Clinical Evaluation of the Rapid Syphilis Antibody Test Card: Accuracy and Diagnostic Performance in a Point-of-Care Setting

Mei Xiao [1], Jian Zeng [2], Bao Ding [3]

[1] *Head of the Biochemistry Department Xiamen University, China*
[2] *Head of Quality Department Boson Biotech Co, Ltd*
[3] *Professor Head of Department Infectious Diseases Zhongshan Hospital, China*

KEYWORDS
Syphilis, Rapid Diagnostic Test, Antibody Detection, Point-of-Care Testing, Clinical Evaluation, Lateral Flow Immunoassay.

ABSTRACT
This study evaluates the clinical accuracy of the Rapid Syphilis Antibody Test Card, a lateral flow immunoassay designed for the detection of syphilis antibodies in human serum and plasma. The evaluation was conducted using 537 clinical samples (178 positive and 359 negative) collected from patients at Zhongshan Hospital Xiamen University. The test results were compared with the Elecsys® Syphilis (ECLIA) reference method, a widely recognized laboratory-based assay. The Rapid Syphilis Antibody Test Card demonstrated an overall accuracy of 98.7%, with a positive agreement of 98.3% and a negative agreement of 98.9%. These findings underscore the test card's reliability and suitability for point-of-care (POC) settings, particularly in resource-limited environments where rapid and accurate diagnosis is critical for effective syphilis management.

1. Introduction

Syphilis, caused by the bacterium *Treponema pallidum*, remains a significant global public health challenge, with an estimated 6 million new cases annually. Early and accurate diagnosis is essential to prevent severe complications, including neurosyphilis, congenital syphilis, and increased HIV transmission risk. Rapid diagnostic tests (RDTs) have emerged as valuable tools for syphilis screening, particularly in point-of-care (POC) settings, due to their simplicity, rapid turnaround time, and minimal infrastructure requirements.

The **Rapid Syphilis Antibody Test Card** is a lateral flow immunoassay designed to detect syphilis antibodies in human serum and plasma. This study aims to evaluate its clinical accuracy and diagnostic performance in comparison to the **Elecsys® Syphilis (ECLIA)** reference method, a widely used laboratory-based assay. The findings will provide critical insights into the test card's suitability for POC applications, particularly in resource-limited settings.

2. Materials and Methods

2.1 Study Design

A blinded clinical evaluation of the **Rapid Syphilis Antibody Test Card** was conducted at **Zhongshan Hospital Xiamen University**. The study included 537 clinical samples (178 positive and 359 negative) collected from patients undergoing routine health checkups or hospital visits. Positive samples were confirmed using the **Elecsys® Syphilis (ECLIA)** reference method, and interfering samples (e.g., hepatitis B, hepatitis C, HIV, antinuclear antibodies, and rheumatoid factor) were included to assess specificity.

2.2 Sample Collection and Preparation

- **Serum Samples**: Venous blood was collected using disposable vacuum blood collection tubes without anticoagulant. Serum was separated after clotting.
- **Plasma Samples**: Venous blood was collected using tubes containing anticoagulant, and plasma was separated by centrifugation.
- Samples were stored at **2–8 C** if not tested immediately or frozen at-**20 C** for long-term storage.

2.3 Test Procedure

The **Rapid Syphilis Antibody Test Card** was used according to the manufacturer's instructions. Results were interpreted visually, and the performance was compared with the **Elecsys® Syphilis (ECLIA)** reference method. The ECLIA results were considered positive if the value was ≥1 and negative if <1.

2.4 Data Analysis

The following metrics were calculated to evaluate the test card's performance:

- **Positive Agreement (%)**: (True Positives / (True Positives + False Negatives)) × 100
- **Negative Agreement (%)**: (True Negatives / (True Negatives + False Positives)) × 100
- **Overall Accuracy (%)**: ((True Positives + True Negatives) / Total Samples) × 100

3. Results

The **Rapid Syphilis Antibody Test Card** demonstrated high diagnostic accuracy, as summarized below:

Test Result	ECLIA Positive	ECLIA Negative	Total
Boson Kit Positive	175	4	179
Boson Kit Negative	3	355	358
Total	178	359	537

- **Positive Agreement**: 98.3% (175/178)
- **Negative Agreement**: 98.9% (355/359)
- **Overall Accuracy**: 98.7% (530/537)

The test card exhibited excellent agreement with the reference method, with only **4 false positives** and **3 false negatives** out of 537 samples.

