ABSTRACT

Introduction. Helicobacter pylori (Hp) is classified as class I carcinogen by WHO and may impact atrophic gastritis, ulcerous diseases and is related to gastric cancer and MALT lymphoma. The prevalence of Hp infection in the Czech Republic is about 42%. "C"-urea breath test is accepted as gold diagnostic standard, alternatively Hp antigen detection in stool can be used.

Aims & Methods. This study evaluates two Hp-antigen rapid tests: helicoCARE direct (Care Diagnostica, Austria) and RAPID Hp STAIRM™ (Oxoid - DAKO), both was compared with ELISA test Amplified IDEIA™ Hp STARM™ with monoclonal antibodies (Oxoid - DAKO). The comparison was performed on 50 stool specimens stored at -70°C. The preanalytical process of both tests were compared as well.

Results. The matching results of helicoCARE direct with ELISA test occurred in 42 cases (Cohen’s $k = 0.672$, 95% CI = 0.465 - 0.878), relative sensitivity, specificity and accuracy to ELISA test were 79%, 94% and 94%. RAPID Hp STAIRM™ test matched with ELISA test in 30 specimens (Cohen’s $k = 0.543$, 95% CI = 0.312 - 0.775), relative sensitivity, specificity and accuracy to ELISA test were 64%, 100% and 76%.

Conclusions. The preanalytical phase is more confident in RAPID Hp STAIRM™ test, where results are prepared by patient, more easily, compared to RAPID Hp STAIRM™, but wholly independently to the laboratory. The analytical accuracy and agreement with ELISA test were higher for helicoCARE direct test.

Rapid tests comparison

<table>
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<tr>
<th>HPV TEST COMPARISON</th>
<th>ELISA IDEIA™ Hp STAIRM™</th>
<th>ELISA IDEIA™ Hp STAIRM™</th>
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<tbody>
<tr>
<td>neg.</td>
<td>14</td>
<td>12</td>
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<tr>
<td>pos.</td>
<td>21</td>
<td>23</td>
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<tr>
<td>Acceptance rate</td>
<td>80%</td>
<td>76%</td>
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Relative sensitivity, specificity and accuracy (compared to ELISA method)

- RAPID Hp STAIRM™: 64%, 100%, 76%
- helicoCARE direct: 79%, 94%, 84%

Amplified IDEIA™ Hp STAIRM™

Amplified IDEIA™ Hp STAIRM™ - qualitative test with diagnostic sensitivity 95.3 - 100% and specificity 96.9 - 99.4%; sandwich ELISA test utilises highly specific monoclonal antibodies combined with a polymer dextran conjugate.

Patient sampling. - to plastic container with spoon extractor fixed to container cap. Stool samples were stored, refrigerated at -70°C.

Laboratory procedure - 100 mg of stool samples were weighed, extracted to buffer solution pH 7.4, centrifuged 30 minutes and left for 12 hours at 4°C to next day. ELISA method was run according to manufacturer instructions. Evaluation of ELISA microplates was performed using vertical ELISA 8-channel reader Spectra, at wavelengths 450 and 650 nm.

Instituce of Clinical Biochemistry & Laboratory Diagnostics, 1st Medical Faculty & General Faculty Hospital, Charles University Prague, Czech Republic

HelicoCARE direct

Test helicoCARE direct - immunochromatographic assay for qualitative determination of Hp antigen in stool with analytical sensitivity 4-40 ng Hp antigen/ml. Diagnostic sensitivity - 89%, specificity 96%.

Patient sampling. - to plastic container with brush extractor fixed to container cap. Only the amount of stool, that remains in the thread of the applicator, should be put into the collection tube with extraction buffer.

Laboratory procedure. - breaking the tip of cassette and adding two drops of sample solution to the cassette.

HelicoCARE direct

Test helicoCARE direct - rapid amplified immunochromatographic assay for qualitative determination of Hp antigen in stool. Rapid test uses the same monoclonal antibodies as ELISA Amplified IDEIA™ Hp STAIRM™. Diagnostic sensitivity - 97.6%, specificity 94.2%.

RAPID Hp STAIRM™

RAPID Hp STAIRM™ - rapid amplified immunochromatographic assay for qualitative determination of Hp antigen in stool. Rapid test uses the same monoclonal antibodies as ELISA Amplified IDEIA™ Hp STAIRM™. Diagnostic sensitivity - 95.3 - 100%, specificity 96.9 - 99.4%.

RAPID Hp STAIRM™ test matched with ELISA test in 30 specimens (Cohen’s $k = 0.543$, 95% CI = 0.312 - 0.775), relative sensitivity, specificity and accuracy to ELISA test were 64%, 100% and 76%.

The preanalytical phase is more confident in RAPID Hp STAIRM™ test, where results are prepared by patient, more easily, compared to RAPID Hp STAIRM™, but wholly independently to the laboratory. The analytical accuracy and agreement with ELISA test were higher for helicoCARE direct test.

CONCLUSIONS

- Stability of Hp antigen in all stool samples stored and refrigerated at –70°C remains stable during tested 5 years.
- Quantity of sampled stool affects rapid tests results at minimal range. Doubling of stool sampling will not cause antibody saturation, and didn’t display false negative results.
- Stool extraction with very high sample concentration didn’t display false positivity.
- Using just half amount of stool sample may cause false negative results.
- Rapid tests are much quicker compared to ELISA method, it is possible to examine one sample only, namely right by the doctor, test does not require laboratory equipment.
- Results of both rapid tests agreed in 80% of cases, concordance rate expressed coefficient $k$ was 0.603. Higher concordance with ELISA method we found with helicoCARE direct, $k = 0.672$. RAPID Hp STAIRM™ test embodied with ELISA method ELISA coincident only in 76% results, concordance rate $k = 0.543$.
- RAPID Hp STAIRM™ tests could be unethically evaluated as artefacts, in light of exogenous factors, they found better helicoCARE direct tests. helicoCARE direct tests could be influenced much more by patient stool sampling and has higher pre-analytical errors. Rapid Hp STAIRM™ tests are fully prepared by laboratory and pre-analytical phase is therefore more reliable.
- Expenses are comparable in both rapid tests.

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