CLIA Waiver by Application Approval Determination

Decision Summary

A. Document Number

CW240007

B. Parent Document Number

K150330

C. CLIA Waiver Type:

CLIA Waiver by Application

D. Applicant

ACON Laboratories, Inc.

E. Proprietary and Established Names

Mission U120 Touch Urine Test System

F. Measurand (analyte)

Urine Creatinine and Microalbumin

G. Sample Type(s)

Urine

H. Type of Test

Semi-quantitative, strip-based detection of microalbumin and creatinine

I. Test System Description

1. Overview

The Mission U120 Touch Urine Test System consists of the Mission® U120 Touch Urine Analyzer and the Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine). The test system was cleared under K150330 and CLIA waived under CW160010. The current submission is for a device modification that includes the addition of a touch screen user interface. Modifications to the labeling include updates to the applicable sections in the user manual, instructing operators to use the touch screen.

To support that the modified device is simple and has an insignificant risk of an erroneous result, the sponsor performed a risk assessment, flex studies and user studies.

2. Test System Components

The Mission U120 Touch Urine Test System consists of the Mission® U120 Touch Urine Analyzer and the Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine).

The Mission® Urinalysis Reagent Strips are plastic strips with color blocks that can semi-quantitatively measure microalbumin and creatinine simultaneously using chemical reactions. The Albumin-to-Creatinine Ratio (A:C) results are based on the color changes obtained on the measurement of microalbumin and creatinine.

The Mission® U120 Touch Urine Analyzer is a semi-quantitative urine analyzer used to determine the amounts of components in urine including albumin, creatinine and ACR (albumin creatinine ratio), display the results on the screen and print the results.

The results of the Mission® U120 Touch Urine Test System are:

- Microalbumin (ALB): 10 mg/L, 30 mg/L, 80 mg/L, 150 mg/L;
- Creatinine (CRE): 10 mg/dL, 50 mg/dL, 100 mg/dL, 200 mg/dL, 300 mg/dL and
- Albumin-to-Creatinine Ratio (A:C): <30 mg/g (Normal), 30-300 mg/g (Abnormal), >300 mg/g (High Abnormal).

J. Demonstrating "Simple"

The sponsor provided information in the form of flex studies and user studies to demonstrate that the modifications did not impact the simplicity of the device.

K. Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-safe Mechanisms

1. Risk Analysis

A risk assessment was performed as part of the design change to identify and evaluate hazards related to the modifications of the Mission U120 Touch Urine Test System. The new risks introduced with the addition of a touch screen interface were evaluated, and all new risks were mitigated to an acceptable level and supported by flex studies and user studies.

2. Flex Studies

Based on the modifications and risk assessment, four flex studies (i.e., (1) evaluating the test system when it is exposed to direct sunlight and (2) to excessive direct light, (3) evaluating the incorrect placement of the test system (tilting) and (4) vibration test) were repeated on the modified test system. The results of the flex studies showed that the modifications did not impact the test system.

L. Demonstrating "Insignificant Risk of an Erroneous Result"- User Study

Usability studies were conducted using the modified test system by CLIA waived users. The operators were given the analyzer, reagent strips, liquid urine controls, blind-labeled urine specimens, user manual and the quick reference guide in order to perform sample testing and quality control testing. No other materials or instructions were provided, and the operators received no additional training to perform the test. Upon completion, each operator completed a questionnaire to evaluate the ease of using the modified device. The participants were able to successfully perform the test, received accurate results, successfully completed the quality control testing and found the Mission U120 Touch Urine Test System easy to use and the user manual and the quick reference guide easy to follow.

M. Labeling for Waived Devices

The labeling consists of:

1. Mission® U120 Touch Urine Analyzer user manual
2. Mission® U120 Touch Urine Analyzer & Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) Quick Start Guide
3. Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) package insert

The following elements are appropriately presented:

- The User’s Manual, Quick Start Guide, and package insert identify the test as CLIA waived.
- The User’s Manual, Quick Start Guide, and package insert contain a statement that a Certificate of Waiver is required to perform the test in a waived setting.
- The User’s Manual, Quick Reference Guide, and package insert contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test as required per 42 USC263a(c)(2).
- The User’s Manual, Quick Start Guide, and package insert provide instructions for conducting quality control procedures.
- The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

N. Conclusion:

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.