Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2171628	11/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Rodas Md, Pllc	25810 Kelly Rd, Roseville, MI	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy of its toxicology testing at least twice annually for 1 (November 2019 to November 2020) of 1 year reviewed. Findings include: 1. An interview on 11/17/20 at 9:38 am with the TC revealed the laboratory started testing in November 2019. 2. A review of the laboratory's test menu revealed it is currently testing the following analytes: a. Amphetamines b. Cocaine c. Opiates d. Oxycodone e. Benzodiazapine 3. A review of the laboratory's proficiency testing documentation revealed a lack of verification of accuracy at least twice annual verification of accuracy for the analytes listed above. 4. A review of the laboratory's established "Proficiency Testing" procedure revealed a section titled "Split Samples" stating, "If proficiency testing is not provided for an analyte, then split samples will be run twice per year. Two samples will be run and each samples difference must be within 25%. A score of less than 80% will be considered failing and corrective action must be taken and documented." 5. An interview on 11/17/20 at 9:38 am with the TC confirmed the laboratory did not perform verification of accuracy testing at least twice annually for the analytes listed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When

	control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to verify the criteria for acceptability of control materials in toxicology testing for 1 (November 2019 to November 2020) of 1 year the laboratory has been testing. Findings include: 1. A review of the laboratory's established "New Lot Control" procedure revealed a section stating, "Whenever you receive a new lot number of control, you must run that control 5 runs or days with the old lot number to verify the new controls package insert values before putting them into use." 2. The surveyor requested the documentation of verification of controls on 11/17/20 at 10:26 am and it was not made available. 3. An interview on 11/17/20 at 9:35 am with the TP1 confirmed the laboratory did not verify the new lots of controls prior to putting them into use.