

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1031844	(X3) Date Survey Completed 01/30/2018
Name of Provider or Supplier Labworks Llc	Street Address, City, State 1630 Miller Park Way, West Milwaukee, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical supervisor, the laboratory has used expired reagents on the Indiko analyzer. Findings include: 1. Review of the Lot Number Log from March 2017 through December 2017 shows the following reagents (abbreviated as listed on the log) put in use after the recorded expiration date: Reagent / Start Date 2017 / Lot # / Expiration Date Creat / April 3 / 72015679 / December 2016 EtOH / April 24 / 72154498 / December 2016 OXID / August 14 / 72272288 / March 2017 Benzo / September 5 / 72072098 / July 2016 THC / October 2 / 72200484 / January 2017 Amph / November 27 / 72192523 / October 2016 Meth / November 27 / 72193600 / August 2017 Opi / December 4 / 72177403 / September 2017 2. Interview with the technical supervisor on January 30, 2018 at 1:15 PM confirmed expired reagents were used for testing on the Indiko analyzer.</p>