Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0452715	09/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Heartland Dermatology Center	1017 C Jackson Square, Great Bend, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's method accuracy verification documentation, and interview with Testing Personnel (TP) #5, the laboratory failed to verify the accuracy of the potassium hydroxide (KOH) Schwartz Lamkins examinations and Lactophenol Cotton Blue, which are not included in subpart I of this part. Findings Include: 1. Direct observation of the laboratory testing area on the date of survey at 3:45 PM found a bottle of Schwartz Lamkins stain and a bottle of Lactophenol Cotton Blue. TP #5 stated the testing personnel use these for fungal slide examinations. 2. Review of the laboratory's method accuracy verification documentation found no indication or documentation demonstrating the laboratory had included the Schwartz Lamkins slide examinations or Lactophenol Cotton Blue slide examinations in the twice annual verifications. 3. TP #5 stated they did not believe the laboratory had method accuracy verification documentation for the Schwartz Lamkins slide examinations or Lactophenol Cotton Blue slide examinations. The interview occurred 09/10/2018 at 3:52 PM.
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 direct observation and interview with Testing Personnel (TP) #5, the laboratory failed to ensure reagents and stains were used when they had exceeded their expiration date. Findings Include: 1. Direct observation of the laboratory testing area on the date of survey at 3:45 PM found a bottle of Lactophenol Cotton Blue with the lot number of K06A61 and expiration date of Oct 2009. 2. TP #5 confirmed the bottle of Lactophenol Cotton Blue located in the testing area was expired by 8 years and 10 months. The interview occurred 09/10/2018 at 3:54 PM.
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 direct observation and interview with Testing Personnel (TP) #5, the laboratory failed to test staining materials for intended reactivity to ensure predictable staining characteristics each day of use, to include both positive and negative reactivity. Findings Include: 1. Direct observation of the laboratory testing area on the date of survey at 3:45 PM found a bottle of Schwartz Lamkins stain and a bottle of Lactophenol Cotton Blue. TP #5 stated the testing personnel use these for fungal slide examinations. 2. The Surveyor requested the laboratory's quality control (QC) documentation from TP #5. TP #5 stated they did not think the laboratory performed or documented stain QC for the Schwartz Lamkins or Lactophenol Cotton Blue stains. The interview occurred 09/10/2018 at 3:56 PM
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 the laboratory's patient test records, electronic final test reports, and interview with Testing Personnel (TP) #5, the laboratory failed to have an adequate manual or electronic system(s) in place to ensure wet preparation, 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 Include: 1. Review of 12 wet preparation, scabies preparation, and KOH preparation patient test records and electronic final test reports found 6 out of 12 patient test results were

	inaccurately transcribed as follows: 04/05/2018 @ 2:02 PM Test Record: Result: False - Final Test Report: Examination of the slide showed: +/- results 01/16/2018 @ 1:56 PM Test Record: Result: BLANK Final Test Report: Showing no mites, stool, or ova 10/24/2017 @ 12:45 PM Test Record: L abdomen, L Flank Result: + Final Test Report: L abdomen Showing branching hyphae 09/27/2017 @ 1:36 PM Test Record: Result: +/- Final Test Report: Showing +/- results **Please note: a KOH cannot be resulted as +/- yeast is either present or absent.** 08/21/2017 @ 1:43 PM Test Record: Lower Back/Abdomen Final Test Report: Performed on the periumbilical skin. 06/14/2017 @ 9:26 AM Test record: Scabies preparation performed on the back, L & R hand Result: + Final Test Report: No scabies preparation performance or results documented. 2. TP #5 confirmed the missing locations, inaccurate transcriptions, missing results, and inaccurate results listed above at 3:04 PM.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with Testing Personnel (TP) #5, the Technical Consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity wet preparation, scabies preparation, and potassium hydroxide (KOH) testing at least annually after the first year the individual tests patient specimens. Findings Include: 1. TP #5 stated TP #2, 3 and 4 perform moderate complexity wet, scabies, and KOH preparation slide examinations. The interview occurred 09/10/2018 at 2:28 PM. 2. Review of the laboratory's policies and procedures failed to find a competency assessment policy and procedure for TP that perform moderate complexity testing. 3. The Surveyor requested competency assessment documentation for TP #2, 3, and 4 from TP #5. TP #5 stated the laboratory did not have any competency assessment documentation for TP #2, 3, and 4. The interview occurred 09/18/2018 at 2:32 PM.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with Testing Personnel (TP) #5, the Technical Consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity wet preparation, scabies preparation, and potassium hydroxide (KOH) testing at least annually after the first year the individual tests patient specimens. Findings Include: 1. TP #5 stated TP #2, 3 and 4 perform moderate complexity wet, scabies, and KOH preparation slide examinations. The interview occurred 09/10/2018 at 2:28 PM. 2. Review of the laboratory's policies and procedures failed to find a competency assessment policy and procedure for TP that perform moderate complexity testing. 3.

	The Surveyor requested competency assessment documentation for TP #2, 3, and 4 from TP #5. TP #5 stated the laboratory did not have any competency assessment documentation for TP #2, 3, and 4. The interview occurred 09/18/2018 at 2:32 PM.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)

	(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of documentation of education and interview with Testing Personnel (TP) #5, the laboratory failed to ensure individuals performing high complexity histopathology grossing, to include specimen marking and orientation, were qualified. Findings Include: 1. TP #5 stated that TP #5 and 7 perform tissue orientation and marking prior to specimen processing. The interview occurred 09/10/2018 at 2:40 PM. 2. TP #5 stated that TP #5 and 5 were certified medical assistants but did not have an Associate's, Bachelor's, or Master's degree in a science. No college transcripts were provided to the Surveyor for assessment of college science semester hours. The interview occurred 09/10/2018 at 2:40 PM.