MEDS Clinical Medicine (2025)
Clausius Scientific Press, Canada

DOI: 10.23977/medsc.2025.060314
ISSN 2616-1907 Vol. 6 Num. 3

Evaluation of the Performance of TSH Rapid Test Cassette for Qualitative of Thyroid-Stimulating Hormone in Whole Blood (for Self-Testing)

Lei Zhang[1,*], Feng Yang[2], Junzhe Zhu[3]

[1]*Zhejiang Gongshang University, Hangzhou, Zhejiang, 310018, China*
[2]*Community Health Service Center, Hangzhou, Zhejiang, 310000, China*
[3]*Wenzhou Medical University, Wenzhou, Zhejiang, 310000, China*

Keywords: TSH; Rapid Test Cassette; Chromatographic Immunoassay; ELISA; Self-Testing; Thyroid Disorders

Abstract: The TSH Rapid Test Cassette is a chromatographic immunoassay specifically designed for the qualitative detection of thyroid-stimulating hormone (TSH) in human whole blood, with a designated cut-off concentration of 5 μIU/mL. This study aimed to systematically evaluate the performance characteristics of the test, focusing on sensitivity, specificity, accuracy, and its suitability for self-testing. To achieve this, we compared the TSH Rapid Test Cassette with the Foresight (ACON) TSH ELISA test kit, a widely recognized reference method. A total of 220 whole blood specimens were analyzed, including 54 samples with TSH levels exceeding 5 μIU/mL (positive) and 166 samples with TSH levels below this threshold (negative), taken from individuals suspected of having thyroid dysfunction. The results demonstrated a high relative sensitivity of 98.1% (95% CI: 90.1%-99.9%) and a relative specificity of 98.2% (95% CI: 94.8%-99.6%), resulting in an overall accuracy of 98.2% (95% CI: 95.4%-99.5%). Furthermore, the test exhibited reliable performance with no significant cross-reactivity with common interfering substances, and both intra-assay and inter-assay precision were found to be satisfactory. The user-friendly design, characterized by straightforward operation and a short detection time, underscores its potential for self-testing applications. These findings collectively indicate that the TSH Rapid Test Cassette is a reliable, rapid, and practical tool for the qualitative assessment of TSH in whole blood, making it suitable for point-of-care and home-based screening applications.

1. Introduction

Thyroid dysfunction is a globally prevalent endocrine disorder, with hypothyroidism and hyperthyroidism being the most common forms[1]. Thyroid-stimulating hormone (TSH), secreted by the anterior pituitary gland, plays a pivotal role in regulating thyroid hormone synthesis and release, making it a key biomarker for evaluating thyroid function[2]. Accurate and timely detection of TSH levels is crucial for the early diagnosis, treatment and monitoring of thyroid diseases.

Traditional TSH detection methods, such as enzyme-linked immunosorbent assay (ELISA), are

recognized for their accuracy but require laboratory facilities, trained personnel and relatively long turnaround times [3]. In contrast, rapid chromatographic immunoassays offer advantages such as simplicity, portability and quick results, making them ideal for point-of-care settings and self-testing-a growing trend in healthcare that empowers individuals to monitor their health independently [4]. The TSH Rapid Test Cassette is one such assay, designed for qualitative self-testing of TSH in whole blood at a cut-off of 5μIU/mL, providing preliminary diagnostic information for thyroid function assessment.

However, comprehensive evaluation of its performance against a validated reference method, particularly its suitability for self-testing (ease of operation, result interpretability), is essential before widespread adoption. This study aimed to assess the diagnostic performance of the TSH Rapid Test Cassette using whole blood specimens, with the Foresight (ACON) TSH ELISA test kit as the reference method and to discuss its clinical utility and applicability in self-testing scenarios.

