Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2159185	12/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Doro Laboratories	109 Meco Lane, Oak Ridge, TN	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: ========== Based on review of the Quality Assurance (QA) Plan, testing personnel records, and an interview with the Laboratory Director, determined the laboratory failed to follow written policy to assess testing personnel for 6 month competency due September 2019 for Blood Volume Analysis (BVA). The findings include: 1. A review of the QA Plan and discussion with Laboratory Director disclosed that testing personnel competencies would be assessed at 6 months after intitnal training and annually thereafter by the Laboratory Director. 2. A review of the personnel records revealed no 6 month competency for testing personnel number 2 for BVA in September 2019. 3. An interview with the Laboratory Director at approximately 1:30 p.m. December 10, 2019 confirmed the laboratory failed to follow QA Plan for assessing 6 month competency for testing personnel number two for BVA in September 2019. ==========
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by:

	========== Based on a review of patient test audits and an interview with the Laboratory Director, the laboratory failed to provide documentation for an authorized order or test request for Blood Volume Analysis (BVA) since patient testing began 3/11/2019. Findings include: 1. A review of patient audits revealed there was no documentation of authorized orders or requests for BVA testing since patient testing began 3/11/2019. 2. An interview at approximately 1:30 p. m. on December 10, 2019 with the Laboratory Director confirmed no documentation of authorized orders or requests for BVA testing since patient testing began 3/11 /2019. ==========
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: ========== Based on review of the Laboratory's Quality Assessment (QA) Plan, lack of Director review of Quality Control (QC) and QA since patient testing began 3/11/2019, and an interview with the Laboratory Director, determined the Laboratory Director did not ensure quality of laboratory services was maintained for the 8 month time period per QA plan. The findings include: 1. A review of the QA Plan stated the Laboratory Director will ensure that Quality Control and Quality Assurance Plans are established and maintained by review to assure the quality of the laboratory services and identify failures as they occur. 2. There was no documentation of Laboratory Director review for Quality Controls or Qualtiy Assessments since patient testing began 3/11/2019. 3. An interview with the Laboratory Director at approximately 1:30 p.m. December 10, 2019 confirmed there was no documentation of Laboratory Director review of the quality controls or quality assessment records to ensure the quality of the laboratory services were maintained for the 8 month period. ==========