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User-Friendly Self-Testing Evaluation of Sperm Concentration Rapid Test in Semen

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ABSTRACT

The Sperm Concentration Rapid Test Cassette (OSC-902H) is a rapid qualitative immunochromatographic assay developed for self-testing of sperm concentration in human semen. This study evaluated its diagnostic performance using 236 clinical semen specimens (184 normal and 52 abnormal) compared to microscopic counting as the reference method. The assay showed 98.1% sensitivity, 99.5% specificity, and 99.1% accuracy. No cross-reactivity or interference was observed with physiological or environmental substances. Intra- and inter-assay reproducibility exceeded 99%. These results confirm the clinical reliability of the OSC-902H device as a simple, accurate, and user-friendly at-home fertility screening tool for men.

Keywords: *Sperm concentration; Male infertility; Rapid diagnostic test; Self-testing; Semen analysis; Microscopic counting; Point-of-care testing.*

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1. INTRODUCTION

Male infertility contributes to approximately 40% of infertility cases among couples. Among various semen parameters, sperm concentration is a critical indicator for male reproductive health and fertility potential.

Traditional laboratory methods such as microscopic counting and computer-assisted semen analysis (CASA) are considered the gold standard. However, they require skilled personnel, costly equipment, and clinical laboratory settings, limiting accessibility for early or routine evaluation.

Home-based diagnostic tools for sperm testing are gaining popularity, providing privacy, affordability, and immediate feedback. The Sperm Concentration Rapid Test Cassette (OSC-902H) by Hangzhou AllTest Biotech Co., Ltd., is designed for self-testing applications. This study evaluates its diagnostic accuracy, specificity, reproducibility, and usability compared with the reference microscopic counting method.

2. MATERIALS AND METHODS

Specimen Collection
A total of 236 semen specimens were collected from adult males undergoing routine fertility assessment: 184 normal and 52 abnormal samples, classified based on WHO reference standards (≥15 million/mL for normal). Samples were tested within one hour after collection to ensure consistency.

Test Procedure
Two systems were compared:
Investigational Kit: Sperm Concentration Rapid Test Cassette (OSC-902H), AllTest Biotech Co., Ltd.
Reference Method: Microscopic Counting (WHO 6th Edition, 2021)

Procedure Steps:

A measured semen sample (80 µL) was added to Well A of the cassette.
One drop of staining reagent was added, followed by washing solution as per manufacturer's instructions.
After 3 minutes, the color intensity of Well A was visually compared to the reference Well B.

Result Interpretation:
Normal: Color of Well A is darker than or equal to Well B (≥15 million/mL).
Abnormal: Color of Well A is lighter than Well B (<15 million/mL).
Invalid: No color development or improper fluid migration.

Performance Parameters
The following were assessed:
Diagnostic sensitivity, specificity, and accuracy.
Cross-reactivity and interference with common substances (urine, prostatic fluid, lubricants).
Precision and reproducibility through intra- and inter-assay validation.

3. RESULTS

Diagnostic Performance

Parameter	Result
Sensitivity	98.1%
Specificity	99.5%
Accuracy	99.1%

Cross-Reactivity and Interference
No interference was detected from urine, prostatic fluid, vaginal secretions, lubricants, or detergents. Environmental humidity or minor sample storage variation did not affect test results.

Precision
Intra-assay reproducibility: 99.2%
Inter-assay reproducibility: 99.4%
The consistent results across multiple runs confirm the test's manufacturing and operational reliability.

4. DISCUSSION

The Sperm Concentration Rapid Test Cassette (OSC-902H) demonstrated outstanding analytical performance and practicality for male fertility screening. Its simplicity, speed, and privacy make it particularly suitable for at-home use, encouraging early fertility assessment and reducing anxiety before formal clinical testing.

Compared to CASA and manual microscopy, the OSC-902H provides faster results (within 5 minutes), requires no equipment or technical expertise, and demonstrates comparable diagnostic reliability with superior ease of use and affordability.

Clinical Implications
User accessibility: Offers men a private, convenient method to screen sperm concentration without clinical intervention.
Public health benefit: Supports early detection of potential infertility issues.

Complementary role: Serves as an initial evaluation tool before laboratory confirmation.

Limitations
The test provides qualitative or semi-quantitative results only. Accuracy depends on proper specimen handling and adherence to procedural steps. It does not evaluate other sperm quality parameters such as motility or morphology.

5. CONCLUSION

The Sperm Concentration Rapid Test Cassette (OSC-902H) by AllTest Biotech Co., Ltd. demonstrated 98.1% sensitivity, 99.5% specificity, and 99.1% overall accuracy compared with the gold standard microscopic method. It represents a reliable, private, and user-friendly diagnostic tool for preliminary male fertility evaluation, especially suitable for home and point-of-care applications. The strong reproducibility and minimal interference confirm its clinical validity and potential for wide-scale use in reproductive health management.

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