Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1031713	11/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Medical Laboratory	8150 Perry Highway Suite 102, Pittsburgh, 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
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 review of the American Proficiency Institute (API) proficiency testing (PT) records, and interview with the laboratory manager (LM) , the laboratory director failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate and identify problems that required corrective action for Chemistry, Immunology and Hematology API PT results in 2020, 2021, and 2022. Findings Include: 1. On the day of the survey, 11/16/2022 at 08:06 am, review of API PT records revealed that the laboratory did not document complete corrective action plans for the following API PT results from July 2020 to the date of the survey: -API 2020 Immunology/Immunohematology Event 3: General Immunology 80% -API 2020 Hematology/Coagulation Event 3: Retic count 50% -API 2022 Chemistry Core Event 2: Lipase 80% -API 2022 Hematology/Coagulation Event 1: Platelet 80% -API 2022 Immunology/Immunohematology Event 2: Lyme 50% 2. The laboratory could not provide documentation that the following API PT results were reviewed and assessed by the LD: -Chemistry Miscellaneous: -API 2020: Event 2 -API 2021: Event 1, Event 2 -API 2022: Event 1, Event 2 -Chemistry Core: -API 2020: Event 3 -API 2021: Event 1, Event 2 -API 2022: Event 1, Event 2 -Hematology/Coagulation: -API 2020: Event 3 -API 2021: Event 1, Event 2, Event 3 -API 2022: Event 1, Event 2 -Immunology/Immunhematology: -API 2020: Event 3 -API 2021: Event 2, Event 3 -API 2022: Event 1, Event 2 3. The LM confirmed the findings above on 11/16/2022 around 12:30 pm.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with the laboratory manager (LM), the laboratory director (LD) failed to ensure that all new and revised procedures were signed and approved for all aspects of the testing process from July 2020 to the date of survey. Findings include: 1. On the day of the survey, 11/16/2022 at 08:20 am, review of the laboratory's procedure manual, revealed that the LD did not sign and approve the following procedures currently in use from July 2020 to the date of the survey: -Policy for non-courier lab specimen transport: Effective 12/21/2005 -Result search with harvest webstation: Effective 02/21/2006 -Specimen processing steps for iron studies: Effective 02/13/2009 -Policy for lab errors/incidents: Effective 03/05/2015 -Alternate lab procedure for power emergencies: Effective 06/01/2015 -C-Reactive protein orders: Effective 02/05/2016 -Procedure for changing testing location for stored orders: Effective 07/26/2016 -Procedure for Clarity Ifobt Kits: Effective 11/15/2016 -Procedure for entering recurring/standing orders: Effective 03/31/2017 2. The LM confirmed the findings above on 11/16/2022 around 12:30 pm.