| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 14D2058078 | 12/04/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pinnacle Dermatology | 595 William Latham Senior Dr, Bourbonnais, IL | |

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 |
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| **D5219** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(2)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, lack of documentation and interview with the laboratory manager (LM), the laboratory failed to perform bi-annual evaluations of direct wet mount preparation of parasitology analyte scabies testing performed in 2024. Findings include: 1. Review of the "CLIA #14D2058078 KOH LOG" revealed two scabies patient tests performed in 2024. MRN: A9070259 DATE: 11/07/2024 MRN: A9081723 DATE: 11/07/2024 2. Review of laboratory records and lack of documentation revealed no bi-annual evaluations of scabies testing was performed in 2024. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory records, lack of documentation and interview with the |

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| | laboratory manager (LM), the laboratory failed to ensure the laboratory procedure manual included documentation of the test procedure for direct wet mount preparation of parasitology analyte scabies for two of two patient tests performed in 2024 (refer to D5401); the laboratory failed to document quality control procedures performed for five of five days of mycology potassium hydroxide (KOH) testing in 2024 (refer to D5485); the laboratory failed to retain documentation of KOH patient test logs for two of two years 2022 and 2023 (refer to D5787). |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, lack of documentation and interview with the laboratory manager (LM), the laboratory failed to establish a test procedure for direct wet mount preparation of parasitology analyte scabies for two of two patient tests performed in 2024. Findings include: 1. Review of the "Pinnacle Dermatology" procedure manual and lack of documentation revealed the laboratory failed to establish a test procedure for the direct wet mount preparation of scabies. 2. Review of the "CLIA #14D2058078 KOH LOG" revealed six KOH patient tests performed in 2024. MRN: MM0000323359 DATE: 06/20/2024 MRN: A548115 DATE: 08/29 /2024 MRN: A9237644 DATE: 09/19/2024 MRN: A9070259 DATE: 11/07/2024 MRN: A9081723 DATE: 11/07/2024 MRN: A301771 DATE: 11/21/2024 3. Review of the patient visit notes of the MRNs listed in Finding 2 revealed scabies testing was performed for two of six patients tested. a) MRN: A9070259 VISIT NOTE DATE: 11 /07/2024 - Scabies (B86) distributed on the right superior upper back and right dorsal foot. b) MRN: A9081723 VISIT NOTE DATE: 11/07/2024 - Associated diagnosis: Scabies 4. On 12/04/2024, at 12:37 p.m., the LM stated the lab does not have a procedure for performing scabies testing. |
| **D5485** | CONTROL PROCEDURES<br>CFR(s): 493.1256(h)<br><br>If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, lack of documentation and interview with the laboratory manager (LM), the laboratory failed to document quality control procedures performed for five of five days of mycology potassium hydroxide (KOH) testing in 2024. Findings include: 1. Review of the "Pinnacle Dermatology KOH Procedure Protocol" revealed the following information: "6 ...Document on the KOH log form the control slide details including lot # and exp date ...8. Following examination by the provider, another provider is asked to blindly read the KOH specimen (and control, if applicable) and verify the appropriate presence or absence of spores or hyphae. The results are documented on the KOH log form." 2. Review of |

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| | the "CLIA #14D2058078 KOH LOG" and lack of documentation revealed no quality control procedure documentation for five of five KOH patient test dates in 2024. MRN: MM0000323359 DATE: 06/20/2024 MRN: A548115 DATE: 08/29/2024 MRN: A9237644 DATE: 09/19/2024 MRN: A9070259 DATE: 11/07/2024 MRN: A9081723 DATE: 11/07/2024 MRN: A301771 DATE: 11/21/2024 3. On 12/04/2024, at 1:35 p.m., the LM stated the laboratory did not ensure KOH quality control procedures were documented. |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, lack of documentation and interview with the laboratory manager (LM), the laboratory failed to retain documentation of mycology potassium hydroxide (KOH) patient test logs for three of three years 2022, 2023 and 2024. Findings include: 1. Review of the "Pinnacle Dermatology KOH Procedure Protocol" revealed the following information: "6 ...Document on the KOH log form the control slide details including lot # and exp date. 7. Documentation of the presence (POSITIVE) or absence (NEGATIVE) of spores or hyphae is recorded in the patient's chart, along with the site from where the specimen was obtained. 8. Following examination by the provider, another provider is asked to blindly read the KOH specimen (and control, if applicable) and verify the appropriate presence or absence of spores or hyphae. The results are documented on the KOH log form." 2. Review of laboratory records revealed no documentation of KOH test logs for two of two years, 2022 and 2023. 3. Review of the "CLIA #14D2058078 KOH LOG" and patient visit notes revealed the laboratory failed to document KOH test results for one of six patient tests in 2024. MRN #: A9237644 KOH LOG DATE: 09/19/2024 - Right medial ankle - NOT INDICATED ON LOG VISIT NOTE DATE: 09/19/2024 - Fungal Hyphal Elements - NEGATIVE 4. On 12/04/2024, at 10:46 a.m., the LM stated due to a change in management the lab failed to retain KOH logs for testing years 2022 and 2023. |
| **D5800** | POSTANALYTIC SYSTEMS<br>CFR(s): 493.1290<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory records and interview with the laboratory manager |

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| | (LM), the laboratory failed to ensure accurate and reliable mycology potassium hydroxide (KOH) test results reported for four of six patient test reports in 2024 (refer to D5801). |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records and interview with the laboratory manager (LM), the laboratory failed to ensure accurate and reliable mycology potassium hydroxide (KOH) test results were reported for four of six patient test reports in 2024. Findings include: 1. Review of the "Pinnacle Dermatology KOH Procedure Protocol" revealed the following information: "7. Documentation of the presence (POSITIVE) or absence (NEGATIVE) of spores or hyphae is recorded in the patient's chart, along with the site from where the specimen was obtained. 8. Following examination by the provider, another provider is asked to blindly read the KOH specimen (and control, if applicable) and verify the appropriate presence or absence of spores or hyphae. The results are documented on the KOH log form." 2. Review of the "CLIA #14D2058078 KOH LOG" revealed six KOH patient tests performed in 2024. MRN: MM0000323359 DATE: 06/20/2024 MRN: A548115 DATE: 08/29/2024 MRN: A9237644 DATE: 09/19/2024 MRN: A9070259 DATE: 11/07/2024 MRN: A9081723 DATE: 11/07/2024 MRN: A301771 DATE: 11/21/2024 3. Review of the patient visit notes of the MRNs listed in Finding 1 revealed the laboratory failed to ensure accurate and reliable KOH test results for four of six patient tests. a) MRN #: A548115 KOH LOG DATE: 08/29/2024 - Upper leg - NEGATIVE VISIT NOTE DATE: 08/29/2024 - Fungal Hyphal Elements - POSITIVE b) MRN #: A9237644 KOH LOG DATE: 09/19/2024 - Right medial ankle - NOT INDICATED ON LOG VISIT NOTE DATE: 09/19/2024 - Fungal Hyphal Elements - NEGATIVE c) MRN #: A9081723 KOH LOG DATE: 11/07/2024 - POSITIVE VISIT NOTE DATE: 11/07/2024 - NO KOH REPORTED d) MRN #: A301771 KOH LOG DATE: 11/21/2024 - R Hand - POSITIVE VISIT NOTE DATE: 11/21/2024 - NO KOH REPORTED 4. On 12/04/2024, at 1:35 p.m., the LM stated the laboratory did not ensure KOH patient test results were verified and accurately reported. |