Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2206672	08/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Smith Lake Family Care	6610 Curry Highway, Jasper, AL	

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
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 a review of a patient test report and an interview with the Laboratory Director, the laboratory failed to include the name and address of the laboratory location where the test was performed. This was noted on one of one patient test report for Complete Blood Count (CBC) reviewed by the surveyor. The findings include: 1. A review of a patient test report revealed the name and address of the laboratory location where the test was performed was not on the CBC patient test report performed on 08/24/2021. 2. During an interview on 08/24/2021 at 1:00 PM, the Laboratory Director confirmed that the name and address was not on the patient test report.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a lack of Proficiency Testing records and an interview with the Laboratory Director, the Laboratory Director failed to ensure the laboratory was enrolled in an approved proficiency testing program for Hematology - Complete Blood Count when patient testing started. This noted from April 21, 2021 (date patient testing started) to August 23, 2021 (date Proficiency Testing was ordered). The findings include: 1. A review of CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification revealed that the laboratory is performing Complete Blood Counts (CBC) on the Horiba ES 60. A CBC includes the following moderate complexity, regulated analytes: White Blood Count (WBC) Differential, Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, and Platelet Count. 2. During an interview on 08/24/2021 at 11:30 AM, the Laboratory Director confirmed the Proficiency Testing was delayed on being ordered until August 23, 2021 due to lack of oversight in getting ordered in April 2021.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the Laboratory Director, the Laboratory Director failed to have in writing the duties/responsibilities to each person involved in all phases of the testing process. This was noted for seven out of seven employees listed on the Laboratory Personnel Report (CMS-209). The findings include: 1. A review of personnel records revealed the Laboratory Director , Clinical Consultant, Technical Consultant, and Testing Personnel duties /responsibilities are not in writing. 2. During an interview on 08/24/2021 at 11:05 AM, the Laboratory Director confirmed the responsibilities/duties (job descriptions) for the positions listed above were not in writing.