

What's so special about this red glucose meter?

**For starters, it's not a meter.**



## The HemoCue® Glucose 201 System: A Dedicated, CLIA-waived Glucose Device Cleared for Aiding in the Diagnosis of Diabetes

The HemoCue® Glucose 201 System is an analyzer, not a meter. Providing results closely correlated with a reference lab method, it is cleared for supplementing the clinical evidence in the diagnosing of diabetes. The HemoCue Glucose® 201 System is for professional use only, and provides lab-quality results for in-office testing needs.

### HemoCue® Glucose 201 System:

- Lab-quality results cleared for aiding in diagnosis
- Can be used on patients at-risk for diabetes\*
- Connectivity options

\* [https://care.diabetesjournals.org/content/42/Supplement\\_1/S13](https://care.diabetesjournals.org/content/42/Supplement_1/S13)



# Not All Finger Stick Glucose Tests Are the Same

Get lab-quality results and remain compliant with CLIA regulations with the HemoCue® Glucose 201 System

If you operate under a CLIA-waived license, the rules for lab tests all center on one main premise: follow the manufacturers' instructions for use. However, clinicians may be unaware of many glucose strip meters being cleared only for use on known diabetics. The HemoCue® Glucose 201 System can be used to aid in diagnosing, as well as testing patients at-risk for diabetes.\*

510(k) Number: K020935

Device Name: HemoCue® Glucose 201 System

#### Indication For Use:

The quantitative determination of the instant blood glucose concentration in circulation supplements the clinical evidence in the diagnosis and treatment of patients with diabetes as well as monitoring of neonatal blood glucose levels... For professional use only.<sup>1</sup>

#### Indication for Use

510(k) Number (if known): K092602

Device Name: FreeStyle Lite Blood Glucose Monitoring System

#### Indication For Use:

The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm; and venous blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates or arterial blood.<sup>1</sup>

510(k) Number: K142089

Device Name: ACCU-CHEK Aviva Expert

#### Indication For Use:

The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes. The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended to be used by a single person and should not be shared. The ACCU-CHEK Aviva Expert blood glucose monitoring system should not be used for the diagnosis or screening of diabetes or for neonatal use.<sup>1</sup>

Contact Your HemoCue Representative to Bring  
Professional Glucose Testing to Your Practice

## Get the HemoCue® Glucose 201 System

\*[https://care.diabetesjournals.org/content/42/Supplement\\_1/S13](https://care.diabetesjournals.org/content/42/Supplement_1/S13)

<sup>1</sup> <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>