

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1084575	(X3) Date Survey Completed 04/22/2024
Name of Provider or Supplier Keystone Derm Ctr For Skin Surg Llc	Street Address, City, State 2525 9th Avenue Suite 2a, Altoona, PA	
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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Supervisor (LS), the laboratory failed to verify twice annually the accuracy of the microscopic examinations performed in Microbiology from 09/12/2022 through the date of the survey. Findings include: 1. The laboratory's procedures for Wright's Giemsa Tzanck Smear and Scabies Preparation state, "A blind peer review will be performed biannually for each qualified persons performing the test." 2. On the day of survey, 04/22/2024 at 12:12 pm, the laboratory could not provide documentation of the twice annual verification of accuracy (peer review) of microscopic examinations performed for virology (Tzack smear) and parasitology (scabies) from 09/12/2022 through 04/22/2024. 3. The LS verified a total of 2 Tzanck smear and 58 scabies microscopic examinations were performed in the laboratory from 09/12/2022 through 04/22/2024. 4. The LS confirmed the findings above on 04/22/2024 at 1:11 pm. *REPEAT DEFICIENCY*</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
Based on lack of quality control (QC) records and interview with the Laboratory Supervisor (LS), the laboratory failed to include a positive and negative control each day of patient testing for microscopic examinations performed in Virology and Parasitology from 09/12/2022 to the day of survey. Findings include: 1. The laboratory's Wright's Giemsa Tzanck Smear procedure states, "All providers will evaluate an example (photograph) of a positive (+) Tzanck smear; this will be done before evaluating the patient slide." 2. The laboratory's Scabies Preparation procedure states, "All providers will evaluate an example (photograph) of a positive scabies slide; This will be done before evaluating the patient slide." 3. On the day of survey, 04/22/2024 at 12:20 pm, the laboratory could not provide documentation of the negative and positive control performed for the microscopic examinations in virology (Tzanck smear) and parasitology (scabies) from 09/12/2022 to 04/22/2024. 4. The LS verified a total of 2 Tzanck smear and 58 scabies microscopic examinations were performed in the laboratory from 09/12/2022 through 04/22/2024. 5. The LS confirmed the findings above on 04/22/2024 at 1:11 pm.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the Laboratory Supervisor (LS), the Technical Consultant (TC) (CMS 209 personnel #1) failed to evaluate and document, at least semiannually during the first year, the performance of 1 of 6 Testing Personnel (TP) who performed scabies microscopic examinations from 04/03/2023 to date of survey. Findings include: 1. On the day of survey 04/22/2024 at 12:38 pm, the laboratory could not provide documentation of the six month competency assessment of TP# 6 (CMS 209 personnel #6) who performed scabies microscopic examinations from 04/03/2023 to 04/22/2024. 2. The laboratory reported an annual test volume of 37 for Microbiology. (CMS-116) 3. The LS confirmed the above findings on 04/22/2024 at 1:11 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 lack of documentation and interview with the Laboratory Supervisor (LS), the Technical Consultant (TC) (CMS 209 personnel #1) failed to evaluate and document the annual competency of 4 of 5 Testing Personnel (TP) who performed microscopic examinations in Microbiology in 2022 and 2023. Findings include: 1. On the day of survey 04/22/2024 at 12:38 pm, the laboratory could not provide documentation of the annual competency assessment for the following TP who

performed Wright's Giemsa Tzanck smear and Scabies microscopic examinations in 2022 and 2023: - TP #2 (CMS 209 personnel #2) - TP#3 (CMS 209 personnel #3) - TP #4 (CMS 209 personnel #4) - TP #5 (CMS 209 personnel #5) 2. The laboratory reported an annual test volume of 37 for Microbiology. (CMS-116) 3. The LS confirmed the above findings on 04/22/2024 at 1:11 pm.