CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES PANEL
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE
Baebies, Seeker Newborn Screening System
August 10, 2016

FDA EXECUTIVE SUMMARY-ERRATA

On Pages 22 and 23 of the executive summary the following change has been made due to a calculation error.

Detection Limits: Baebies evaluated the detection limits of this assay following a recognized guideline[10] using 3 lots of their reagent and estimated the following detection limits:

- The limit of the blank (LoB) was defined as the highest analyte concentrations expected to be found when replicates of a sample containing no analyte are tested with 95% confidence. This is often a way of determining what concentration(s) the assay cannot distinguish from "noise." Baebies estimates that the LoB of the IDUA assay was 1.78 µmol/L/h (note the final high-risk cutoff for the assay was 1.5 µmol/L/h).

- The limit of detection (LoD) was defined as the lowest analyte concentration likely to be reliably distinguished from a blank sample with 95% confidence. The LoD of the IDUA assay was determined to be 2.77 µmol/L/h.

- The limit of quantification was defined as the lowest concentration where the total imprecision was ≤ 1.5 µmol/L/h or 20% CV whichever was greater. Baebies estimated that the LoQ for the IDUA assay was 2.77 µmol/L/h which was the concentration where the imprecision was less than 1.5 µmol/L/h (and the CV could be as high as 54%). Based on the data provided in support of the LoQ of the assay, FDA estimates that the LoQ based on an imprecision goal of 20% CV (which is the typical imprecision goal for the LoQ of quantitative assays) is ~~approximately~~ greater than 4~~3~~.7 µmol/L/h ~~(although FDA notes that this estimate is not consistent with the precision evaluation of the test which demonstrated higher imprecision at this concentration).~~