

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

A. 510(k) Number:

k042641

B. Purpose for Submission:

New test strip for urinalysis

C. Measurand:

Glucose

Blood

Note: other analytes on the test strip (urobilinogen, ketones, bilirubin, protein, nitrite, pH, specific gravity, leukocytes) are Class I exempt and therefore not reviewed.

D. Type of Test:

Qualitative colorimetric test

E. Applicant:

Cenogenics Corporation

F. Proprietary and Established Names:

CHEMVIEW-10

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1340 Urinary glucose (nonquantitative) test system

21 CFR §864.6550 Reagent, Occult Blood

2. Classification:

Class II (glucose and blood)

3. Product code:

JIL

KHE

4. Panel:

Chemistry (75)

Hematology (81)

H. Intended Use:

1. Intended use(s):

See below.

2. Indication(s) for use:

“CHEMVIEW-10 is a visual qualitative and semi-quantitative test for the determination of urobilinogen, glucose, ketones, bilirubin, protein, nitrite, pH, blood, specific gravity, and leukocytes in urine.

The product will be marketed to physicians’ office laboratories, clinics, hospitals, and reference laboratories.”

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

None required; this is a single-use visually read device.

I. Device Description:

The device is a reagent test strip for urinalysis. It consists of 100 individual strips packed in a desiccated plastic vial with a full-color chart for reading test results on the label, and product instructions. Each individual strip has 10 different solid-phase reagent areas.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Chemstrip 10 with SG

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

k896454

3. Comparison with predicate:

Both devices are visual qualitative tests, measure the same analytes, have the same or very similar detection ranges, and use the same test principles. The tests have different manufacturers.

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

None referenced by the submission.

L. Test Principle:

Solid-phase qualitative colorimetric enzymatic reactions are used by each test.

Glucose: Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Peroxidase then catalyzes the reaction of hydrogen peroxide with potassium iodide chromogen to form colors ranging from blue to dark brown depending on the glucose concentration.

Blood: The pseudoperoxidase activity of hemoglobin catalyzes the reaction of o-tolidine and cumene hydroperoxide to form colors ranging from sky blue to dark blue depending in the amount of blood in the urine.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Only glucose and occult blood, as Class II analytes, are subject to performance characteristic review.

a. *Precision/Reproducibility:*

Glucose: Reproducibility of glucose results was tested with standard solutions of glucose prepared in urine negative for glucose. Each solution was tested with 10 CHEMVIEW strips from three different lots:

Glucose Reproducibility Testing with the CHEMVIEW-10

	Glucose Concentration				
	0 mg/dL	100 mg/dL	250 mg/dL	500 mg/dL	1000 mg/dL
Expected Result	-	+/-	+	++	+++
Lot 1	10/10*	10/10	10/10	10/10	10/10
Lot 2	10/10	10/10	10/10	10/10	10/10
Lot 3	10/10	10/10	10/10	10/10	10/10

* Number of strips with expected results

Occult Blood: Reproducibility of occult blood results was tested with standard solutions of glucose prepared in urine negative for glucose. Each solution was tested with 10 CHEMVIEW strips from three different lots:

Occult Blood Reproducibility Testing with the CHEMVIEW-10

	Hemoglobin Concentration					
	0 mg/dL	0.015 mg/dL	0.03 mg/dL	0.06 mg/dL	0.15 mg/dL	0.75 mg/dL
Expected Result	-	+/-	+/-	+	++	+++
Lot 1	10/10*	10/10	10/10	10/10	10/10	10/10
Lot 2	10/10	10/10	10/10	10/10	10/10	10/10
Lot 3	10/10	10/10	10/10	10/10	10/10	10/10

* Number of strips with expected results

b. *Linearity/assay reportable range:*

Not applicable.

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

No traceability was provided.

Unopened shelf life of the strips is 2 years from the date of manufacture; opened, the strips are stable for 6 months. Real-time studies established these parameters.

