Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2040291	08/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kimberly U Hurvitz, Md Inc	2431 Castillo St, Santa Barbara, CA	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the surveyor's observations during the survey and an interview with laboratory's director and office manager; the laboratory failed to follow safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory failed to follow their safety policy and procedure to provide protection from physical, chemical, biochemical, and biohazardous materials as needed based on the laboratory's risk assessment. 2. Surveyor's observations during the tour and an interview with the OM indicated that the fire extinguisher was not serviced or checked for proper functioning for the past 4 years. 3. The safety of laboratory personnel and patients could not be assured at this time. 4. The annual testing declaration form submitted at the time of survey stated 920 samples were processed and reported for Dermatopathology, Mycology, and Parasitology during the time when safety concern for all personnel and patients could not be assured.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) (a)(7) Slide, block, and tissue retention-- (a)(7)(i) Slides. (a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). (a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination. (a)(7)(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination. (a)(7)(iii) Tissue. Preserve

	remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on the lack of update of policies and procedures reflecting the current practice, review of randomly selected patient test records, and interview with the office manager; the laboratory failed to provide an approved and signed policy and procedure for retention of documents and storage requirements. Findings include: 1. In reference to the retention requirements in 42 CFR Part 493.1105 (Standard Retention Requirements), the laboratory is herein cited for the deficient practice of lacking an approved and signed retention and storage requirements policy and procedure. 2. The OM stated during an interview on 8/7/2025 at approximately 3:30 p. m., that the laboratory does not have a policy and procedure for record retention and storage for: test results, test procedures, quality system assessment record, and Histopathology slides. 3. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory performed an estimated 920 patient samples during the time that no retention and storage policy and procedure was implemented.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the lack of a Quality Assurance plan (QA), review of the laboratory's policies and procedures, and interview with the office manager; the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. The findings include: 1. Based on the day survey on August 7, 2025, at approximately 2:30 p.m., no documentation could be retrieved by the laboratory to show that a written QA plan was in place for the years 2023, 2024, and 2025. 2. The OM confirmed by interview on August 7, 2025, at approximately 2:45 p.m., that the laboratory did not establish a QA plan to follow written policies and procedures reflecting the current practice for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. 3. According to the testing declaration submitted on the day of the survey 8/7/2025, signed and dated by the laboratory director, the laboratory performed annually 920 tests and diagnosis without an established, approved, signed and dated written QA plan.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 the lack of laboratory's written policies and procedures for KOH (yeast and fugal elements) and Sarcoptes scabiei (scabies) tests and an interview with the office manager (OM); the laboratory failed to have an established policy and procedure that met 493.1251. The findings include: 1. The surveyors' review of the policies and procedures showed that the laboratory lacked protocols for criteria and examples of micrographs for patient sample testing for KOH and scabies detection and diagnosis. 2. The OM affirmed on August 7, 2025, at approximately 2:30 p.m. that the laboratory lacked written policies and procedures for those tests mentioned in statement #1. 3. Based on the testing volume declaration submitted at the time of survey, the laboratory processed and reported approximately 15 KOH and 5 scabies samples annually for which the laboratory lacked written policies and procedures for KOH and scabies in patients' sample testing and criteria for satisfactory specimens.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, five (5) randomly selected Histopathology patient records, and interview with the office manager (OM); the laboratory failed to have an established and approved policy and procedure for corrective action. Findings include: 1. Based on the review of the policies and procedures, no corrective action policy or documentation log were found, including any criteria necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. 2. The OM affirmed by interview that the laboratory did not have a corrective action log for quality assessment that included the corrective action procedure as mentioned in statement #1. 3. Based on the testing declaration submitted at the time of the survey, the laboratory performed and reported 920 tests annually during the time that no corrective action policy and procedure was implemented; thus, the quality and accuracy of patient records cannot be assured.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on the surveyor's review of patient test records and interviews with the laboratory director (LD) and office manager (OM), the laboratory failed to maintain a system that identified the records and dates of all specimens tested, including the identities of the personnel who performed the test. Findings include: 1. Based on the

	interviews with the LD and OM at approximately 2:30 p.m. on August 7, 2025, it was determined that the practice of the laboratory is to directly enter the results of the testing directly into the patient chart. 2. Based on the findings during the patient test record review, it was found that the KOH (yeast and fungus elements) and Sarcoptes scabiei var hominis (scabies) test results were not recorded for date, patient name, source-location of the specimen, no signature or initials of the testing person who performed the test. In addition no patient log sheet was maintained for reagents used; KOH and mineral oil lot number, expiration date, type of quality control used, or competency of the person performing the tests. 3. The LD and OM affirmed by interview on August 7, 2025, at approximately 2:45 p.m. that the laboratory failed to keep documentation for every patient tested for KOH and scabies. 4. According to the laboratory testing declaration submitted at the time of the survey, the laboratory performed 15 KOH and 5 scabies tests annually during the time the laboratory failed to maintain a record system for all specimens tested, including the name of the person who performed the test.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures, lack of a quality assessment plan, randomly selected patient test records, and interview with the office manager on August 7, 2025, the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytical, analytic, and postanalytic phases of the laboratory testing were monitored. The findings include: D3011, D3043, D5291, D5401, D5779, and D5787.