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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D0911386 | (X3) Date Survey Completed 09/11/2023 |
| Name of Provider or Supplier Pinnacle Dermatology Brighton | Street Address, City, State 6888 Grand River Avenue, Brighton, MI | |
| 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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| D3031 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician, the laboratory failed to retain its cryostat temperature monitoring documentation at least two years for 6 (January 2022 to June 2022) of 24 months reviewed. Findings include: 1. A review of the laboratory's cryostat temperature monitoring documentation revealed a lack of documentation between January 2022 and June 2022. 2. An interview on 9/12/23 at 4:15 pm with the Mohs Technician confirmed the cryostat temperature monitoring documentation from January 2022 to June 2022 was not available.</p> |
| D5008 | <p>PARASITOLOGY CFR(s): 493.1204</p> <p>If the laboratory provides services in the subspecialty of Parasitology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1264, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to establish competency assessment policies to assess testing personnel performing scabies testing (refer to D5209) and establish policies and procedures for its scabies testing (refer to D5401).</p> |
| D5209 | PERSONNEL COMPETENCY ASSESSMENT POLICIES |

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Laboratory Director, the laboratory failed to establish competency assessment policies to assess testing personnel performing scabies testing for 2 (one previously employed testing personnel and Testing Personnel #5) 5 testing personnel. Findings include: 1. A review of the laboratory's "KOH Log" revealed scabies testing was performed for four patients between January 2023 and August 2023 by one previously employed testing personnel and Testing Personnel #5. 2. An interview on 9/12/23 at 2:27 pm with the Laboratory Director revealed testing personnel had not been assessed for their competency for scabies testing.

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 record review and interview with the Laboratory Director, the laboratory failed to perform verification of accuracy testing at least twice annually for its Potassium Hydroxide (KOH) preparation testing in 2022. Findings include: 1. A review of the laboratory's "Potassium Hydroxide (KOH)" policy revealed a section titled "Quality Control Procedures" stating, "Semi-annually test one patient in duplicate and have a second provider (MD, RN, PA) examine specimen as well. This should be testing personnel listed on CMS form 209." 2. A review of the laboratory's "KOH Log secondary evaluation to be completed semiannually" log revealed a lack of documentation showing the laboratory verified the accuracy of its KOH preparation testing in 2022. 3. An interview on 9/12/23 at 4:15 am with the Mohs Technician confirmed the laboratory did not have documentation of twice annual verification of accuracy testing for its KOH preparation testing in 2022.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Laboratory Director, the laboratory failed to establish policies and procedures for its scabies testing since testing began on 11/9/22. Findings include: 1. A review of the laboratory's "KOH log" revealed four patients had been tested for scabies between 11/18/22 and 6/13/23. 2. The surveyor

requested the laboratory's scabies test procedure on 9/12/23 at 4:15 pm and it was not made available. 3. An interview on 9/12/23 at 4:15 pm with the Mohs Technician confirmed the laboratory did not establish a scabies test procedure.

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 observation and interview with the Mohs Technician, the laboratory failed to ensure its tissue marking dye had not exceeded its expiration date since 8/31/23. Findings include: 1. The surveyor observed Blue Tissue Marking dye with the expiration date of 8/31/23 on 9/12/23 at 2:16 pm during a tour of the laboratory. 2. An interview on 9/12/23 at 2:16 pm with the Mohs Technician confirmed the Blue Tissue Marking dye had been expired.

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:
. A. Based on record review and interview with the Mohs Technician, the laboratory failed to ensure the anatomical site was accurately documented on the test report for 1 (Patient M22-253) of 7 patients reviewed. Findings include: 1. A review of patient test records revealed Patient M22-253 had mohs surgery histopathology testing performed on 9/13/22 with the site of "Nose" listed on the mohs surgery map and "Nasal Dorsum" listed on the visit note and the biopsy test report prior to mohs surgery. 2. An interview on 9/12/23 at 3:41 pm with the Mohs Technician confirmed the sites "Nose" and "Nasal Dorsum" were used interchangeably for the same site for the patient listed above. B. Based on record review and interview with the Mohs Technician, the laboratory failed to ensure results for a Potassium Hydroxide (KOH) preparation test were accurately entered in the final report for 4 (Patients #1-#4) of 4 KOH testing patients reviewed. Findings include: 1. A review of the laboratory's "Potassium Hydroxide (KOH)" policy revealed a section titled "Diagnosis Value" stating, "Superficial fungal disease or dermatophytosis of the skin, hair, nails including Candidiasis, Tinea Versicolor, Chromomycosis, and fiberglass dermatitis are commonly diagnosed using the KOH exam." 2. A review of patient test records revealed the following patients had KOH testing performed or ordered had missing or discrepant results on the test reports: a. Patient #3 had KOH preparation testing performed and documented on the KOH log on 2/24/22. No results were indicated on

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| | <p>the patient test report. b. Patient #2 had KOH preparation testing performed on 8/11/22 with the result of "branching hyphae" and "the KOH Slide was NEGATIVE" on the same test report. c. Patient #1 had KOH preparation testing ordered on 11/18/22 with the result of "scabies." d. Patient #4 had KOH preparation testing ordered on 6/3/23 with the result of "no mites or scybala." 3. An interview on 9/12/23 at 4:15 pm with the Mohs Technician confirmed the patient test reports above with KOH preparation testing performed or ordered had missing or discrepant results.</p> |
| <p>D6000</p> | <p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews, the Laboratory Director failed to ensure a quality assessment program was established to include its Potassium Hydroxide (KOH) preparation and scabies testing (refer to D6021), ensure results for Potassium Hydroxide (KOH) preparation tests were accurately entered in the final report (refer to D6026), ensure competency assessment policies were established to assess testing personnel performing scabies testing (refer to D6029), and ensure policies or procedures for its scabies testing had been established and approved (refer to D6031).</p> |
| <p>D6021</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician, the laboratory failed to ensure a quality assessment program was established to include its Potassium Hydroxide (KOH) preparation and scabies testing for 2 (September 2021 to September 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's quality assessment documentation revealed a lack of a documentation of quality assessments performed for its KOH preparation and scabies testing between September 2021 and September 2023. 2. An interview on 9/12/23 at 4:15 pm with the Mohs Technician confirmed a process for quality assessments for KOH preparation and scabies testing had not been established.</p> |
| <p>D6026</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)</p> <p>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, and record and report test results promptly, accurate, and proficiently</p> |

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the Laboratory Director failed to ensure results for Potassium Hydroxide (KOH) preparation tests were accurately entered in the final report. Refer to D5801 B.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the Laboratory Director failed to ensure competency assessment policies were established to assess testing personnel performing scabies testing. Refer to D5209.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

. Based on record review and interview, the Laboratory Director failed to ensure policies or procedures for its scabies testing had been established and approved. Refer to D5401.