

Introduction

The HemoCue® Albumin 201 system is classified as Waived under the CLIA guidelines and can be used by all laboratories holding a certificate of waiver. If the laboratory modifies the HemoCue Albumin 201 test procedure, the test no longer meets the requirements for waived categorization. A modified test is considered to be highly complex and is subject to all applicable CLIA requirements.

The HemoCue Albumin 201 system consists of the HemoCue Albumin 201 Analyzer and the HemoCue Urine Albumin Microcuvettes. The system provides rapid, simple and reliable quantitative determination of albumin in urine with accuracy and precision.

Note! The complete test procedure including Quality Control recommendations should be read before performing the test.

This guide is to be used as a reference. For complete instructions and expected values, please refer to the HemoCue Albumin 201 system Operating Manual and the package insert for HemoCue Urine Albumin Microcuvettes or contact HemoCue, Inc. Technical Support: 800-426-7256. Please note that the system is only to be used for the analysis of albumin in human urine.

System components

HemoCue Albumin 201 Analyzer



HemoCue Urine Albumin Microcuvettes



The HemoCue Albumin 201 Analyzer is delivered together with:

- Operating Manual
- Quick Reference Guide
- Power Adapter

Frequently Asked Questions

How do I get a CLIA Certificate of Waiver?

To obtain a Certificate of Waiver, call your state department of health for an application and refer to the Centers for Medicare and Medicaid Services CLIA program.

How should I store my cuvettes?

Store the HemoCue Urine Albumin Microcuvettes in their package in a refrigerator, at 35 - 46 °F. Do not store the cuvettes in the freezer. The cuvettes are stable until the expiration date printed on each container as well as on each individual package. Do not use a cuvette past the expiration date.

Specimen collection and preparation

The first morning urine specimen after rest is recommended since muscle activity influences the excretion of albumin in urine. Spot samples during the day may be used, but higher results can be expected.

- The system is designed for testing at the point-of care using fresh urine, preferably within 1-2 hours from collection. Frozen specimen should not be used.
- The turbidity scale in the operating manual can be used to detect the grade of turbidity. Cloudy samples should not be analyzed.

The concentration of albumin in spot urine samples, even if collected as the first-morning urine, are subject to variability from the degree of dilution or concentration of the urine because of variability in hydration. For additional information, please refer to the package insert for the HemoCue Urine Albumin Microcuvettes.

HemoCue and our distributors will provide our customer with technical support.

Contact us at:
HemoCue, Inc.
40 Empire Drive
Lake Forest, CA 92630
Phone (General): 800-881-1611
Orders: 800-323-1674
Technical Support: 800-426-7256
Fax (Cust. Service): 800-333-7034
www.hemocue.com



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HemoCue® Albumin 201 QUICK REFERENCE GUIDE



Setup

Take the time to examine and familiarize yourself with the contents of the HemoCue Albumin 201 system.

1 The analyzer



Make sure that the analyzer lid is closed. Press and hold the left button until the display is activated. The display shows the version number and an internal quality control, the "self test" is performed. Three flashing dashes are displayed when the analyzer is ready for use.

2 Cuvettes*



Take out only as many cuvettes from the package as you need for immediate use. Keep unused cuvettes in the original package in the refrigerator.

3 Quality Control (QC)*

- The system should be verified by measuring a commercially available urine albumin control on days of testing, for each new shipment of cuvettes and new lots. HemoCue recommends the control material EuroTrol AlbuTrol. If the control result is out of range, please refer to the Operating Manual for corrective action. Do not run patient samples unless the QC results are in the expected range. Contact HemoCue Inc, Technical Support, if the problem persists. Results for QC testing should be documented in the laboratory records.
- Every time the analyzer is turned on it will automatically perform an internal QC, the "self test". The self test verifies the performance of the optical unit of the analyzer.

Erroneous handling of the system

Please note that erroneous readings may occur if the system is not handled according to manufacturer's recommendations. In such cases error codes may not be displayed. For further information read the Troubleshooting Guide in the Operating Manual.

- *For information and order
- HemoCue Urine Albumin Microcuvettes
 - EuroTrol AlbuTrol
- contact HemoCue, Inc. (order).

Test procedure

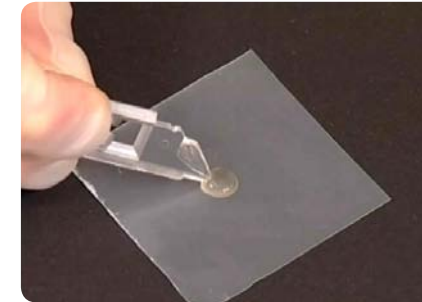
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1 Pipette a drop



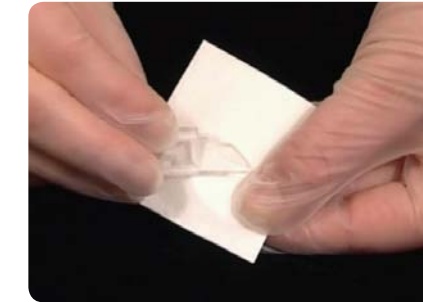
Pipette a drop of urine onto a laboratory plastic film, such as Parafilm. Use fresh urine specimens and avoid cloudy samples.

2 Fill the cuvette



- Open the single packaged cuvette.
- Hold the cuvette by the rectangular end as shown in the photo and bring it into contact with the urine sample. Allow the cavity of the cuvette to fill completely in one step. Do not refill the cuvette.
- The cuvette cannot be overfilled. If too little specimen is added, discard and repeat with a new cuvette.

3 Wipe off the cuvette



When completely filled, carefully wipe off the excess urine from the outside of the cuvette with a clean lint free wipe. Visually inspect that no sample is drawn out of the cuvette during this procedure.


4 Insert the cuvette in the analyzer



Open the lid and place the filled cuvette into the cuvette holder, it is important that the cuvette "snaps" properly into the cuvette holder. The filled cuvette must be measured within 30 seconds of filling.

5 Close the lid



Gently close the lid. The display shows and three fixed dashes. 

6 Record the result



Within 90 seconds, the result is displayed in mg/L. Record the result. The result will remain on the display until the lid is opened. If the display shows:

- LLL, the result is below 7 mg/L
- HHH, the result is above 150 mg/L
- Exx, an error has occurred

See the Troubleshooting Guide and the Maintenance section in the Operating Manual for additional information.

7 Discard the cuvette



Open the lid and discard the used cuvette. Close the lid. When the display shows the HemoCue symbol and three flashing dashes, the analyzer is ready for a new measurement. When the measurements for the day have been completed, switch off the analyzer with the ON/OFF button.

8 Maintenance

The cuvette holder should be cleaned after each day of use. The cover glasses of the optical unit should be cleaned when directed to do so in the Troubleshooting Guide. Please refer to the Operating Manual.