

**Indiana WIC Program  
Indiana State Department of Health**

**CLIA Waiver**

**Policy**

WIC clinics must be in compliance with Clinical Laboratory Improvement Amendment (CLIA) standards in order to perform client hemoglobin testing. The local agency (LA) must have a valid CLIA waived certificate encompassing all WIC clinics performing Hemocue Hb201+ hemoglobin testing and must submit to CLIA review upon request.

**Authority**

42 CFR 493.15(b)(2) & (c)(1)(iii) Laboratories performing waived tests;  
*Criteria; Certificate of waiver tests.*  
HemoCue Operating Manual; HB 201+

**Procedure**

- I. Temperature and cleaning/disinfectant logs must be maintained in each testing area to ensure optimal operation of testing equipment and accurate and reliable test results.
- II. Temperature Requirements
  - A. The HemoCue Hb 201+ analyzer and microcuvettes must be stored at the temperature required by the manufacturer. Operating temperature is 59-86°F.
    1. The individually packaged microcuvettes are to be stored at room temperature (59-86°F).
    2. The HemoCue Hb 201+ analyzer can be stored at 32-122°F.
  - B. The LA is responsible for having an accurate, easy to read thermometer posted in each testing and microcuvette storage area. Thermometer reliability may be tested using an ice bath solution and obtaining a reading of 32°F +/- 2°F.
- III. Use the WIC Temperature, Cleaning and Control Log for Hemoglobin Testing Area to record daily temperature readings and cleaning and disinfection. Indicate on the log, days the clinic is closed. (See log sheet for instructions on completing the form.)
- IV. File completed logs in the WIC Temperature, Cleaning and Control Log for Hemoglobin Testing Areas file.