Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2162622	12/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Revere Health Lehi Willow Creek Family Medicine	2183 West Main Street #A107, Lehi, UT	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on direct observation, procedure manual review, and interview with staff, the laboratory failed to establish and follow written policies and procedures to ensure positive identification of patient specimens at the time of collection for 1 of 1 specimen collections observed. Finding include: 1. The surveyor observed a patient blood sample collection on 12/20/2019 at approximately 2:00 p.m. 2. The phlebotomist failed to confirm the identity of the patient being drawn to ensure the patient being drawn matched the order. 3. The procedure manual failed to include a policy to ensure positive identification of patient specimens. 4. The phlebotomist stated after the draw, she did not always confirm the patient's identify before drawing blood, especially if she was busy. 5. The technical consultant confirmed on 12/20 /2019 at approximately 2:30 p.m. the procedure manual did not include instructions on how to positively identify the patient before collecting samples to ensure samples were collected from the intended patient.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on PocH-100i operator's manual review, instrument maintenance record review, and interview with staff, the laboratory failed to follow the manufacturer's instructions to perform instrument shutdown each day of testing for 5 of 25 testing days reviewed in November 2019. Findings include: 1. The PocH-100i operator's manual states, "Shutdown must be performed at least every 24 hours". 2. The laboratory's maintenance records failed to include documentation the PocH-100i shutdown procedure was performed on November 16. 22, 25, 26, and 27 of 2019. 3. The technical consultant confirmed on 12/20/2019 at approximately 12:00 p.m., the laboratory failed to document instrument shutdown each day of testing.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on Complete Blood Count (CBC) test report review and interview with staff, the test report failed to include the correct location where testing was performed for 3 of 5 CBC test reports reviewed. Finding include: 1. Test reports for patient 1000080353 tested on 09/14/2019, patient 1024051 tested on 11/04/2019 and patient 1156931 tested on 12/12/2019 listed the test location as 1055 N. 500 W. in Provo Utah. 2. The technical consultant confirmed on 12/20/2019 at approximately 12:00 p. m. CBC testing for the 5 reports reviewed had been performed onsite at 2183 West Main Street, in Lehi Utah.