



Technical Bulletin

North Carolina State Laboratory of Public Health | Laboratory Improvement Unit

Testing at a Glance: Waived Glucose

Blood Glucose Testing

The purpose of determining the level of glucose in blood is, most commonly, for either diagnosing or for monitoring known diabetic patients. A screening or diagnostic glucose level may indicate that a patient is diabetic, at risk for diabetes or has gestational diabetes during pregnancy. The best time to test a blood sample for glucose for these diagnostic purposes is after fasting (nothing to eat or drink, except water) for at least 8 hours. It is important to know the patient's fasting status when testing is performed in order to properly interpret blood glucose results.

Diabetic patients may need to know their blood glucose level at several different times during the day to adjust their dietary intake or the amount of insulin necessary to maintain a desirable blood glucose level as determined by a health care professional. This is known as glucose monitoring and is performed with a glucometer (meter) which is a testing device approved by the FDA for this purpose.

Waived Methodology

The Clinical Laboratory Improvement Amendments (CLIA) Final Rule 1993 defined waived tests/systems as those that "(1) are cleared by the FDA for home use, (2) ... are so simple and accurate as to render the likelihood of erroneous results negligible or (3) pose no reasonable risk of harm to the patient if the test is performed incorrectly." Blood glucose by monitoring devices was included by CLIA on the list of the first 9 tests classified as waived by the FDA. In 1995, the first analyzer was classified as waived for glucose testing without the description of a monitoring device included. Since then only five additional analyzers have been classified as waived for glucose testing *without* being a monitoring device. In contrast, hundreds of glucose monitoring devices have received a waived classification since 1993.

It is important to use the testing device that corresponds to the type of testing being performed. A glucometer cannot be used for diagnostic testing, because it is not approved by the FDA for that purpose.

The five analyzers classified by the FDA as waived without being described as a monitoring device are:

1. HemoCue® B-Glucose System (1995); since replaced by the 201 Glucose System in 2002.
2. Alere Cholestech LDX®
3. Abbott iStat®
4. Abaxis Piccolo®
5. PTS Diagnostics CardioChek®.

These five analyzers can be used for both diagnostic and monitoring purposes, which may make them attractive for point-of-care settings.

Specimen: Whole Blood

Waived glucose devices are categorized as such, partly because the specimen to be tested does not require processing. The specimen used with these devices is whole blood, not serum. Capillary whole blood obtained by skin puncture is the required specimen when using a glucometer and is a suitable specimen when using the diagnostic analyzers.

When the glucose test results are used for diagnostic purposes, as in an O'Sullivan Test (post-50 gram glucose load) and a 3-hour oral glucose tolerance test, whole blood obtained by venipuncture is the preferred specimen and is a requirement for participants in the North Carolina State Laboratory of Public Health CLIA Contract Program. Venous blood should be collected in a tube containing an anticoagulant recommended by the manufacturer of the analyzer. Blood collected in a serum separator tube should not be used for testing, since clotting begins immediately and may impact the accuracy of the glucose result.

Manufacturer's Instructions

The manufacturer's instructions must be followed exactly in order for the glucose test system to perform accurately and to comply with CLIA regulations. The manufacturer may state requirements for the following items:

- Environmental conditions: There may be strict temperature and humidity ranges for the storage of the analyzer and the reagents, as well as during the operation of the analyzer. If a temperature range is listed, the testing facility must document the monitoring of the range for acceptability.
- Quality Control (QC):
 - External: The manufacturer may state a minimum requirement for the frequency of testing external quality control materials. When stated, that frequency must be adhered to, but can be increased if desired. Running external controls evaluates the entire testing process, which includes user technique as well as analyzer function.
 - Internal: Many waived glucose test systems are designed with internal quality checks that may occur automatically without prompting or require a separate cuvette or cassette to be used. Internal checks are designed to evaluate the electronic or optical components of the analyzer. Typically, the analyzer will display an error code or lock the analyzer when the checks are unsatisfactory.
- Procedure: The manufacturer will include the step-by-step procedure in the analyzer's operating manual and the corresponding reagent package insert. Important details will be included in the procedure, such as wiping away the first (or second) drop of blood before testing.

- Cleaning and maintenance: It is important to note the type of cleaning product and frequency of cleaning required. Using a harsh cleaner may damage the result display unit or corrode plastic parts of the analyzer. Cleaning and maintenance activities should be documented when performed.

Limitations

All analyzers have some limitations. Check the reportable range for the analyzer and establish a policy to address actions to be taken when a result is out of that range.

If the temperature and/or QC levels are unacceptable, patient results cannot be reported until the situation is resolved. If reagents are expired, testing cannot be performed.

Often medications will interfere with the accuracy of the glucose result. The reagent package insert will list those medications, as well as other clinical factors, such as anemia or hemoglobinopathies, that may cause inaccuracies.

Conclusion

Waived glucose testing seems so simple at first glance. The reality is that to get an accurate and reliable glucose result from a waived analyzer requires thorough training and a complete understanding of the manufacturer's instructions for its use. Additionally, proper specimen selection (capillary vs. venous whole blood) and collection has a significant impact on this test. Monitoring of proper environmental conditions and acceptable quality control contributes to the ability to report patient results. Understanding these factors will assure that this "simple" test is performed correctly and a quality result is reported.

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References

1. Accu-Chek® InstantPlus® Dual Testing System User's Manual; Roche Diagnostics Corporation, Indianapolis, IN, 2002.
2. CardioChek® PA Portable Whole Blood Test System User Guide; Polymer Technology Systems, Inc. Indianapolis, IN, http://apps.pt diagnosti cs.com/pdf_files/cardiochek_pa/user_guides/pa_user_guide_english.pdf Accessed 5/14/15.
3. CDC. Good Laboratory Practices for Waived Testing Sites. MMWR 2005; 54: No.RR-13.
4. CDC. Waived Tests, <https://wwwn.cdc.gov/clia/Resources/WaivedTests/> Accessed 4/9/15.
5. Cholestech LDX® System User Manual and Calibration Verification Package Insert; <http://www.alere.com/us/en/product-details/choleste ch-ldx-system.html> Accessed 5/6/15.
6. FDA. Currently Waived Analytes **list**; <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm> Accessed 4/9/15.
7. HemoCue Glucose 201 with Plasma Conversion Operating Manual; HemoCue® AB, Angelholm, Sweden.
8. iStat®1 System Manual; Abbott Laboratories Abbott Park, IL, <http://www.alere.com/us/en/product-details/choleste ch-ldx-system.html> , Accessed 5/14/15.
9. Lab Tests Online® Glucose Tests; <http://labtestsonline.org/understanding/analytes/glucose/tab/glance> American Association of Clinical Chemistry, Accessed 4/9/15.
10. Piccolo Xpress® FAQ; Abaxis, Inc. <http://www.piccoloxpress.com/products/piccolo/faq/> Accessed 5/14/15.
11. Tests Granted Waived Status Under CLIA; <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/waivetbl.pdf> Accessed 5/14/15.



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