The performance of this method, Acetaminophen 03R11 (y) was compared with the performance of Acetaminophen 2K99-20 at an external laboratory on the Architect c8000 (x). A combination of 57 natural and spiked patient serum samples ranging from (02K99: 3.8 – 340.7 µg/mL, 03R11: 4.3 – 368.9 µg/mL) spanning each assay’s measuring interval (3 – 377 µg/mL) gave a correlation coefficient of 1.000. Linear regression analysis gave the following equation:

This method = 1.079 (reference method) + 0.5266 μg/mL (3.5 μmol/L).

Figure 1 below displays the feasibility method comparison fit (Figure 1a) and difference plot (Figure 1b) of Acetaminophen Part number 03R11 versus Acetaminophen Part number 02K99 on the Architect *c*8000.

The data was fit using a Passing-Bablok regression analysis (Figure 1a). The slope, y-intercept, and correlation coefficient (R2) are 1.079, 0.5266, and 1.000, respectively. These parameters meet the acceptance criteria for the slope (1.0 ± 0.1) and R2 (≥ 0.975). This fitting was performed according to CLSI EP09-A3.1 The only exception to the EP09 protocol was the spiking and dilution of more than 20% of the total number of unmodified patient samples.

**Figure 1.** (a) Passing-Bablok fitting of method comparison data for part number 03R11 versus part number 02K99. (b) Difference plot displaying the difference (03R11 – 02K99) between the means of the two assays versus part number 02K99.