Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2150724	07/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Coosa Family Care Llc	310 West Grand Ave, Rainbow City, 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
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 a review of the American Proficiency Institute (API) proficiency test records and an interview with Testing Personnel #1, the laboratory failed to implement a mechanism to verify the accuracy of non-regulated analytes in the specialty of Microbiology. This was noted for four of twenty analytes reviewed in 2023 and 2024. The findings include: 1. A review of the API proficiency records revealed the following analytes did not have documented accuracy verification or proficiency testing performed since 3/8/22: a) Haemophilus influenzae b) Moraxella catarrhalis c) Streptococcus pneumoniae d) Staphylococcus aureus 2. During an interview on 7/31 /2024 at 12:01 PM, Testing Personnel #1 said the analytes listed above had accuracy verification performed when sending split samples to another laboratory bi-annually. The laboratory began using API and thought all analytes were included in the Microbiology panel.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency test records and an interview with Testing Personnel #1, the Laboratory Director failed to implement a mechanism to verify the accuracy of non-regulated analytes in the specialty of Microbiology. This was noted for four of twenty analytes reviewed in 2023 and 2024. The findings include: Refer to D 5217. .