

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

A. 510(k) Number:

k033114

B. Purpose for Submission:

Premarket Notification 510(k) of intention to manufacture and market the Neo Diagnostics, Inc., KetoChecks for over the counter use.

C. Analyte:

Urinary Ketones

D. Type of Test:

Qualitative and semi-quantitative

E. Applicant:

Neo Diagnostics, Inc.

F. Proprietary and Established Names:

Neo Diagnostics, Inc. KetoChecks

G. Regulatory Information:

1. Regulation section: 21 CFR § 862.1435; 21 CFR 862.9 (c)(9)
2. Classification: Class I meets limitation of exemptions
3. Product Code: JIN
4. Panel: 75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

The Neo Diagnostics KetoChecks is intended for the identification of ketones in urine and can be used in the diagnosis of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as Acetoacetic acid) and for monitoring patients on ketogenic diets and patients with diabetes. The test is indicated for use by professionals and for Over the Counter use by lay people.

2. Indication(s) for use:

The Neo Diagnostics KetoChecks is intended for the identification of ketones in urine and can be used in the diagnosis of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by

increased production of ketone bodies such as Acetoacetic acid) and for monitoring patients on ketogenic diets and patients with diabetes. The test is indicated for use by professionals and for Over the Counter use by lay people.

3. Special condition for use statement(s):

This submission is for a professional and over-the-counter version of a cleared professional device for urine ketones. Professionals and consumers can perform the test using the midstream technique or the dip and read technique.

4. Special instrument Requirements: Not Applicable

I. Device Description:

The Neo Diagnostics, Inc. KetoChecks consists of a firm plastic strip to which a reagent area is affixed. Depending on the product being used, KetoChecks provides a test for Ketone (Acetoacetic acid) in urine. Test results may provide information regarding the status of carbohydrate metabolism.

KetoChecks is packaged along with a drying agent in a plastic bottle with a twist-off cap. Each strip is stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. The directions must be followed exactly. Results are obtained by direct comparison to the test strip with a color blocks printed on the bottle label. Accurate timing is essential to provide optimal results. To obtain optimal results, it is necessary to use fresh, well mixed, and un-centrifuged urine. No calculations or laboratory instruments are needed.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Ketostix reagent strips, Urine Dipstick or tablet analysis, non automated

2. Predicate K number(s): k801270

3. Comparison with predicate:

Strip Name Distributor	KetoChecks Neo Diagnostics, Inc.	Bayer Ketostix Bayer
Reagents for:		
Ketone (Acetoacetic acid)	Sodium nitroprusside	Sodium nitroprusside Buffer
Time required to Read strips	30 to 120 seconds	15 to 120 seconds
Storage	Between 10-30° C (50° F - 86° F). Do Not Store in refrigerator or freezer. Do Not expose direct heat, light or Moisture.	Between 10-30° C (50° F - 86° F). Do Not Store in refrigerator or freezer. Do Not Store in Direct Sunlight

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

NCCLS GP16 T

L. Test Principle:

This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink for a “Negative” reading to a pink and pink-purple for a “Positive” reading.

M. Performance Characteristics (if/when applicable):1. Analytical performance:*a. Precision/Reproducibility:*

The data demonstrated adequate reproducibility between masked operators and between different strip lots

b. Linearity/assay reportable range:

The data demonstrated a linear relationship between spiked-in values and the semi-quantitative reading for ketones.

c. Traceability (controls, calibrators, or method):

None Stated

d. Detection limit:

The sensitivity was determined by spiking in the different concentration of the Lithium Acetoacetate to determine the point that can identify or notice the color change on the strips. Sensitivity was demonstrated to the lowest reported block of 5 mg/mL.

e. Analytical specificity:

Color reaction that could be interpreted as false positive may be obtained with urine specimens containing MESNA or large amounts of phenylketones or L-dopa metabolites.

f. Assay cut-off:

Not Applicable

2. Comparison studies:*a. Method comparison with predicate device:*

In this submission the sponsor demonstrated that untrained consumers, after reading the proposed package insert could use the test correctly and achieve results comparable to trained professional users. Clinical studies were conducted at 5 different sites. (Site 1 Neo Diagnostics on site = 90 samples, Site 2 = 96 samples, Site 3 = 44 samples, Site 4 = 43 samples, and Site 5 = 43 samples). The volunteers were given the package insert to read and then requested to perform the test on specified control solutions that spanned a range from (0 to 160 mg/dl) ketone concentration, using both the Neo Diagnostics KetoChecks and the

predicate Bayer Ketostix, comparing the reagent areas to corresponding color charts.

The qualitative comparison of % agreement for each of the 5 sites is listed below:

Site 1 = 97.8% (in-house data)

Site 2 = 97.9%

Site 3 = 97.9%

Site 4 = 95.4%

Site 5 = 97.7%

In a separate study, samples were tested with the proposed device and compared with Bayer using one lot. In addition, two lots of the proposed device were compared with each other. The following results were obtained:

KetoChecks Lot1 versus Bayer Ketostix Lot 3A04A

	Same Color Block		Within 1 Color Block	
Evaluation One-Lot 1	212/218	97.2%	217/218	99.5%
Evaluation Bayer	254/254	100/0%	254/254	100.00%

KetoChecks Lot 1 versus KetoChecks Lot 2

	Same Color Block		Within 1 Color Block	
Evaluation One-Lot 1 vs Lot 2	134/138	97.1%	137/138	99.3%

b. Matrix comparison:
Not Applicable

3. Clinical studies:

a. Clinical sensitivity:
Not Applicable

b. Clinical specificity:
Not Applicable

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

4. Clinical cut-off:
Not Applicable

5. Expected values/Reference range:

Normally, no ketones are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate situations, ketones appear in the urine in excessively large amounts before serum ketones are elevated.

N. Conclusion:

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