Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1099562	04/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Diagnostics	900 Towne Center Drive, Langhorne, PA	

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
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 the general laboratory policy/procedure manual review and interview with the Laboratory Manager (LM) the Laboratory Director (LD) listed on the CLIA certificate failed to approve, sign and date 5 of 5 laboratory procedure manuals reviewed at the time of complaint investigation (4/12/19). Findings include: 1. The LD name listed on the CLIA certificate is Dr. Deborah Carroll. 2. Three of five were procedure manuals were signed by Dr. Thomas Domenico on 06/20/18. a. Reporting of Results, Ref #9013, Revised 12/17/15 b. Specimen Requisition & Receipt of Specimens, Ref #9012, Revised 06/26/17 c. Error Reporting and Investigation, Ref #9007, Revised 12/17/15 3. Two of five were not signed by the current LD. 4. At 09: 14 am on 04/15/19, LM confirmed over the phone the person listed on the CLIA certificate is the LD.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on review of patient reports from Genesis Diagnostics and Quest Diagnostics and interview with the Laboratory Manager (LM) the Laboratory failed to report 6 of

	7 patient results in a timely and reliable manner and failed to notify the ordering physician of delayed reporting from 02/11/19 to 03/19/19. Findings include: 1. The Quality Management Program policy, Ref # 9003, Effective 04/01/11, section 9. Information Management, states, e) Reporting Systems: Each laboratory system is adequate to report results in a timely, accurate and reliable manner. 2. The turnaround time (TAT) policy Ref # JCL - 10019, Revised 02/01/16, section Procedure #4 states, If there is to be a specific delay in TAT for any testing (due to instrument malfunction, etc) preventing the reporting of STAT results within 4 hours and/or routine tests within 6 - 8 hours the client/physician are to be notified. 3. LM interviewed at around 10:20 am on 04/12/2019 stated, there was a delay in reporting patients because some specimens were sent to Quest Diagnostics but records reviewed indicated that Quest Diagnostics reported results 5 to 6 before Genesis Diagnostics issued the final report. a. Patient A: Lab Accession Number: 190227438 Specimen Collected: 02/26/2019 Specimen Received: 02/27/2019 Quest Reported: 03/03/2019 Genesis Reported: 03/12/19 b. Patient B: Lab Accession Number: 190227412 Specimen Collected: 02/26/2019 Specimen Received: 02/27/2019 Quest Reported: 03 /01/2019 Genesis Reported: 03/07/2019 c. Patient C: Lab Accession Number: 190307454 Specimen Collected: 03/06/2019 Specimen Received: 03/07/2019 Quest Reported: 03/14/2019 Genesis Reported: 03/19/2019 4. Reports of patient specimens that were not sent to Quest Diagnostics also showed a delay in reporting. The following specimens were tested at Genesis Diagnostics: a. Patient D: Lab Accession Number: 1902200225 Specimen Collected: 02/19/2019 Specimen Received: 02/20 /2019 Specimen Reported: 03/05/2019 b. Patient E: Lab Accession Number: 1902200226 Specimen Collected: 02/19/2019 Specimen Received: 02/20/2019 Specimen Reported: 02/28/2019 c. Patient F: Lab Accession Number: 1902200223 Specimen Collected: 02/19/2019 Specimen Received: 02/20/2019 Specimen Reported: 02/28/2019 5. Laboratory could not provide documentation that the physicians or patients were notified of delayed reporting.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of patient results and Error Reporting and Investigation policy the laboratory failed to identify and correct the error on patient report and prevent recurrence on 4 of 5 patient reports from 02/11/2019 to 03/31/2019 (patient results reviewed at the time of complaint, 04/12/2019). Findings include: 1. The Error Reporting and Investigation policy, Ref #9007, Revised 12/17/2015 states the following: Subtitle: "Principle" "All laboratory errors are documented and investigated to identify the root cause of the error and to then implement measures to prevent reoccurrence." Subtitle: "Procedure" 1. "Laboratory errors may occur at any of the three phase of testing: pre-analytic, analytic and post-analytic." a-4) "Errors associated with sample receipt and accessioning." c. "Post-analytic (post-examination) phase of testing: includes activities related to reporting results and archiving results. Problems that require investigation: Transcriptional errors and reporting errors." 2. "Complete a "Laboratory Error/Report Investigation" form to document the steps

	involved in the investigation and measures that were taken to prevent reoccurrence." 2. Laboratory Manager stated at 10:20 am on 04/12/2019 the laboratory accession number is the year, month, day and unique identification (ID) but the received date on the report did not match the receipt date embedded in the accession number. a. Patient A: Lab Acc #: 190308184 Collected: 03/07/2019 Received: 03/07/2019 b. Patient B: Lab Acc #: 190308183 Collected: 03/07/2019 Received: 03/07/2019 c. Patient C: Lab Acc #: 190308214 Collected: 03/07/2019 Received: 03/07/2019 d. Patient D: Lab Acc #: 190308216 Collected: 03/07/2019 Received: 03/07/2019 3. The laboratory could not provide Laboratory Error/Report Investigation report completed for the errors on the patients reports.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview with Laboratory Manager (LM) and Vice President (VP), Laboratory Director (LD) failed to provide effective direction over the laboratory. The LD failed to ensure that tests results were reported promptly and accurately. Findings include: 1. LD failed to approve, sign, and date procedure manual. Refer to D5407. 2. The LD failed to ensure that results were reported promptly. Refer to D5815. 3. The LD failed to ensure that the Laboratory identified, corrected and prevented recurrence of error on patient report. Refer to D5893. 4. The LM and VP confirmed the findings above at the exit interview at 11:15 am on 04/12 /19.