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User-Friendly Self-Testing Evaluation of SP-10 Male Fertility Rapid Test (OSP-902H) in Semen

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ABSTRACT

The SP-10 Male Fertility Rapid Test Cassette (OSP-902H) is a chromatographic immunoassay for qualitative detection of acrosomal protein SP-10 in human semen. This study evaluated its diagnostic performance using 114 clinical semen specimens (62 normal and 52 abnormal) compared with a Computer-Assisted Semen Analysis (CASA) reference method. The test demonstrated 98.1% sensitivity, 98.3% specificity, and 98.2% overall accuracy. No cross-reactivity or interference was observed with common interfering substances or biological fluids. Both intra- and inter-assay reproducibility achieved 100% consistency. These results confirm the SP-10 assay as a rapid, reliable, and user-friendly diagnostic tool for self-testing of male fertility.

Keywords: *SP-10 protein; Male fertility; Sperm concentration; Rapid test cassette; Immunochromatographic assay; Point-of-care testing; Self-testing; Male infertility.*

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1. INTRODUCTION

Male infertility is a global health concern contributing to approximately 40% of infertility cases among couples. The detection of SP-10 (acrosomal protein 10), a sperm-specific antigen, plays an important role in assessing sperm presence and concentration in semen. SP-10 is expressed exclusively in the acrosomal region of mature spermatozoa, making it a highly specific biomarker for male fertility testing.

Traditional semen analysis, including microscopic counting and Computer-Assisted Semen Analysis (CASA), remains the gold standard. However, these methods require laboratory facilities, skilled operators, and significant time investment, making them unsuitable for rapid or home-based screening. Point-of-care testing (POCT) technologies—especially self-administered tests—offer accessible and confidential alternatives for early male fertility assessment.

This study aims to evaluate the diagnostic accuracy, reproducibility, and usability of the AllTest SP-10 Male Fertility Rapid Test Cassette (OSP-902H) compared to the CASA reference method.

1. MATERIALS AND METHODS

Specimen Collection

A total of 114 semen samples were collected from adult males undergoing fertility evaluation. Of these, 62 were classified as normal and 52 as abnormal according to WHO 6th Edition reference criteria (sperm concentration ≥15 million/mL considered normal). All samples were analyzed within one hour of collection to maintain biological integrity.

Test Procedure

Two systems were compared:

Investigational device: AllTest SP-10 Male Fertility Rapid Test Cassette (OSP-902H).

Reference method: CASA (Computer-Assisted Semen Analysis).

Procedure Steps:
80 µL of diluted semen specimen was added to the test's sample well.
The reaction was allowed to develop for 5 minutes at room temperature.

Results were interpreted visually:
Positive: Both control (C) and test (T) lines appear.
Negative: Only the control (C) line appears.
Invalid: No control (C) line visible.

Performance Evaluation
Performance was assessed for:
Diagnostic parameters (sensitivity, specificity, accuracy).
Cross-reactivity and interference with >20 substances (bilirubin, hemoglobin, prostatic fluid, urine, seminal vesicle fluid, water-based lubricant).
Precision and reproducibility under intra-assay and inter-assay conditions.

2. RESULTS

Diagnostic Performance

Parameter	Result
Sensitivity	98.1%
Specificity	98.3%
Accuracy	98.2%

Cross-Reactivity and Interference
No cross-reactivity was observed with over 20 tested substances, including bilirubin, hemoglobin, glucose, and non-sperm biological fluids. Interference studies confirmed robustness under realistic self-testing conditions.

Precision
Both intra-assay and inter-assay reproducibility achieved 100% agreement, confirming test consistency and manufacturing quality.

3. DISCUSSION

The SP-10 Male Fertility Rapid Test Cassette provides a rapid, accurate, and accessible method for assessing sperm concentration in semen. Its ease of use and non-invasiveness make it suitable for home-based or point-of-care fertility screening, reducing reliance on laboratory testing.

Compared to CASA and microscopic sperm counting, the SP-10 test delivers faster results (≤5 minutes), requires no specialized equipment or professional training, and offers high specificity due to monoclonal antibody targeting of SP-10 acrosomal protein.

Limitations
The test provides qualitative results only and depends on sample quality and procedural adherence. It evaluates only sperm concentration, not motility or morphology.

User Benefits
The SP-10 test democratizes male fertility assessment, offering privacy, convenience, and reliability. It facilitates early detection of infertility risks and encourages timely medical consultation.

4. CONCLUSION

The SP-10 Male Fertility Rapid Test Cassette (OSP-902H) demonstrated high diagnostic sensitivity (98.1%), specificity (98.3%), and accuracy (98.2%), with zero cross-reactivity and 100% reproducibility. Its strong correlation with CASA supports its use in both clinical and home-based fertility assessments. This assay represents an efficient, cost-effective, and user-friendly diagnostic tool for preliminary male fertility evaluation.

REFERENCES

1. Yang JH. Modern Diagnosis and Treatment of Male Infertility. Shanghai Science and Technology Literature Press, 2007.
2. Xiong CL. Human Sperm Science. Wuhan: Hubei Science and Technology Press, 2002.
3. World Health Organization. WHO Laboratory Manual for the Examination and Processing of Human Semen. 6th ed. Geneva: WHO Press, 2021.
4. Cooper TG, Noonan E, von Eckardstein S, et al. World Health Organization reference values for human semen characteristics. Hum Reprod Update, 2010; 16(3): 231–245.
5. Li Y, Zhang H, Wang L. Acrosomal protein SP-10 as a specific marker for human spermatozoa. Andrologia, 2005; 37(4): 145–150.