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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D2110303 | (X3) Date Survey Completed 09/09/2020 |
| Name of Provider or Supplier Dermatology Physicians, Inc https://Web.Qiesnet.Org | Street Address, City, State 1613 Oregon Pike, Lancaster, 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 |
|---------------------------|--|
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessment policy, competency assessment records and interview with the nursing supervisor (NS), the laboratory failed to follow their competency assessment procedure to assess the competency of 1 of 2 clinical consultants in 2019. Findings Include: 1. The competency assessment policy states, "Staff who hold CLIA supervisor positions: General supervisor, technical consultant, technical supervisor, or clinical consultant will be assessed annually for their supervisory competence in addition to laboratory testing competence, if performing testing samples." 2. On the day of survey, 09/09/2020, the laboratory could not provide competency assessment records for 1 of 2 clinical consultants, for their supervisory responsibilities in 2019. 3. The NS confirmed the findings above on 09/09/2020 around 12:45 pm.</p> |
| 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 review of KOH/ wet mount peer review records and interview with the nursing supervisor (NS), the laboratory failed to ensure 4 of 5 testing personnel (TP)</p> |

performed in the verification of accuracy for KOH/ wet mount examinations analyzed in 2018, 2019 and 2020. Findings Include: 1. On the day of survey, 09/09/2020, the NS could not provide peer review records performed onsite for 4 of 5 TP analyzing KOH/ wet mount examination in 2018, 2019 and 2020. 2. The NS confirmed the finding above on 09/09/2020 around 1:05 pm. ***KOH = Potassium Hydroxide

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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.

This STANDARD is not met as evidenced by:

Based on review of KOH/ wet mount examination quality control (QC) records and interview with the nursing supervisor (NS), the laboratory failed to document QC procedures each day of patient testing for 40 of 50 KOH/ wet mount examinations analyzed from 2019 to 2020. Findings Include: 1. On the day of survey, 09/09/2020, review of KOH/wet mount examination QC records revealed, the laboratory did not document QC procedures for KOH/ wet mount examinations each day of patient testing for 32 of 36 patient specimen analyzed in 2019 and 8 of 14 patient specimen analyzed in 2020. 2. In 2019, 36 KOH/ wet mount examinations were analyzed. 3. In 2020, 14 KOH/ wet mount examinations were analyzed. 4. The NS confirmed the findings above on 09/09/2020 around 1:00 pm. *** = Potassium Hydroxide
****Repeat Deficiency****

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 review of testing personnel (TP) competency assessment records and interview with the nursing supervisor (NS), the technical consultant (laboratory director) failed to evaluate and document the performance of 1 of 4 TP analyzing KOH and wet mount examinations at least semiannually during the first year in 2020. Findings Include: 1. On the day of survey, 09/09/2020, review of TP #4 (1 of 4 TP) competency assessment records revealed, TP#4 was not assessed at least semiannually during the first year of testing patient specimens for KOH and wet mount examinations. 2. TP# 4 was initially assessed for competency on 08/12/2019 and not again until 08/04/2020. 3. The NS confirmed the findings above on 09/09/2020 around 12:40 pm. ***KOH = Potassium Hydroxide