Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2184737	01/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Genetics Associates, Inc	7852 Kemberton Dr W, Nolensville, TN	

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 observation of the laboratory, lack of laboratory records, and an interview with the Laboratory Director, the laboratory failed to verify the accuracy of remote chromosome analysis at least twice a year for 2020, 2021, and 2022. The findings include: 1. Observation of the laboratory on 01/06/23 at approximately 8:30 a.m. revealed patient testing was being performed by remote chromosome analysis. 2. During the review of laboratory records for 2020, 2021, and 2022, it was revealed that the laboratory did not have documentation of twice a year accuracy verification for remote chromosome analysis testing. 3. Interview with the Laboratory Director on 1/6 /23 at 12:00 pm confirmed the laboratory did not verify the accuracy of remote chromosome analysis testing at least twice a year for 2020, 2021, and 2022.
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 observation of the laboratory, review of the laboratory's procedure manual, and interview with the laboratory director, the current laboratory director failed to approve, sign and date laboratory procedures. The findings include: 1. Observation of the laboratory on 01/06/23 at approximately 8:30 a.m. revealed patient testing was

	being performed by remote chromosome analysis. 2. Review of the laboratory's procedure manual revealed no signature or date indicating approval by the current laboratory director. 3. Interview with the laboratory director on 01/06/23 at approximately 12 p.m. confirmed the laboratory's procedures had not been signed, dated, and approved by the current laboratory director.
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 final test reports and an interview with the Laboratory Director, the final laboratory test reports failed to contain the name and address where remote chromosome analysis were performed. The findings include: 1. A review of 4 final test reports from 5/29/20, 6/28/21, 9/23/22 and 12/9/22 failed to show name and address of laboratory where remote chromosome analysis was performed. 2. An interview with the Laboratory Director on 1/6/23 at 12:00 p.m., confirmed the final patient reports did not contain the laboratory name and address where the remote chromosome analysis testing was performed.