Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2261023	05/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Us Dermatology Partners - Wichita	3730 N Ridge Road, Wichita, KS	

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
D0000	A routine recertification survey was conducted May 13-15, 2024. It was determined that Immediate Jeopardy existed for the following condition level deficiencies: 42 C.F.R. 493.1290 Condition: Postanalytic Systems 42 C.F.R. 493.1341 Condition: Laboratories Performing High Complexity Testing: Laboratory Director
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the lack of postanalytic procedures, lack of documented postanalytic processes, and patient test results within the EMR that did not match the test logs, the laboratory failed to monitor and evaluate overall quality of the post analytic system and correct problems identified in testing performed for each specialty and subspecialty. (Refer to D5801, D5891, D5893)
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to

	network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of three of three patient test records, electronic medical record reports (EMR), and interview with the office manager, the laboratory failed to have an adequate manual or electronic system(s) in place to ensure scabies preparation and potassium hydroxide (KOH) preparation test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. Findings: 1. Review of 1 scabies preparation, and 2 KOH preparation patient test records and electronic final test reports found 3 of 3 patient test results in the EMR did not match the laboratory patient test record. a. Scabies test log- 9/12/(no year entry). The test result showed a minus sign (negative), single entry. The EMR record from 9/12/22 showed the KOH prep was listed with "Examination of slide showed +/- results" for examinations of both left radial dorsal hand and right ulnar dorsal hand. Review of "Impression/Plan" reveals: "Scabies (B86)" b. KOH test log-6/28/22. The test result showed "negative." The EMR record for the KOH prep showed "Examination of slide showed: branching hyphae." c. KOH test log 10/2//22. The test result showed "negative." The EMR record showed no documentation of a KOH exam or test result. 2. Interview with the office manager on 5 /13/24 at 11:30 a.m. confirmed, the laboratory failed to have an adequate manual or electronic system(s) in place to ensure scabies preparation and potassium hydroxide (KOH) preparation test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based upon the lack of procedures, test log with results that did not correlate with the patient EMR, and interview with the office manager, the laboratory failed to have written policies and procedures for an ongoing process to monitor, assess, and correct problems in the postanalytic system. Findings: 1. The surveyor requested the post analytic quality assessment procedure after evidence was found of test logs and EMR records that did not match. 2. No postanalytic system procedure was available for review. 3. Interview with the office manager on 5/13/24 at 11:45 a.m. confirmed, the laboratory failed to have written policies and procedures for an ongoing process to monitor, assess, and correct problems in the postanalytic system.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of

	postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the lack of postanalytic review documentation, lack of corrective action (CA) documentation, and interview with the office mnager, the laboratory failed to document postanalytic quality assessment. Findings: 1. No postanalytic quality assessment documentation was available at the time of survey. 2. Interview with the office manager on 5/13/24 at 11:45 a.m. confirmed, the laboratory failed to document postanalytic quality assessment.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: The laboratory director (LD) failed to provide overall management and direction in accordance with 493.1445 (Refer to D6078, D6079, and D6094).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be

	qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on notification given on 5/10/24 for the survey scheduled on 5/13/24, lack of documentation, and interview with the office manager, the laboratory failed to have a laboratory director (LD) to provide overall operation and administration to the laboratory since 7/11/23. Findings: 1. No documentation was available to qualify a person for the position of LD for high complexity. 2. Interview with the laboratory manager on 5/10/24 and the office manager on 5/13/24 at 11:15 a.m. confirmed the laboratory failed to have a person in the position of LD since 7/11/23.
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 the review of the Form CMS-209, lack of 2022 and 2023 competency documentation for testing personnel (TP) #2, and interview with the office manager, the laboratory director (LD) failed to ensure that TP #2 was competent to perform patient testing in 2022 and 2023. Findings: 1. Based on the review of the Form CMS-209 revealed the LD and one other person were listed as TP. 2. No documentation for 2022 and 2023 competency assessments for TP#2 was available for review. 3. Interview with the office manager on 5/13/24 at 12:05 p.m. confirmed, the LD failed to ensure that TP#2 was competent to perform patient testing in 2022 and 2023.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Review of the test menu, lack of accuracy checks performed for 2022 and 2023 for histopathology testing, and interview with the office manager, the laboratory director (LD) failed to ensure acceptable levels of analytical performance. Findings: 1. Review of testing performed from 12/14/22 to 7/11/23 revealed 303 patient pathology reports

	were released. No documentation of accuracy checks were provided at the time of survey. 2. Interview with the office manager on 5/13/15 at 12:05 p.m. confirmed, the laboratory director failed to ensure acceptable levels of analytical performance for histopathology testing.