

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

A. 510(k) Number:

k081908

B. Purpose for Submission:

New Device

C. Measurand:

Multiple constituents in urine (Glucose, Bilirubin, Ketones, specific gravity, blood, pH, protein, Urobilinogen, Nitrite, leukocytes, hCG, Microalbumin, Creatinine, Galactose, red blood cells, white blood cells, and crystals)

D. Type of Test:

Not applicable

E. Applicant:

CLINIQA Corporation

F. Proprietary and Established Names:

CLINIQA[®] Liquid QC[™] Urinalysis Controls, Levels 1 and 2

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1660 Quality control material (assayed and unassayed)
2. Classification:
Class I (reserved)
3. Product code:
JJW, Urinalysis Controls (Assayed and Unassayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
CLINIQA[®] Liquid QC[™] DipScopics Urinalysis Control is intended for use as an assayed quality control material for various urinalysis reagent strips, qualitative hCG methods as well as confirmatory tests such as Acetest[®], Clinitest[®], and Ictotest[®]. This control is also intended to evaluate microscopic examination test procedures.
2. Indication(s) for use:
See Intended Use section above

3. Special conditions for use statement(s):

For *In Vitro* Diagnostic Use
For Prescription Use Only

4. Special instrument requirements:

The instruments are listed in the product insert.

I. Device Description:

CLINIQA[®] Liquid QC[™] Urinalysis Controls, Levels 1 and 2 are prepared by blending together various salts, stabilizers, preservatives, buffers, plant based materials, human based materials and purified human proteins with a human urine base to achieve the desired manufacturing targets for Glucose, Bilirubin, Ketones, specific gravity, blood, pH, protein, Urobilinogen, Nitrite, leukocytes, hCG, Microalbumin, Creatinine, Galactose, red blood cells, white blood cells, and crystals. The controls are provided in ready-to-use liquid form.

Each human donor unit used to manufacture this product was tested for Hepatitis B Surface Antigen (HBsAg), HIV-1 antigen, antibody to Hepatitis C Virus (HCV), and antibody to HIV-1/2 and found non-reactive using FDA accepted test methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Quantimetrix Urine Dipstick Control; Quantimetrix Urinalysis Microscopics Control

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

k874890; k925256

3. Comparison with predicate:

All are human urine based products containing analytes at clinically relevant concentrations. The difference between the predicate devices and the CLINIQA device is the constituents and their target concentrations.

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

No standards were referenced

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not Applicable

b. *Linearity/assay reportable range:*

Not Applicable

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Traceability: Traceability was not provided.
Stability: Closed vial stability: the Arrhenius model of accelerated elevated temperature studies was used to support CLINIQA[®] Liquid QC[™] Urinalysis Controls, Levels 1 and 2 storage stability at 2-8 °C. The controls are stable for 1.5 years when stored unopened at 2-8 °C. CLINIQA[®] Liquid QC[™] Urinalysis Controls, Levels 1 and 2 have been on real time stability for over 10 months to support the closed-vial stability claim at 2-8 °C.
Open vial stability: the Arrhenius model of accelerated elevated temperature studies was used to support CLINIQA[®] Liquid QC[™] Urinalysis Controls, Levels 1 and 2 storage stability at 2-8 °C. The controls are stable for 90 days when stored tightly capped at 2-8 °C or 30 days when stored at 20-25 °C. CLINIQA[®] Liquid QC[™] Urinalysis Controls, Levels 1 and 2 have been on real time stability for 40 days to support the open-vial stability claim at 2-8 °C.

Expected values: The expected values printed on the CLINIQA[®] Liquid QC[™] Urinalysis Controls, Levels 1 and 2 product insert will be specific to that lot. The values will be obtained from replicate assays derived by multiple laboratories using the test methodologies listed in the product insert. Multiple data points will be used to determine the mean (expected) value. Assignment of values will be performed using the reagents, calibrators, and controls available at the time of assay by the instrument manufacturer.

- d. *Detection limit:*
Not Applicable
- e. *Analytical specificity:*
Not Applicable
- f. *Assay cut-off:*
Not Applicable
2. Comparison studies:
a. *Method comparison with predicate device:*
Not Applicable
- 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):*
Not Applicable
- 4. Clinical cut-off:
Not Applicable
- 5. Expected values/Reference range:
Not Applicable

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.