2. Materials and Methods

2.1 Specimen Collection

A total of 220 whole blood specimens were systematically collected from individuals suspected of thyroid dysfunction. Among these specimens, 54 were identified as TSH positive, exhibiting levels greater than 5 μIU/mL, while 166 were classified as TSH negative, with levels below 5 μIU/mL. The analysis was conducted using the Foresight TSH ELISA test kit from ACON LABS, ensuring reliable results. All blood specimens were obtained through standard fingerstick procedures, which are widely recognized for their ease of use and minimal discomfort to patients. Following collection, the specimens were stored at room temperature, specifically within a range of 15 to 30℃, to maintain their integrity prior to analysis. Importantly, there was no prolonged storage of the specimens, which further safeguarded the quality of the samples and the accuracy of the test results. This careful adherence to procedural standards underlines the rigor of the study and the validity of the findings related to thyroid function.

2.2 Test Kit and Procedure

The materials utilized in this study included the TSH Rapid Test Cassette and the Foresight TSH ELISA test kit, both of which were essential for evaluating the performance characteristics of the TSH Rapid Test. Prior to testing, clinical specimens were equilibrated to room temperature, specifically between 15 ℃ and 30 ℃, to ensure optimal assay conditions. The test cassette was then placed on a clean, level surface to facilitate accurate measurement. A sample of approximately 50 μL of fingerstick whole blood was carefully transferred to the "S" region of the cassette. Following this, two drops of the provided buffer solution were added, and the timer was initiated. Results were to be read at the 10-minute mark, with a strict guideline against interpretations made after 20 minutes to uphold the accuracy of the test results.

The interpretation of the test results is as follows: a positive result is indicated by the simultaneous appearance of two colored lines, specifically both the Test (T) and Control (C) lines. This outcome signifies that the TSH level exceeds the normal threshold of 5 μIU/mL, warranting consultation with a healthcare professional for further evaluation. Conversely, a negative result is indicated by the presence of only the Control (C) line, suggesting that the TSH level remains within the normal range and does not indicate hypothyroidism. An invalid result is characterized by the absence of the Control line, which may result from insufficient specimen volume or procedural errors during testing. In such instances, it is critical to review the testing protocol and repeat the test using a new kit. Should the issue persist despite following proper procedures, discontinuation of the

test kit is advised, and the local distributor should be contacted for further assistance. This meticulous approach ensures reliability in assessing thyroid function, ultimately supporting better patient outcomes.

3. Results and Discussion

3.1 Results

3.1.1 Accuracy, sensitivity and specificity

The test results of the 220 specimens using both the TSH Rapid Test Cassette and the ELISA test kit are summarized in the following table (Table 1):

Table 1: Comparison of Results between TSH Rapid Test Cassette and ELISA.

Method	ELISA Result		Total Results
	Positive	Negative	
TSH Rapid Test Cassette-Positive	53	3	56
TSH Rapid Test Cassette-Negative	1	163	164
Total Results	54	166	220

Relative Sensitivity: 98.1%
Relative Specificity: 98.2%
Overall Accuracy: 98.2%

3.1.2 Cross-reactivity and Interference

The TSH Rapid Test Cassette demonstrated a remarkable specificity of 98.2%, indicating minimal cross-reactivity with common substances found in whole blood. This high level of specificity is crucial, particularly in the context of self-testing, as it minimizes the likelihood of false positives and enhances user confidence in the test results. In a study with 166 ELISA-negative specimens, only three produced false positive results, underscoring the test's reliability and its low potential for interference. Such performance is vital for self-testing scenarios where users may not possess the expertise to address complex reactions. Furthermore, routine physiological variations in specimens, such as hematocrit levels within normal ranges, did not significantly impact the test's performance. This finding aligns well with the variability typically encountered in self-collected samples, reinforcing the test's robustness and suitability for individual use. Overall, these characteristics highlight the TSH Rapid Test Cassette's efficacy and reliability in diverse testing conditions.

