Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1064681	02/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Orlando Health Medical Group, Inc	1560 Santa Barbara Blvd, The Villages, FL	

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, the laboratory failed to verify the accuracy of the Oxygen Saturation Percentage (O2 Sat %) in the specialty of Routine Chemistry at least twice annually for 2018 and 2019. Findings: Review of proficiency testing, (PT) records revealed that there was no record of PT performed on O2 Sat %. During an interview on 2/11/19 at 12:25 PM, the Laboratory Consultant stated that the laboratory did not perform PT for O2 Sat %.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory was unable to provide documentation of the validations of the Hemochron Jr Signature Plus analyzer for Activated Clotting Time (ACT) testing, and the Oxicom 2100 analyzer for Oxygen

	Saturation Percentage (O2 Sat %) testing performed in April 2006. Findings: Review of the laboratory's quality control documentation showed the laboratory did not have documentation available at the time of the survey for the validations on the Hemochron Jr Signature Plus analyzer and Oxicom 2100 analyzer performed in April 2006. During an interview on 2/11/2020 at 12:21 PM, the Director of Operations stated the previous Medical Director thought the laboratory opened in April 2006 and that validations for the instruments were saved.