3.1 Detailed Results Table

The table below provides a comprehensive overview of the 537 samples tested, including patient demographics, clinical diagnoses, and test results from both the **Rapid Syphilis Antibody Test Card**and the **Elecsys® Syphilis (ECLIA)** reference method:

No.	Sample No.	Gender	Age	Clinical Diagnosis	Boson Kit Result	ECLIA Result
1	1310497037	Male	24	Herpes simplex	Positive	265.86
2	1310913207	Female	29	Dermatitis	Negative	0.27
3	1310921771	Female	39	Skin tumors	Negative	0.69
4	1310932580	Male	26	Phimosis	Positive	2.71
5	1310919197	Male	33	Phimosis	Negative	0.27
6	1310909599	Male	44	Subcutaneous tumor	Negative	0.57
7	1310932520	Male	49	Skin tags	Negative	0.03
8	1310922752	Female	30	Skin tumors	Positive	34.15
9	1310958322	Male	78	Prostatic hyperplasia	Negative	0.34
10	1310953352	Female	38	Double vision	Negative	0.75
...	...	...	...	...	...	...
528	1310908009	Male	68	Skin tumors	Negative	0.53
529	1310943921	Male	45	Stomach ache	Negative	0.38
530	1310488091	Male	48	Balanitis	Positive	87.66
531	1310498571	Female	28	Tinea versicolor	Positive	54.93
532	1310504118	Female	63	Gastric polyps	Positive	3.68
533	1310851054	Female	40	Internal hemorrhoids	Negative	0.27
534	1310945649	Male	60	Multiple colon polyps	Negative	0.87
535	1310941791	Female	52	Hyperthyroidism	Negative	0.86
536	1310903343	Male	48	Subcutaneous tumor	Negative	0.25

No.	Sample No.	Gender	Age	Clinical Diagnosis	Boson Kit Result	ECLIA Result
537	1310908993	Male	49	Subcutaneous tumor	Negative	0.79

(The full table with all 537 samples is included in the appendix.)

4. Discussion

The **Rapid Syphilis Antibody Test Card** demonstrated exceptional diagnostic accuracy, with an **overall agreement of 98.7%** compared to the **Elecsys® Syphilis (ECLIA)** reference method. The high positive agreement (98.3%) and negative agreement (98.9%) indicate that the test card is both sensitive and specific, even in the presence of potential interfering substances such as hepatitis B, hepatitis C, HIV, antinuclear antibodies, and rheumatoid factor.

The ability to use both serum and plasma samples enhances the test card's versatility, making it suitable for diverse clinical settings. Its simplicity and rapid turnaround time (results within minutes) further underscore its utility in resource-limited environments, where access to laboratory infrastructure is often constrained.

These findings align with global efforts to expand access to rapid and accurate syphilis diagnostics, particularly in high-burden regions. The **Rapid Syphilis Antibody Test Card** represents a promising tool for improving syphilis screening and management, particularly in POC settings.

5. Conclusion

The **Rapid Syphilis Antibody Test Card** is a highly accurate and reliable diagnostic tool for the detection of syphilis antibodies in point-of-care settings. Its performance is comparable to laboratory-based methods, and its ease of use makes it an ideal choice for early diagnosis and treatment of syphilis, particularly in resource-limited environments. Future studies should explore its performance in larger, more diverse populations and its integration into national syphilis screening programs.

References

[1] ISO 20916:2019 - In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice.

[2] Clinical Trials of In Vitro Diagnostic Reagents (Circular No. 16 of 2014 of the State Food and Drug Administration).

[3] Elecsys® Syphilis (ECLIA) - Roche Diagnostics.