Calibration of the CHEMVIEW-10 by the user is not required.

d. *Detection limit:*

Glucose:

Standard solutions of glucose were prepared in urine negative for glucose at concentrations of 100 mg/dL, 250 mg/dL, 500 mg/dL, and 1000 mg/dL. Each solution and negative urine was tested with ten strips. The expected results were obtained 10/10 times at all concentrations tested, demonstrating a glucose sensitivity of 100 mg/dL.

Occult Blood:

Standard solutions of hemoglobin were prepared in urine negative for occult blood at concentrations of 0.015 mg/dL, 0.03 mg/dL, 0.06 mg/dL, 0.15 mg/dL, and 0.75 mg/dL. Each solution and negative urine was tested with ten strips. The expected results were obtained 10/10 times at all concentrations tested, demonstrating occult blood sensitivity of 0.015 mg/dL

Red blood cell suspensions were prepared in normal urine at concentrations of 5 cells/ul, 10 cells/ul, 20 cells/ul, 50 cells/ul, and 250 cells/ul. Cell count was confirmed by microscopic examination. Each suspension and a negative urine sample were tested with ten strips. Expected results (10/10 samples) were obtained at all concentrations except 5 cells/ul, where 3/10 samples were positive. Thus, the data demonstrates that the CHEMVIEW-10 occult blood test can detect 10 intact red blood cells per microliter of urine.

e. *Analytical specificity:*

Glucose: Specificity of the test for glucose was challenged by testing the strip with solutions of lactose, fructose, and galactose prepared in normal urine. Ten strips were tested at five concentrations up to 1000 mg/dL; no positive results were observed.

Interfering substances were tested by preparing glucose solutions in normal urine then adding different concentrations of ascorbic acid, acetoacetic acid (for ketone bodies). Each combination was tested with 10 CHEMVIEW-10 test strips. Ascorbic acid concentrations of 60 mg/dL or greater, and ketone bodies in concentrations greater than 80 mg/dL may cause false negatives in urine samples containing a small amount of glucose. At high pH (pH 9) the color reaction on the strip was slower to develop and the reactivity was decreased. Specific gravity, tested between 1.005 and 1.030, did not affect the glucose test.

Occult Blood: Solutions of myoglobin were prepared in normal urine at six concentrations up to 0.75 mg/dL. Each solution was tested ten times; the expected result was seen in all tests, indicating that the CHEMVIEW-10 occult blood test is as sensitive to myoglobin as to hemoglobin.

Substances that were tested for interference with the occult blood test were:

bacteria, ascorbic acid, protein, hypochlorites, and specific gravity. Ten strips were used at each test point; standard hemoglobin solutions were prepared in normal urine. Nitrite-positive bacterially contaminated urine specimens may produce a false positive. Increasing concentrations of ascorbic acid decreases the reactivity of the occult blood test, particularly at lower hemoglobin concentrations. Increasing concentrations of protein reduced the reactivity of the occult blood test. Testing hypochlorites showed that even trace amounts of strong oxidizing agents may produce a false positive occult blood test result. Sensitivity of the occult blood test may be reduced in specimens with low specific gravity.

- f. Assay cut-off:*
Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Clinical urine samples (n=142) were compared to the predicate at three different clinical laboratories. An additional 23 spiked samples were tested at two of these laboratories (n= 46) for a total of 188 samples. The methods described in the package inserts were followed.

Glucose:

Agreement between the two strips was 99.5% within the same color block and 100% within one color block.

Occult Blood:

Agreement between the tests was 86.7% within the same color block and 97.3% within one color block. Interpretation of the agreement between the tests is challenging because the scale of the two tests does not exactly correspond. Only three of 188 samples were markedly discrepant. The other discrepant results varied by one color block, usually as a difference between 'trace' and negative

b. Matrix comparison:

Not applicable; this device is only used with urine.

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):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The following should not be detectable in the urine of healthy persons with this test: glucose, blood, ketones, bilirubin, nitrite, and leukocytes.

Protein: Normal urine may contain a small amount of protein; consistently elevated levels of protein indicate further clinical testing.

pH: Normal urine is usually slightly acidic, with a pH around 6.

Specific gravity: Normal specific gravity in adults ranges from 1.002 – 1.030 depending on fluid intake and state of hydration.

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.