Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0388536	06/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Richard E Neils Md	888 Thackeray Trail Ste 212, Oconomowoc, WI	

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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on surveyor review of records and interview with the office manager, the laboratory did not retain the gross examination test reports from the reference laboratory when the director performed the microscopic diagnostic interpretation for three of three random samples reviewed. Findings include: 1. Review of reports and records of three patient results with microscopic diagnostic interpretations performed by the laboratory director showed no evidence of the report from the reference laboratory that performed the gross examination of the tissue. 2. Interview with the office manager on June 2, 2022, at 9:25 AM confirmed the laboratory did not retain the reference laboratory's gross examination test reports received with the slides for microscopic diagnostic interpretation by the laboratory director.
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 surveyor review of quality assurance and prior survey records and interview

	with the office manager, the laboratory director did not maintain the quality assessment program to assure the quality of services and identify failures in quality as they occurred for three of three quality evaluations from the second half of 2021 and the two evaluations in 2022. Findings include: 1. Review of the 'Plan of Correction' form submitted for the survey performed on July 19, 2021, showed the laboratory would, on a biannual basis, identify ten biopsy slides from cases within the last three months to send for peer review. 2. Review of the 'Confidential Peer Review Document, Quality Control Evaluation / Slide Examination' Forms showed the laboratory did not submit slides or did not submit them timely to the physician performing the peer review. The laboratory submitted slides from the second half of 2021 in April 2022. The laboratory submitted slides for the first half of 2022 in May 2023. No records were available showing submission of slides from the second half of 2022. 3. Review of the 'Confidential Peer Review Document, Quality Control Evaluation / Slide Examination' form for slides evaluated from February 2022 showed one discrepancy and two minor disagreements between the reviewer and the original diagnoses of the laboratory director. 4. Interview via email with the office manager (staff A) on June 23, 2023, at 10:06 AM confirmed the laboratory did not submit the slides for the quality assessment program timely for the second half of 2021 or the first half of 2022 and confirmed the laboratory had not submitted the slides for the second half of 2022 prior to the survey. This is a repeat deficiency previously cited on July 19, 2021.