Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2173587	09/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hematology/Oncology Office Lab At Regional	8931 Colonial Center Drive Suite 300, Fort Myers, FL	

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
D0000	An announced CLIA recertification survey was conducted at Hematology/Oncology Office Lab at Regional Cancer Center on 09/16-09/18/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish a policy to be onsite once every six months and document the onsite visits from 1/1 /2025 to 9/16/2025. Findings included: 1. The Laboratory Director Responsibilities policy signed by the Laboratory Director on 8/18/2025, item #18 showed laboratory directors not onsite were to perform onsite visits. However the policy did not state the frequency, what the visits were to include or that the visits were to be documented. 2. Technical Consultant #B on 9/16/25 at 1:28 p.m. stated the Laboratory Director came onsite to the laboratory frequently but there was no documentation of the visits. 3. Via email on 09/17/2025 at 8:13 a.m., the Laboratory Director was questioned if she was aware of the current CLIA regulations that the Lab Director was required to document being onsite in the laboratory at least every six months to include documentation of what activities performed during the visits? The request was for a response to be received by 9/18/25 at 4:00 p.m. No response was received as requested.

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred for two of two years (2023-2025). Findings included: 1. The Quality Management Program policy signed by the Laboratory Director on 8/18/2025, showed the Laboratory Quality Management Program conformed to the minimum requirements of regulations and was designed to cover all sections of the laboratory and aspects of care. 2. The Laboratory Director Responsibilities policy signed by the Laboratory Director on 8/18/2025, showed under item #5 the laboratory director would ensure an effective laboratory quality management program was designed, implemented, and maintained. 3. The Laboratory Director Delegation of Functions policy signed by the Laboratory Director on 2/11/2025, showed under #3 Functions and responsibilities many not be delegated included "Review of Laboratory Quality Management Program. 4. At the time of the survey there was no documentation of the Laboratory Director's involvement or establishment of a Laboratory Quality Program. Technical Consultants B and C both confirmed on 9/16/2025 at 1:24 p.m., there was no documentation available for review of the Laboratory Director's involvement with any established Laboratory Quality Program. 5. Via email on 09/17/2025 at 8:13 a.m., the Laboratory Director was questioned as to the process for her to provide oversight to ensure the laboratory Quality activities for General, Pre-Analytic, Analytic, and Post-Analytic were performed and what was her input regarding the monitoring activities. The request was for a response to be received by 9/18/25 at 4:00 p.m. No response was received as requested.