for Pronto dry rapid urease®. Pronto dry rapid urease® test had sensitivity of 100% (97.5%-100%) against 73.6% (64.8%-81.3%) for culture. Specificity was 96.1% (91.1%-98.7%) for Pronto dry rapid urease® compared to 35.3% (95% CI 24.1%-47.8%) for culture. Positive predictive value was 96.7% (92.5-98.9%) for Pronto dry rapid urease® compared to 97.8% (92.3%-99.7%) for culture. Negative predictive value was 100% (97%-100%) for Pronto dry rapid urease® against 82.5% (76.2%-87.7%) for culture. There was significant difference between both Pronto dry rapid urease® and culture test performance with histology in all validity measures, $P < 0.001$. On the other hand, there was no significant difference between Pronto dry rapid urease® and culture in all validity measures due to overlapping confidence intervals.

Conclusion: Pronto dry rapid urease® out-performed culture in sensitivity and NPV. It would be the method of choice in *H. pylori* detection where histology is untenable and antimicrobial profiling which require culturing the bacterium is needless.

Keywords: Helicobacter pylori; diagnosis; pronto dry rapid® urease test; biopsy; rapid urease; diagnostic tests

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