Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0524801	11/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kelly W Hubbard Md Pc	2245 N 400 E, Ste 104, North Logan, UT	

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 lack of documentation and interview with staff, the laboratory failed to establish a written policy and procedures to assess employees performing Mohs frozen section testing from August 2018 to November 2019. The laboratory performed approximately 6 Mohs frozen sections per month. The laboratory employed two people to process and perform frozen section tests. Findings include: 1. The laboratory lacked documentation Mohs frozen section testing personnel were evaluated for testing competency twice annually from August 2018 to August 2019. (See D6127) 2. In an interview with staff on 11/24/2019 at approximately 12:30 P.M. staff confirmed the laboratory had not established a competency evaluation policy for Mohs frozen section specimen testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on patient record review, procedure manual review, lack of documentation, and interview with staff, the laboratory failed to ensure their procedure manual included specimen collection, labeling, processing, specimen acceptability and rejection criteria, step by step performance of the procedure, including interpretation of results, preparations of slides, reagents and stains,control procedures, panic or alert values if applicable, and pertinent literature references for Mohs surgery frozen section testing. 1. Patient testing records review included the laboratory started testing and reporting histopathology frozen section testing in August 2018. 2. Procedure manual review failed to include a procedure for Mohs frozen section processing and testing. 3. In an interview with staff on 11/14/2019 at approximately 12:45 P.M. staff stated the laboratory performed Mohs surgery testing and did not have an approved Mohs specimen testing procedure.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on lack of documentation, patient test records review, and interview with staff, the laboratory failed to document Hematoxylin and Eosin stain lot number, expiration dates and the dates the stains were in use from August 2018 to November 2019 to ensure reagents were not used past their expiration dates. The laboratory tested approximately 6 frozen specimen testing per month. Findings include: 1. The laboratory failed to document they recorded the H&E stain lot numbers, expiration dates and the period of time the stain reagents were in use. 2. Patient test records review include documentation patient tests were performed once per month from August 2018 to November 2019. 3. In an interview with staff on 11/14/2019 at approximately 12 :15 P.M. staff stated test records failed to include the H&E stain lot numbers and expiration dates of the stains.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer

	must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on lack of documentation, patient test records review, and interview with staff, the laboratory failed to verify Mohs frozen section testing accuracy and precision prior to reporting patient test results for Mohs tests performed from August 2018 to November 2019. The laboratory performed approximately 4 to 6 cases of Mohs frozen section analysis one day a month. Findings include: 1. The laboratory started reporting Mohs frozen section histology (dermatopathology) testing in August of 2018 as evidenced by patient case number 2018 -03 on 08/29/2019 for a basal cell carcinoma removal. 2. The laboratory failed to document test precision and accuracy prior to reporting patient test results on 08/29/2019. 3. In an interview conducted on 11 /14/2019 at approximately 12:50 P.M. staff stated they had started Mohs surgery frozen section testing and did not perform accuracy and precision studies to establish the test system's accuracy and precision performance specifications.
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 lack of documentation and interview with staff, the laboratory failed to establish cryostat function checks and maintenance protocols for the cryostat used for Mohs frozen section testing for 14 months of testing reviewed from August 2018 to November 2019. The laboratory performed testing one day per month using the Cryostat instrument to freeze and cut the frozen specimens into specimens thin enough for microscopic examination for the presence or absence of previously identified dermal tumors. Findings include: 1. The laboratory failed to document cryostat temperatures were within an established range for freezing Mohs tissue for optimum sections being cut on the microtome for mounting on glass slides. 2. The laboratory failed to have an established Cryostat maintenance program for the integrated Microtome oiling and cryostat defrosting. 3. In an interview with staff on 11 /14/2019 at approximately 12:30 P.M. staff confirmed the laboratory failed to establish a maintenance program for the cryostat since initiating Mohs frozen section testing in August of 2018.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to evaluate new testing personnel performing Mohs frozen section testing the first year of Mohs frozen section testing (August 2018 to November 2019). Findings include: 1. The laboratory failed to document the dermatologist performing histopathology testing for dermatology frozen section testing and the person performing tissue gross analysis were evaluated for competency twice annually from August 2018 to November 2019. 2. In an interview with staff on 11/14/2019 at approximately 12:45 P. M staff stated the new personnel performing Mohs specimen testing monthly were not evaluated for competency twice the first year of frozen section testing performance for Mohs surgery specimens. The laboratory performed approximately 72 cases per year. Each case included from 1 to 3 samples (Stages).