Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0875304	02/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
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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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the current, approved policies and procedures, lack of personnel training records, as well as interview with the laboratory director (LD), the LD failed to perform and document clinical consultant (CC) competency assessment. Findings: 1. There was no documentation of CC competency evaluation. 2. Current, approved policies and procedures did not include written description of CC job duties, responsibilities, and written instructions for performing CC competency evaluation. 3. LD confirmed findings on February 15, 2024, at 1:00 P.M.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the current, approved standard operating procedures, fume hood

	maintenance records, and interview with the Histotechnician (HT), and LD, the HT failed to perform the required weekly XVS fume hood maintenance. Findings: 1. The XVS fume hood maintenance log required weekly alarm performance test. 2. There was no documentation of weekly alarm test for 2023. 3. This is contrary to instructions indicated in the current, approved standard operating procedures. 4. TP and LD confirmed findings on February 15, 2024, at 1:00 P.M.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Tissue-Tek TEC temperature log and manufacturer's specifications, lack of corrective action records, as well as interviews with the LD and HT, no corrective action was performed and documented for embedding consul out-of-range temperatures. Findings: 1. The WK platform, left side, and right side have a temperature range of 66-70C, and the forceps have a range of 65-75C. 2. According to the Tissue-Tek TEC temperature log, all 2023 calendar year documented temperatures were below the minimum range when patient specimen processing occurred; Approximately 2000 patient specimens were processed in 2023. 3. No documentation of corrective action performed was available. 4. According to the LD, if patient specimen tissue was not properly embedded, evidence of such would be observed during slide review. 5. LD confirmed findings on February 15, 2024, at 1:00 P.M.
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 review of the current, approved policies and procedures, lack of personnel

	training records, as well as interview with the LD, the LD failed to perform and document CC competency evaluation in compliance with applicable regulations. Refer to D5209 and D6107.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the current, approved policies and procedures, lack of personnel training records, as well as interview with the LD, the LD failed to draft and approve CC job duties and responsibilities. Refer to D5209.