Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1067994	01/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics - Tuscaloosa	300 Towncenter Blvd Suite D, Tuscaloosa, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing records and an interview with the Laboratory Manager, the Laboratory Director and Testing Personnel failed to sign the attestation statements provided by College of American Pathologists (CAP). This was noted on 27 out of 29 2019 - 2021 Proficiency Testing Events. The findings include: 1. A review of Proficiency Testing records revealed the attestation statements were not signed by the Laboratory Director (or Designee) and/or the Testing Personnel for 27 out of the 29 Proficiency Testing Events. 2. Instructions on the CAP Attestation forms specified the Laboratory Director (or Designee) and the analyst(s) performing the tests should sign the attestation statement. 2. During an interview on 01/13/2022 at 1:00 PM, the Laboratory Manager confirmed the above attestations were not signed by the Laboratory Director/delegate and/or the Testing Personnel.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Procedure Manuals, the Policy for Document Control, and an interview with the Laboratory Manager, the current Laboratory Director failed to

	approve the Procedure Manuals within 3 months of becoming the Laboratory Director. This was noted on all Procedures Manuals reviewed by the surveyor. The findings include: 1. A review of the Procedure Manuals revealed the current Laboratory Director signed the Sysmex XN-1000 Procedure 10/08/2021, the Chemistry Procedures 11/21/2021, Sysmex CA 600 Procedure 01/07/2022, Routine Urinalysis 01/12/2022, and General Laboratory Procedures 01/07/2022. 2. A review of the Policy for Document Control revealed "...Document Approval ... When there is a change in laboratory directorship, the new Laboratory Director must ensure that laboratory procedures are current and have been appropriately reviewed and approved. For laboratories with less than or equal to 200 technical procedures, this must be completed within 3 months..." 3. During an interview on 01/13/2022 at 11:15 AM, the Laboratory Manager confirmed the current Laboratory Director assumed this position in April 2021 and he did not sign the procedures within 3 months, as per the laboratory policy.