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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 51D2142639 | (X3) Date Survey Completed 09/15/2020 |
| Name of Provider or Supplier Dermatology Associates & Surgery Center | Street Address, City, State 1401 Hospital Drive Suite 101, Hurricane, WV | |
| 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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| D0000 | An announced, on-site CLIA recertification survey was conducted at Dermatology Associates and Surgery Center on September 15, 2020 by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the CLIA regulations under 42 CFR 493. Specific deficiencies are explained below. |
| 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 policies and procedures, personnel competency records, and interview with the laboratory supervisor, the laboratory failed to establish and follow written policies and procedures for the assessment of employee and consultant competency. Findings: 1. During review of the Moh's Log Book, competency assessments for four employees who are Moh's assistants were found. 2. No record of competency assessment was found for the Clinical Consultant (CC), Technical Supervisor (TS), General Supervisor (GS), or for the two physicians who are Testing Personnel (TP). 3. No record of a written policy or procedure for assessing employee competency was found during the procedure manual review. 4. During review of the Job Description for the Laboratory Director, a duty was found listed under section 12 that states, "[Laboratory director will] Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently. Also, whenever necessary, identify the need for remedial training or continuing education to improve skills." 5. Upon interview with the laboratory supervisor on 9/15/2020 at approximately 10:30am, the laboratory</p> |

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| | <p>supervisor stated that no written policy exists for the competency assessment of personnel.</p> |
| D5291 | <p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory policies and procedures, quality assurance records, and interview with the laboratory supervisor, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the general laboratory systems. Findings: 1. During review of the policies and procedures manual, no quality assurance (QA) policy or procedure could be located. 2. Review of the quality assurance forms found that an adequate review of the preanalytic, analytic, and postanalytic phases of testing on a monthly basis. There was no section on the form for general laboratory systems. 3. During interview with the laboratory supervisor on 9/15/2020 at approximately 10:35am, the laboratory supervisor stated that no written QA policy or procedure has been established and that general laboratory systems are not assessed with the monthly QA.</p> |
| D5391 | <p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory policies and procedures, quality assurance records, and interview with the laboratory supervisor, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the preanalytic system. Findings: 1. During review of the policies and procedures manual, no quality assurance (QA) policy or procedure could be located. 2. Review of the quality assurance forms found that an adequate review of the preanalytic, analytic, and postanalytic phases of testing occurs on a monthly basis. 3. During interview with the laboratory supervisor on 9/15/2020 at approximately 10:35am, the laboratory supervisor stated that no written QA policy or procedure had been established.</p> |
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if</p> |

applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a tour of the laboratory and interview with the laboratory supervisor, the laboratory failed to ensure the accurate monitoring of the laboratory (2) temperatures and (3) humidity. Findings: 1. Tour of the laboratory conducted on 9/15/2020 at approximately 9:50am found the traceable room temperature thermometer calibration had expired in October of 2019. 2. During the same tour, it was found that the Cryostat external traceable thermometer calibration had expired in July of 2020. 3. During interview with the laboratory supervisor at approximately 9:55am, the laboratory supervisor stated that the laboratory was unaware that the thermometers had expired calibrations.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory policies and procedures, quality assurance records, and interview with the laboratory supervisor, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic system. Findings: 1. During review of the policies and procedures manual, no quality assurance (QA) policy or procedure could be located. 2. Review of the quality assurance forms found that an adequate review of the preanalytic, analytic, and postanalytic phases of testing occurs on a monthly basis. 3. During interview with the laboratory supervisor on 9/15/2020 at approximately 10:35am, the laboratory supervisor stated that no written QA policy or procedure had been established.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory policies and procedures, quality assurance records, and interview with the laboratory supervisor, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the postanalytic system. Findings: 1. During review of the policies and procedures manual, no quality assurance (QA) policy or procedure could be located. 2. Review of the quality assurance forms found that an adequate review of the preanalytic, analytic, and postanalytic phases of testing occurs on a

monthly basis. 3. During interview with the laboratory supervisor on 9/15/2020 at approximately 10:35am, the laboratory supervisor stated that no written QA policy or procedure had been established.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, competency assessment records, and interview with the laboratory supervisor, the laboratory director failed to ensure the establishment of policies or procedures for determining employee and consultant competency. Findings: 1. Review of the Moh's Log Book demonstrated competency assessments for four employees who are Moh's assistants. 2. No record of competency assessments was found for the Clinical Consultant (CC), Technical Supervisor (TS), General Supervisor (GS), or for the two physicians who are Testing Personnel (TP). 3. No record of a written policy or procedure for assessing employee competency was found. 4. Review of the Job Description for the Laboratory Director found a duty listed under section 12 that states, "[Laboratory director will] Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently. Also, whenever necessary, identify the need for remedial training or continuing education to improve skills." 5. Upon interview with the laboratory supervisor on 9/15/2020 at approximately 10:30am, the laboratory supervisor stated that no written policy or procedure exists for the competency assessment of personnel.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview with the laboratory supervisor, the director failed to specify, in writing, the responsibilities and duties of the Technical Supervisor (TS) and Testing Personnel (TP). Findings: 1. Review of the Moh's Procedure Manual demonstrated job descriptions for the Laboratory Director, General Supervisor, and Clinical Consultant. No job description

was found for the Technical Supervisor or Testing Personnel. 2. During an interview with the laboratory supervisor on 9/15/2020 at approximately 10:35am, the laboratory supervisor stated that no job descriptions exist for the TS and TP.