

24 Hour Summary
Clinical Chemistry and Clinical Toxicology Devices
General Issues Panel Meeting
Capillary Blood Glucose Testing in Hospital Settings
March 30, 2018

Introduction:

This meeting of the Clinical Chemistry and Clinical Toxicology Devices Advisory Panel was convened to discuss the use of capillary blood samples with blood glucose meters in patients throughout the hospital. Advisory Panel members discussed the general use of blood glucose meters with capillary samples from patients throughout the hospital. FDA sought the panel's opinion on the benefits and risks of measuring capillary blood using blood glucose meters in patients receiving intensive medical intervention/therapy, and the considerations for CLIA waiver for this use.

Panel Deliberations/FDA Questions:

- 1) Given the data presented, please discuss any factors that should be considered in assessing the benefits and risks of glucose meters intended for measuring blood glucose in capillary blood in patients receiving intensive medical intervention/therapy.
 - a) Please discuss the benefits of such testing.
 - b) Please discuss whether there are unique risks when capillary blood is tested in patients receiving intensive medical intervention/therapy.
 - c) If there are unique risks, please discuss potential mitigations for each risk.
 - d) Please discuss the benefit to risk balance for this intended use.

Panel Consensus Summary: The panel felt that the benefits of using glucose meters for measuring blood glucose in capillary blood in patients receiving intensive medical intervention/therapy outweigh the risks. However, the panel also recognized that there are many clinical conditions (e.g., hypothermia, hypotension, shock, edema, etc.) in which capillary blood testing may be problematic. Potential risk mitigation strategies included increased training of medical personnel using point-of-care testing and quality control programs.

- 2) Given the data presented, what are the relevant factors FDA should weigh in considering whether capillary blood glucose meter testing in intensively treated population would meet

the criteria for CLIA waiver (i.e., “simple” and with “an insignificant risk of an erroneous result”)?

Panel Consensus Summary: The panel felt that a major issue was the quality of the capillary blood sample being assessed by the blood glucose meter rather than the blood glucose meter itself. As such, there was no consensus as to whether modifications of the current CLIA status of blood glucose meters in the hospitalized setting would address this issue. There were comments made both in favor and against maintaining a CLIA waiver for using glucose meters for measuring blood glucose in capillary blood in patients receiving intensive medical intervention/therapy.

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