Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0672804	03/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Richard W Hempstead Md Pa	509 S Main Street Suite B, Las Cruces, NM	

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 onsite recertification survey conducted at Richard W. Hempstead MD PA on February 07, 2024, found the laboratory to be out of compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following condition not met: 493.1250 - Analytic Sysytems 493.1441 - Laboratory Director, high complexity
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, test menu, and staff interview, the laboratory failed to meet analytic system requirements as evidenced by: 1. The laboratory failed to provide a procedure manual for 550 of 550 patient tests in 2023. Refer to D5401. 2. The laboratory failed to document quality control for Hematoxylin and Eosin-stained slides in 2023. Refer to D5473. 3. The laboratory failed to provide documentation of an established quality assessment program for 550 of 550 patient tests in 2023. Refer to D5791.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks

	may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the Laboratory Director failed to provide a procedure manual for 550 of 550 patient tests in 2023. Findings included: 1. The laboratory was asked to provide an approved procedure manual outlining the testing process. No procedures were provided. 2. A review of laboratory records revealed an annual volume of 550 histopathology tests were performed in 2023. 3. In an interview on 03/07/2024 at 9:30 am, the Laboratory Director was asked to provide written policies and procedures related to the laboratory's testing process. No documentation was provided. This confirmed the findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu and staff interview, the laboratory failed to document quality control for Hematoxylin and Eosin (H&E) stained slides in 2023. Findings included: 1. Review of the laboratory's test menu revealed 550 H&E-stained slides were interpreted in 2023. 2. A request was made to the Laboratory Director to provide documentation that quality control was evaluated for each day. No documentation was provided. The laboratory failed to ensure H&E predictive staining characteristics were evaluated. 3. During an interview on 03/07/2024 at 09:15 am, after review of the above records, the Laboratory Director confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the Laboratory Director failed to provide documentation of an established quality assessment program for 550 of 550 patient tests in 2023. Findings included: 1. The laboratory was asked to provide documentation indicating a quality assessment program has been established to ensure the quality of laboratory services provided. No documentation was provided. 2. A review of laboratory records revealed an annual volume of 550 histopathology patient tests performed. 3. In an interview on 03/07/2024 at 9:30 am, the Laboratory Director was asked to provide written policies and procedures related to the laboratory's quality assessment program. No documentation was provided. This confirmed the findings.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, and staff interview, the laboratory director failed to provide overall management and direction as evidenced by: 1. The laboratory director failed to endure a quality control program was established. Refer to D6093. 2. The laboratory director failed to establish a written quality assessment program. Refer to D6094. 3. The laboratory director failed to provide an approved procedure manual. Refer to D6106.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 review of laboratory records and staff interview, the Laboratory Director failed to establish a quality control plan as evidenced by: 1. The Laboratory Director failed to document quality control for Hematoxylin and Eosin-stained slides in 2023. Refer to D5473.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 review of laboratory records and staff interview, the Laboratory Director failed to establish a quality assurance plan as evidenced by: 1. The Laboratory Director failed to provide documentation of an established quality assessment program for 550 of 550 patient tests in 2023. Refer to D5791.
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 laboratory records and staff interview, the Laboratory Director

	failed to provide a procedure manual for 550 of 550 patient tests in 2023. Refer to D5401.