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INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GA 477-2004

Rapid test strips for human prostate specific antigen(PSA)

人前列腺特异性抗原(PSA)金标检验试剂条

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" drafting:

This document replaces GA 477-2004 "Human Prostate Specific Antigen (PSA) Gold Standard Test Reagent Strips", and is consistent with GA 477-2004 in addition to structural adjustments and editorial changes, the main technical changes are as follows:

---Changed the scope of application of the standard (see Chapter 1, Chapter 1 of the:2004 edition);

--- Changed the terms and definitions (see Chapter 3, Chapter 3 of the:2004 edition);

--- Deleted the classification of reagent strips (see Chapter 4 of the:2004 edition);

---Delete the plastic sampling straw in the plate-shaped packaging (see 5.1:5 of the:2004 edition);

---Change the potency and sensitivity (see 4.2, 5:2 of the:2004 edition);

--- Changed the specificity (see 4.3, 5:3 of the:2004 edition);

--- Changed the appearance characteristics (see 5.1, 7:1 of the:2004 edition);

--- Changed the material (see 5.2:1:3~5:2:1:4, 7:2:1:3~7:2:1:4 of the:2004 edition);

--- Changed the determination (see 5.2:2, 7:2:2 of the:2004 edition);

---Changed the result judgment in titer and sensitivity determination (see 5.2:3, 7:2:3 of the:2004 edition);

---Changed the result determination in the specificity determination (see 5.3:3, 7:3:3 of the:2004 edition);

---Changed the detection rules (see Chapter 6, Chapter 8 of the:2004 edition);

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--- Changed the flag (see 7.1, 6:1 of the:2004 edition);

--- Changed the packaging (see 7.2, 6:2 of the:2004 edition);

--- Changed the transportation (see 7.3, 6:3 of the:2004 edition);

--- Changed the storage (see 7.4, 6:4 of the:2004 edition):

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying patents:

1 Scope

This document specifies the terms, definitions and techniques of human prostate-specific antigen (PSA) gold standard test strips used in forensic physical evidence testing:

Requirements, test methods, inspection rules, marking, packaging, transportation and storage:

This document is applicable to the production, inspection and trade of human prostate-specific antigen (PSA) gold standard test strips:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references for documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document:

GB/T 2828.1-2012 Counting sampling inspection procedure Part 1: Batch-by-batch inspection sampling retrieved by acceptance quality limit (AQL) plan:

3 Terms and Definitions

The following terms and definitions apply to this document:

Test strips for confirmatory testing of human semen (spot) in biological samples:

4 Technical Requirements

4.1

Appearance

4.1.1

The human prostate-specific antigen (PSA) gold standard test strip (hereinafter referred to as the human PSA gold standard test strip) is straight and neat:

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4.1.2

The width of the human PSA gold standard test strip should not be less than 3mm:

4.2

Potency and sensitivity at room temperature, the potency of the human PSA gold standard test strip should reach 40,000 times within 10 minutes (that is, for the mixed human dose diluted 40,000 times):

positive in semen); or positive in a human PSA solution with a concentration greater than or equal to 100 ng/mL:

4.3

Specificity

At room temperature, within 30 minutes, it is 20 times, 100 times, 1000 times diluted for normal human serum, saliva, vaginal secretion extract and colostrum, etc:

Release solution showed no positive reaction:

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