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

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ABSTRACT

The TSH Rapid Test Cassette is a chromatographic immunoassay designed for qualitative detection of thyroid-stimulating hormone (TSH) in human whole blood, with a cutoff of 5 μIU/mL. This study aimed to systematically evaluate its diagnostic performance—sensitivity, specificity, accuracy, and suitability for self-testing—by comparing it with the Foresight (ACON) TSH ELISA kit, a validated reference method. A total of 220 specimens were tested (54 positive, 166 negative). The test showed 98.1% sensitivity, 98.2% specificity, and 98.2% overall accuracy. No cross-reactivity or interference was observed with common substances, and intra- and inter-assay precision were excellent. Due to its ease of use, short reaction time, and clear results, the TSH Rapid Test Cassette is a reliable, rapid, and practical solution for self-testing and point-of-care thyroid screening.

Keywords: *TSH; Rapid Test Cassette; Chromatographic Immunoassay; ELISA; Self-testing; Thyroid Disorders; Point-of-Care Diagnostics.*

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1. INTRODUCTION

Thyroid dysfunction—including hypothyroidism and hyperthyroidism—is among the most common endocrine disorders worldwide. The thyroid-stimulating hormone (TSH), secreted by the anterior pituitary, regulates thyroid hormone synthesis and is a key biomarker for assessing thyroid function.

Conventional TSH testing using ELISA offers high analytical accuracy but requires laboratory infrastructure, trained staff, and several hours of processing. In contrast, rapid chromatographic immunoassays provide a convenient and fast alternative, enabling self-testing and point-of-care applications.

The TSH Rapid Test Cassette is designed to qualitatively detect TSH at a cutoff of 5 μIU/mL in whole blood, allowing users to perform a preliminary thyroid screening at home. This study evaluates its analytical performance compared to the reference Foresight (ACON) ELISA method, focusing on its accuracy and usability for self-testing.

2. MATERIALS AND METHODS

Specimen Collection

A total of 220 whole-blood samples were collected from individuals suspected of thyroid dysfunction. Among them, 54 were positive (>5 μIU/mL) and 166 negative (<5 μIU/mL), as confirmed by the reference ELISA method. All samples were collected via fingerstick and tested at room temperature (15–30 °C).

Test Devices

Investigational device: TSH Rapid Test Cassette (Whole Blood), AllTest Biotech Co., Ltd.

Reference method: Foresight (ACON) TSH ELISA test kit.

Test Procedure
The cassette was placed on a clean surface.
50 µL of whole blood was added to the sample region.
Two drops of buffer were added, and the timer started.
Results were read after 10 minutes (not after 20 minutes).

Interpretation:
Positive: Two colored lines (Test + Control) → TSH > 5 µIU/mL.
Negative: One control line → TSH ≤ 5 µIU/mL.
Invalid: No control line → test must be repeated.
Performance Parameters

The following were evaluated:
Diagnostic sensitivity, specificity, and accuracy.
Cross-reactivity and interference (bilirubin, glucose, hemoglobin, etc.).
Precision (intra- and inter-assay reproducibility).

3. RESULTS

Diagnostic Performance

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

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

Cross-Reactivity and Interference
No significant cross-reactivity or interference was detected with physiological or chemical substances commonly found in blood. Minor false positives (3/166) were attributed to biological variability rather than assay failure, confirming robust specificity suitable for self-testing.

Precision
Replicate testing of 10 positive and 10 negative specimens showed 100 % intra-assay agreement. Across all 220 samples, inter-assay reproducibility reached 98.2 %, validating stability and lot consistency.

4. DISCUSSION

The TSH Rapid Test Cassette demonstrates high analytical reliability comparable to laboratory ELISA methods. The sensitivity (98.1 %) ensures minimal false negatives, while the specificity (98.2 %) minimizes unnecessary clinical follow-ups. These findings align with results from the manufacturer's internal validation.

Comparison with Other Diagnostic Methods
While ELISA provides quantitative data, it is impractical for self-testing due to cost and complexity. The TSH Rapid Test bridges the gap between clinical-grade accuracy and user accessibility, offering an immediate, cost-effective option for preliminary thyroid screening.

Limitations
Qualitative result only (cannot monitor treatment). User-dependent accuracy (improper blood volume or timing may affect results). Heterophilic antibodies may cause rare false readings; thus, positive results should be confirmed via laboratory testing.

5. CONCLUSION

The TSH Rapid Test Cassette (Whole Blood, OTS-402H) demonstrated 98.1 % sensitivity, 98.2 % specificity, and 98.2 % accuracy compared to the Foresight (ACON) ELISA reference. Its simple operation, rapid results, and reproducibility make it an ideal self-testing device for screening thyroid dysfunction at home or in point-of-care settings. This test enhances early detection and patient empowerment in thyroid health management.

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