Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2067740	04/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Scottsboro Urgent Care	102 Micah Way, Suite 1107, Scottsboro, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel (TP) #1, it was determined the laboratory failed to ensure the Laboratory Director or a qualified designee signed the attestation statements for Hematology proficiency testing events performed in 2018-2019. This affected four out of eight surveys reviewed for the survey time-period of 2018 - 2020. The findings include: 1. The Laboratory Director or a qualified designee (Technical Consultant) did not sign the attestation statements for API proficiency testing records events for the following surveys: A) 2018 Hematology Event #2 and Event #3 B) 2019 Hematology Event #1 and Event #2 2. During an interview on 04/06/2021 at 3:00 PM, Testing Personnel #1 confirmed the above noted findings.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of the 2018-2020 American Proficiency Institute (API) proficiency testing records and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director or qualified designee failed to sign the performance review evaluation for seven of the eight proficiency testing events reviewed by the surveyor. The findings include: 1) A review of the API proficiency testing records revealed the Laboratory Director failed to sign the performance review evaluations for the following surveys: A) 2018 Hematology Event #2 and Event #3 B) 2019 Hematology Event #1, Event #2, and Event #3 C) 2020 Hematology Event #1, and Event #2 2) In an exit interview on 04/06/2021 at 3:00 PM, TP #1 confirmed the above noted findings.