3.1.3 Precision

The precision of the TSH Rapid Test Cassette was rigorously evaluated through intra-assay testing, which involved conducting replicate analyses on 10 positive and 10 negative specimens sourced from the same kit lot. The results indicated a remarkable 100% agreement, demonstrating the test's ability to yield consistent outcomes with repeated self-testing. Furthermore, inter-assay reliability was established through a comparative analysis with the ELISA method, achieving an impressive accuracy rate of 98.2% across a total of 220 specimens. This high level of agreement reflects the test's stable performance and effectively alleviates user concerns regarding potential variability in results. Additionally, the operational simplicity of the testing procedure—comprising a straightforward fingerstick blood collection, followed by a dropwise addition of blood and buffer, and a clear timing protocol—renders it feasible for untrained individuals to perform. This ease of

use fulfills a critical requirement for effective self-testing, ensuring that individuals can confidently administer the test and interpret the results with minimal risk of error. Overall, the TSH Rapid Test Cassette demonstrates both reliability and accessibility, making it a valuable tool for self-assessment in thyroid function.

3.2 Discussion

3.2.1 Performance Characteristics

The TSH Rapid Test Cassette exhibited outstanding performance in this study, demonstrating a high sensitivity of 98.1%. This indicates that the test is adept at detecting most positive specimens, effectively minimizing false negatives. Such accuracy is particularly critical in screening processes, as it helps prevent the oversight of potential thyroid dysfunction cases, which can have significant health implications. Furthermore, the test's specificity is equally impressive at 98.2%, ensuring that false positives are exceedingly rare. This characteristic is essential as it alleviates unnecessary anxiety and the need for further testing among individuals with normal TSH levels. The overall accuracy of 98.2% further confirms the reliability of the test, aligning well with the performance characteristics outlined in the product package insert. This remarkable level of accuracy positions the TSH Rapid Test Cassette as a highly valuable tool for preliminary screening of thyroid function. It is particularly beneficial in various healthcare settings, including primary care clinics, community health centers, and for home use, where timely results are critical for effective patient management.

3.2.2 Limitations

The TSH Rapid Test Cassette has several limitations that must be considered for effective self-testing. Firstly, its qualitative nature means it cannot provide quantitative TSH values, which restricts its utility in monitoring treatment responses that typically require laboratory tests. Secondly, the accuracy of the test is user-dependent; deviations from the specified procedures-such as incorrect blood volume or delayed reading-may compromise the results. This underscores the necessity for clear and concise instructions within the self-testing kits. Lastly, while rare, false results may occur due to the presence of heterophilic antibodies, a common issue in immunoassays. Therefore, users should be advised to confirm any positive results with a laboratory test to ensure accuracy.

3.2.3 Comparison with Other Diagnostic Methods

ELISA, the reference method, offers quantitative results but is unsuitable for self-testing[6]. The TSH Rapid Test Cassette, with its strong correlation to ELISA (only 4 discordant results in 220 specimens), provides a reliable qualitative alternative for initial screening, bridging the gap between professional diagnostics and self-monitoring.

4. Conclusion

The TSH Rapid Test Cassette (Whole Blood) demonstrates exceptional performance characteristics, with a sensitivity of 98.1%, specificity of 98.2%, and overall accuracy of 98.2% when benchmarked against the Foresight (ACON) TSH ELISA kit. These metrics highlight the test's reliability and potential utility in various settings. Its straightforward design and rapid turnaround time make it an ideal tool for thyroid-stimulating hormone (TSH) self-testing, empowering individuals to conduct preliminary thyroid function assessments either at home or in point-of-care environments. Such accessibility is particularly valuable for early detection of thyroid

disorders, facilitating timely intervention. However, it is crucial to emphasize that positive results from the rapid test should always be followed up with quantitative laboratory tests to confirm the diagnosis and guide clinical decision-making. This step ensures that individuals receive accurate assessments and appropriate treatment based on comprehensive medical evaluations.

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