

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D1102295	(X3) Date Survey Completed 11/14/2023
Name of Provider or Supplier Integrated Dermatology Of Montrose, Llc	Street Address, City, State 3480 Wolverine Dr, Ste F, Montrose, CO	
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
D5028	<p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the laboratory failed to establish and follow written policies and procedures to assess the competency of the Clinical Consultant (CC), Technical Supervisor (TS) and General Supervisor (GS) (refer to D5209), failed to perform twice annual verification testing for: Potassium Hydroxide (KOH) preparations and MART-I immunohistochemical (IHC) testing (refer to D5217), failed to establish and document the acceptable temperature range for the refrigerator storing MART-I IHC reagents at least daily (refer to D5413), failed to label a liquid filled staining jar with the identity, storage requirements, preparation or expiration dates (refer to D5415), failed to ensure that the MART-I IHC stain was verified for performance prior to the start of patient testing (refer to D5421), and failed to document Quality Control (QC) each time of use for the MART-I IHC stain (refer to D5601). The laboratory performs approximately 250 histopathology tests annually.</p>
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:</p>

Based on review of the laboratory's policies and procedures manual, and an interview with the office manager, the laboratory failed to establish and follow written policies and procedures to assess the competency of the Clinical Consultant (CC), Technical Supervisor (TS) and General Supervisor (GS) since the laboratory's last survey on 4/28 /2021. The laboratory conducts a total of approximately 250 histopathology tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that the laboratory failed to establish and follow written policies and procedures to assess the competency of one out one of the clinical consultants (CC), one out of one of the technical supervisors (TS) and, one out of one of the general supervisors (GS) listed on the CMS-209 Form. The laboratory conducts a total of approximately 250 histopathology tests annually. 2. Based on an interview with the office manager, on November 14, 2023, at approximately 10:15 AM, confirmed that the laboratory failed to assess the competency of or establish a written policy or procedure for assessing the competency of personnel in the positions of CC, TC, and GS.

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 records review and an interview with the office manager (not included on CMS-209), the laboratory failed to perform twice annual verification testing for: Potassium Hydroxide (KOH) preparations and MART-I immunohistochemical (IHC) testing since the last survey was conducted on 4/28/2021. The laboratory performs approximately 250 Mohs histopathology and MART-I IHC procedures, approximately 50 KOH preparations per year. Findings include: 1. Records review revealed that the laboratory failed to perform twice annual accuracy verification for MART-I IHC slide interpretation, and KOH preparations since the last survey was conducted on 4/28 /2021. 2. An interview with the office manager (not included on CMS-209 form) at approximately 10:45 AM on November 14, 2023, confirmed that the laboratory failed to perform twice annual accuracy verification for MART-I IHC slide interpretation, and KOH preparations since the last survey was conducted on 4/28/2021.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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 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 records review, a review of the laboratory's policies and procedures, and an interview with the office manager (not included on CMS-209), the laboratory failed to establish and document the acceptable temperature range for the refrigerator storing

MART-I immunohistochemical (IHC) reagents at least daily since the last survey was conducted on 4/28/2021. The laboratory performs approximately 250 histopathology tests annually. Findings include: 1. Records review revealed that the laboratory failed to establish and document an acceptable temperature range for the refrigerator storing the MART-I IHC stain at least daily. 2. A review of the laboratory's policies and procedures manual revealed no policy or procedure was written for the MART-I IHC stain. 3. An interview with the office manager (not included on CMS-209) at approximately 10:50 AM on November 14, 2023, confirmed that the laboratory did not have a written policy or procedure for the IHC stain, did not establish or document an acceptable temperature range for the refrigerator storing the MART-I IHC stain at least daily since the last survey was conducted on 4/28/2021.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on direct observation, and an interview with the office manager (not included on CMS-209), the laboratory failed to label a liquid filled staining jar with the identity, storage requirements, preparation or expiration dates of the reagent contained within for MART-I immunohistochemical (IHC) staining. The laboratory performs approximately 250 histopathology tests annually. Findings include: 1. Based on direct observation of the laboratory on November 14, 2023 at approximately 09:10 AM, revealed the laboratory failed to label a liquid filled staining jar with the identity, storage requirements, preparation or expiration dates of the reagent contained within for the MART-I IHC staining procedure. 2. Based on an interview with the office manager (not included on CMS-209) at approximately 10:40 AM, on November 14, 2023, confirmed the laboratory failed to label a staining jar with the identity, storage requirements, preparation or expiration dates of the reagent contained within for the MART-I IHC staining procedure.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based a record review and an interview with the office manager (not included on CMS-209), the laboratory failed to ensure that the MART-I immunohistochemical (IHC) stain was verified for performance prior to the start of patient testing in April

	<p>2021. The laboratory performs approximately 250 histopathology tests annually. Findings include: 1. Records review revealed the laboratory failed to verify the performance specifications for accuracy, precision, reportable range, and reference range for the MART-I IHC stain since the start of testing in April 2021. 2. Based on an interview with the office manager (not included on CMS-209), at approximately 10:50 AM, on November 14, 2023, confirmed that the laboratory failed to verify the performance specifications of the MART-I IHC stain for accuracy, precision, reportable range, and reference range since the start of testing in April 2021.</p>
<p>D5601</p>	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on a record review, and an interview with the office manager (not included on CMS-209), the laboratory failed to document a positive and negative slide reaction for their MART-I immunohistochemical (IHC) stain at least each time of use since patient testing began in April 2021. The laboratory performs approximately 250 histopathology tests annually. Findings include: 1. Records review revealed the laboratory failed to document a positive and negative slide reaction for the MART-I IHC stain with each time of use since patient testing began in April 2021. 2. An interview with the office manager (not included on CMS-209), at approximately 10:50 AM, on November 14, 2023, confirmed that the laboratory failed to document with each patient use a positive and negative slide reaction for IHC stains since patient testing began in April 2021.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the Laboratory Director (LD) failed to provide an approved procedure manual for personnel to reference during all aspects of the Potassium Hydroxide (KOH) preparation, and the MART-I immunohistochemical staining testing process (refer to D6106).The laboratory performs approximately 250 histopathology tests annually.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p>

This STANDARD is not met as evidenced by:

Based on a record review and an interview with the office manager (not included on CMS-209 form), the laboratory director failed to ensure that a procedure manual was made available and followed by testing personnel who performed Potassium Hydroxide (KOH) preparations, and MART-I immunohistochemical (IHC) procedures since the last survey on 04/28/2021. Findings include: 1. A review of the laboratory procedure manual revealed the laboratory failed to ensure procedures were established for KOH preparations, and MART-I IHC procedures. 2. An interview with the office manager (not included on CMS-209 form) at approximately 12:00 PM, on November 14, 2023 confirmed the laboratory director failed to ensure that a procedure manual was made available for testing personnel who performed KOH and IHC testing.