

Questions for Panel Discussion

July 22, 2016

Clinical Chemistry and Clinical Toxicology Devices Panel

k153726

Afinion HbA1c Dx test system

Alere Technologies AS

FDA wishes to get further input from the clinical community, via our Advisory Panel, to determine whether the concerns that prompted the ADA to recommend against the use of POC HbA1c tests for diabetes diagnosis, may be adequately addressed or mitigated. In addition, though the sponsor's current submission is for a HbA1c test for use in moderately complex POC laboratories, if this test is cleared, the sponsor is considering a future request for a CLIA waiver for this test system. Because proficiency testing is clearly a driving concern behind the ADA's recommendations and CLIA-waived laboratories are not subject to proficiency testing requirements, we would like input from the panel on considerations/mitigations that may be necessary when FDA receives future requests for CLIA waiver for diagnostic HbA1c tests.

We have the following discussion questions for the panel to address during the Advisory Committee Meeting:

1. In their "Standards of Medical Care in Diabetes" practice guidelines, the American Diabetes Association recommends against the use of POC HbA1c tests for the diagnosis of diabetes.
 - a. Does the panel have any concerns about risks to health regarding the use of POC HbA1c devices in general for the diagnosis of diabetes? If so, please describe these concerns.
 - b. Does the Afinion HbA1c Dx test system, with an intended use in moderate complexity POC settings, raise any new concerns about risks to health? If so, please describe these concerns.
 - c. If the panel has concerns about risks to health for a or b above, what mitigations, if any, may be implemented to address those concerns?
2. The sponsor has proposed a number of ways to separate their current CLIA waived monitoring HbA1c test from their proposed moderately complex diagnostic HbA1c test. However, laboratories in the clinical community will be aware that the Afinion HbA1c diagnostic test and the current Afinion HbA1c monitoring test are the same test with two different names.

Is the sponsor's proposed strategy to differentiate the current CLIA waived monitoring Afinion HbA1c test system from the proposed Afinion HbA1c diagnostic test system

adequate to address concerns about the use of POC monitoring HbA1c tests to diagnose diabetes in CLIA waived settings by untrained personnel?

3. Based on the design of the Afinion HbA1c Dx test system:
 - a. Please discuss the potential advantages and disadvantages of using this test as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes in CLIA waived point-of-care settings?
 - b. If there are any risks to health associated with the use of this device in CLIA waived point-of-care settings, are there potential mitigations that may be employed by the manufacturer that are adequate to address these risks to health?