Evaluation and comparison of four stool antigen tests for the detection of *Helicobacter pylori*

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Comparison of 4 lateral flow assays

- To evaluate the performance of 4 rapid stool antigen tests for detection of *Helicobacter pylori*
- 3 immunochromatographic tests
  - H. PYLORI QUIK CHEK™ (TECHLAB)
  - H.pylori Ag Rapydtest® (APACOR)
  - Helico HpSA Immunocard STAT! ® (MERIDIAN)
- 1 immunofluorescent test
  - Curian ® HpSA ® (MERIDIAN)

Materiel & methods : Performances

- Prospective analysis of 124 stool samples obtained from consecutive non-duplicate symptomatic and asymptomatic patients between June and October 2021.
- Samples with insufficient amount or inappropriate quality (diarrhea) were excluded.
- Samples were analyzed with the four cited methods performed according manufacturer instructions.
- Reference method (routine and literature): Helico HpSA Immunocard STAT! ® (MERIDIAN).
- We defined sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV) for each test.

Stability, Repeatability & reproducibility studies

- Stability study

- Aliquoted samples were frozen at -80°C and tested with four devices at day 1, 7, 15 and 30.

- Repeatability/reproducibility study

Two positive (one weak and one strong positive) samples were tested three times each day during 5 days with 4 methods.

Results

Performance of our routine antigenic test, namely Helico HpSA Immunocard STAT! ® (MERIDIAN, Europe) was established before in several studies :

- Sensitivity : 69% to 100%.
- Specificity : 89% to 93.2%.
- Accuracy : 96.3% to 97.5%.

Methods	Result	Reference method result (ImmunoSTAT Meridian)	
		Positive (n=28)	Negative (n=96)
Curian	Positive	24	
	Negative	4	96
Apacor	Positive	25	
	Negative	3	96
Techlab	Positive	22	
	Negative	6	96

Results

Performance compared to the reference method (n=124)	H. PYLORI QUIK CHEK™ (TECHLAB)	H.pylori Ag Rapydtest® (APACOR)	Curian ® HpSA ® (MERIDIAN)
Sensitivity % (95% CI)	79 (66-84)	89 (76-92)	86 (73-90)
Specificity %	100 (96-100)	100 (96-100)	100 (96-100)
Accuracy %	96	98	97
NPV %	94	97	96
PPV %	100	100	100

Stability, Repeatability & reproducibility studies

- Repeatability/reproducibility analyses showed excellent performance (all tests were positive) for all devices.

- Regarding stability, all devices showed positive results for samples tested at day 1, day 7, day 15 and day 30.

Discussion: HpSA Immunocard STAT! ® (MERIDIAN)

- **Pros :**

- User friendly
- Well studied
- High performance

- **Cons :**

- Hands on time (17 min)
- 2 visual reading are necessary (5’ and 15 minutes)
- No traceability
- No electronic transmission to LIS

Discussion: H. PYLORI QUIK CHEK™ (TECHLAB)

- **Pros :**

- Visual method
- Non-inferiority compared to the routine method

- **Cons :**

- Reverse capillarity phenomenon
- Multiple handling steps
- High consumables
- Hands on time (30 min)
- No electronic transmission to LIS
- No traceability

Discussion: H.pylori Ag Rapydtest® (APACOR)

- **Pros :**

- User friendly
- Hands on time (12 min)
- Non-inferiority compared to the routine method

- **Cons :**

- No traceability
- No electronic transmission to LIS

Discussion: Curian ® HpSA ® (MERIDIAN)

- **Pros:**

- Objective measure by the reader
- Traceability through the reader
- Possible electronic transmission to LIS
- Non-inferiority compared to the routine method

- **Cons:**

- No visual reading possible by the operator
- Exact reading time required at 20 minutes
- Problem of restarting
- Hands on time (24 min)

Conclusion

- All tests were reliable showing a perfect specificity and PPV.
- All four devices were easy to use.
- Curian ® HpSA ® (MERIDIAN) reduces the subjectivity of the operator's reading but does not allow the technologist to interpret without the manufacturer's reading device.

References

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