Revisions to the FDA issue summary are listed below.

Page 6, 5th paragraph, 1st sentence: The sentence is revised as follows, “A study by Jacobs et al, published in 2011, demonstrated that rapid testing, performed on the day of transfusion, was able to detect 9 contaminated units that were missed by a culture conducted early in the storage of the units, 7 of which were interdicted before transfusion.”

Page 7, 1st paragraph under Section III.A.1, line 8: The sentence is corrected as follows, “Based on the two nonreactive rapid test cases, the false negative rate was calculated as 2/10,424.”