

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K063864

B. Purpose for Submission:

Traditional 510(k) for a new indication for use of a previously cleared device.

C. Measurand:

Leukocytes (WBCs) and pH in semen

D. Type of Test:

Two-parameter test strip for determination of pH and non-quantitative measurement of leukocytes in semen.

E. Applicant:

Medical Electronic Systems, Ltd.

F. Proprietary and Established Names:

QwickCheck™ Test Strips-Reagent Strips for Semen Analysis

G. Regulatory Information:

1. Regulation section:

There are no regulations for semen analysis devices.

2. Classification:

Class II

3. Product code:

MNA

4. Panel:

85 (Ob/Gyn)

H. Intended Use:

1. Intended use(s):

QwickCheck Test Strips are for in vitro diagnostic use for the determination of pH and leukocytes (WBCs) in semen. Test results are determined by comparing the color of the test patches to the color chart provided on the bottle label. The test is for professional use only.

2. Indication(s) for use:

N/A

3. Special conditions for use statement(s):

N/A

4. Special instrument requirements:

N/A

I. Device Description:

The QwickCheck Test Strip is a two parameter test strip (dipstick) for the determination of pH and leukocytes (WBCs) in semen. Test results are determined by comparing the color of the test patches to the color chart provided on the bottle label.

J. Substantial Equivalence Information:

1. Predicate device name(s):

International Newtech Development Inc. Urinalysis Reagent Strips

2. Predicate 510(k) number(s):

K993850

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Material Composition on Reagent Pads	pH: methyl red and bromothymol blue Leukocytes: 3-indolyphenol ester and benzendiazonium salt	Same
Procedural Steps	<ul style="list-style-type: none"> • Fresh undiluted sample is used • Sample applied to test pads by dropper. • Read result at appropriate time intervals (1 min for pH, 2 min for WBCs; color of test patch is compared to color scale on bottle. 	Same
Shelf Life	18 months	Same
Storage Conditions	Room temperature (15-30° C). Keep away from direct sunlight and moisture.	Same

Differences		
Item	Device	Predicate
Matrix	Semen	Urine

K. Standard/Guidance Document Referenced (if applicable):

N/A

L. Test Principle:

For pH: Acid/base color reaction between two indicators (methyl red and bromothymol blue).

For Leukocytes: The color of the leukocyte reagent pad reacts to the presence of esterases found in granulocytes.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

A field study was designed to test the ability of typical lab and clinic users to accurately interpret the QwickCheck test strips for pH and WBCs based on the color reaction. The study was performed at three sites, one in-house at MES and two external sites with a minimum of three operators per site.

The data indicated that correct interpretations were achieved 100% of the time. The study included 132 pH results and 132 WBC results (12 samples x 11 testers). For pH, the exact level was recorded in 126/132 cases (95%), and there were six cases where the pH was interpreted as 0.5 units (one color block) higher than the assigned value: the protocol allowed a variance of plus/minus one color block. For WBCs, the correct interpretation was achieved in 132/132 cases (100%).

b. *Linearity/assay reportable range:*

N/A

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Shelf life is 18 months.

d. *Detection limit:*

N/A

e. *Analytical specificity:*

f. *Assay cut-off:*

N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

N/A

b. *Matrix comparison:*

N/A

3. Clinical studies:

a. *Clinical Sensitivity:*

N/A

b. *Clinical specificity:*

N/A

c. Other clinical supportive data (when a. and b. are not applicable):

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.