Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0524801	12/14/2022
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
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on patient test record review and interview with the Office Manager, the laboratory failed to retain test requisitions for Hematoxylin and Eosin (H&E) and special stain preparations for at least 2 years since the last survey that was conducted on 11/14/2019. The laboratory performed approximately 1700 histopathology tests annually. Findings include: 1. Review of patient test records failed to include requisition for 2 of 2 patients for H&E preparations that were performed on patient samples. 2. Staff confirmed during interview on 12/14/2023 at approximately 12:30 PM, that test requisitions for special stains are not retained for at least 2 years.
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 a review of Quality Assurance (QA) and Competency Assessment records for the Potassium Hydroxide (KOH) test and an interview with the Office Manager, the laboratory failed to have a system that annually evaluates the competency for 3 of 3 testing personnel who performed KOH testing during 2020, 2021, and 2022. The

	laboratory performs approximately 400 mycology annually. Findings include: 1. A review of QA and Competency Assessment records for the KOH test revealed that the laboratory failed to have a system that annually evaluates the competency for 3 of 3 testing personnel who performed KOH testing during 2020, 2021, and 2022. 2. In an interview at approximately 2:00 PM on 12/14/22, the Office Manager confirmed that the laboratory failed to have a system that annually evaluates the competency for 3 of 3 testing personnel who performed KOH testing during 2020, 2021 and 2022.
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 procedure manual, record review, and interview with the Office Manager, the laboratory failed to follow the procedure for running quality controls for Potassium Hydroxide (KOH) examination of skin, hair, or nails. Findings include: 1. Review of the procedure manual for KOH examinations revealed that positive and negative control samples should be analyzed each day the procedure is performed. 2. A review of laboratory records revealed the laboratory failed to include records of KOH controls were examined each day of patient testing since the last survey on 11/14 /2019. 3. An interview on 12/14/2022, at 2:15 PM, with the Office Manager confirmed the laboratory failed to perform control analysis each day patient specimens were examined for KOH preparations.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory failed to check quality controls for potassium hydroxide (KOH) for each new lot number and shipment of KOH reagent. The laboratory performs approximately 400 mycology annually. Finding include: 1. Record review on 12/14/2021 at approximately 1:45 PM, revealed that positive and negative controls were not tested with each new lot of KOH. 2. In an interview on 12/07/2021 at approximately 1:45 PM, the laboratory director confirmed that quality controls were not evaluated with each new lot of KOH.
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 stain quality control documentation, and interview with staff, the laboratory failed to document Hematoxylin and Eosin (H&E) and special stain quality controls. The laboratory performed approximately 1700 histopathology tests annually. Findings include: 1. The laboratory quality control records failed to include histopathology H&E stains and special stains quality control for 2020, 2021 and 2022. 2. The Laboratory Director confirmed during an interview on 12/14/2022 at approximately 2:25 PM, that the laboratory failed to record H&E stain and special stains quality controls each day of testing.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to list the correct address of the laboratory's location since the laboratory moved on 09 /06/2022. Findings Included: 1. Laboratory patient test reports stated the address of the laboratory as 2380 North 400 East, SUITE B, North Logan, Utah 84341. 2. At the time of the survey, the location of the laboratory was at 2245 N 400 E STE 104, North Logan, UT 84341. 3. Interview with the Office Manager on 12/14/2022 at 2:35 PM confirmed the patient final test report did not reflect the actual testing site of where testing was performed since the laboratory moved on 09/06/2022.
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 lack of documentation and interview with staff, the Laboratory Director failed to ensure a quality assessment plan was established to assure quality of laboratory services through the pre-analytical, analytical, and post-analytical phases.

	The laboratory performs approximately 1800 tests annually. Findings include: 1. The document review of the procedure manual failed to include a written Quality Assessment (QA) plan. 2. The Office Manager confirmed during an interview on 12 /14/2022 at approximately 3:05 PM, the laboratory did not have a written QA plan.