Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0704813	01/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kristin K Walker Md, Inc	89 Davis Rd Ste 180, Orinda, 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
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 request for policy or procedures documents on day of survey January 2, 2018, the laboratory failed to establish 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. Findings include: a. Although the laboratory manager could verbalize corrective actions that that had been identified, and how the laboratory had corrected them; the laboratory did not have documented policies or procedures for an ongoing process to monitor and ensure that identified problems were successfully corrected. b. The laboratory manager affirmed this deficient practice on January 2, 2018 at approximately 10:30 am. c. The laboratory reports performing approximately 1985 histopathology slide reviews annually, and 15 KOH skin preparations annually.
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 request for laboratory polices or procedures on the day of survey January 2, 2018, the laboratory failed to have a procedure manual for the testing performed. Findings include: a. On the day of survey the laboratory manager verbally indicated the procedures as performed in the laboratory. b. The laboratory did not have an approved procedure manual for the subspecialty's performed in the laboratory, histopathology and mycology(KOH), or for quality assessment and monitoring. c. The laboratory manager affirmed the lack of written procedures for the testing performed in the laboratory. d. The laboratory reports performing approximately 2000 tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on request and review of the laboratorys testing Microscope on the day of Survey January 2, 2018, the laboratory failed to perform and document for unmodified manufacturer testing equipment function checks as indicated by the manufacturer. Findings include: a. The laboratory performs microscopic review of histopathology slides and KOH skin preparations. b. Although the microscope had the maintenance sticker on it, the dates of service were not documented on the sticker. The laboratory did not have documentation indicating when the last the function checks had been performed. c. This deficient practice was affirmed by the laboratory manger by interview on January 2, 2018 at approximately 11:00 am. d. The laboratory reports performing approximately 2000 microscopic tests annually.
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 review of the laboratory processes and the deficient practices cited, the laboratory director failed to ensure that quality assessment and documentation procedures are established for the laboratory personnel performing preanalytical, analytical and post analytical patient testing. Findings include: a. The laboratory does not have an approved policy or procedure manual for performing quality assurance monitoring. See D5291 b. The laboratory failed to ensure that functions checks were performed. See D5429
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

	This STANDARD is not met as evidenced by: Based on interview with the laboratory manager and the lack of documents available upon request on January 2, 2018, the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings include: a. On the day of survey the laboratory affirmed that they do not have a procedure manual for the testing performed in the laboratory. See D5401