Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2090351	11/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology Villa Linde	2256 W Hill Road, Flint, 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
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 Liaison (LL), the laboratory failed to assess testing personnel, clinical consultant, technical supervisor, and the general supervisor competency for 2 (Testing Personnel #1 (TP1) and Testing Personnel #2 (TP2)) of 2 personnel listed on the CMS 209 form. Findings include: 1. A review of the laboratory's competency records revealed a lack of competency records in 2021 for the following employees: a. TP1, also functioning as Clinical Consultant #1, Technical Supervisor, and the General Supervisor b. TP2, also functioning as Clinical Consultant #2 2. An interview on 11/02/2021 at 11:06 am, the LL confirmed competency assessments were not performed on the two laboratory employees listed above.
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 Liaison (LL), the laboratory failed to verify the accuracy of the tissue specimen grossing and microscopic tissue examinations as part of Mohs surgery for 1 (2020) of 2 years

	reviewed. Findings include: 1. A review of the laboratory's "Mohs' Policy and Procedure Manual" revealed in section XII "Mohs Proficiency Testing" that "2 cases /calendar year or on a semi-annual basis" will be reviewed by another Mohs' Surgeon, dermatopathologist or dermatologist. 2. On 11/02/2021 at 11:21 am, the surveyor requested the laboratory's verification of accuracy documentation and it was not made available. 3. An interview on 11/02/2021 at 1:50 pm, the LL confirmed the laboratory did not have verification of accuracy documentation available for 2020.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on observation and interview with the Laboratory Liaison (LL), the laboratory failed to perform and document thermometer calibrations for 1 (Serial number (S/N) 192293497) of 1 thermometers before the expiration date. Findings include: 1. During a tour of the laboratory on 11/02/2021 at 9:35 am, the surveyor observed the ThermoScientific traceable thermometer in use that measured the room temperature and humidity with an expiration date of 7/01/2021. 2. An interview on 11/02/2021 at 1:50 pm, the LL confirmed the laboratory failed to perform and document thermometer calibration for the expired thermometer or replace it.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Liaison (LL), the laboratory failed to ensure the Hematoxylin and Eosin (H&E) stain was performed and documented each day of patient testing for 3 days (December 11, 2020, August 30, and September 7 in 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Laboratory Control Staining" log for the H&E stain quality revealed the following days a lacked documentation as follows: a. December 11, 2020 - 14 cases performed (FVA20-0098 to FVA20-0111) b. August 30, 2021 - six cases performed (FVS21-0014 to FVS21-0019) c. September 7, 2021 - seven cases performed (FVS21-0020 to FVS21-0026) 2. A review of the laboratory's "Mohs Policy and Procedure Manual" revealed in section IV "Mohs Surgery" stated a control slide from the 1st Mohs case of the day will be performed and documented each day of patient testing. 3. An interview on 11/02/2021 at 1:1:50 pm, the LL confirmed there was no documentation of the H&E stain quality on the days listed above.
D5787	TEST RECORDS CFR(s): 493.1283(a)

	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). This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Liaison (LL), the laboratory failed to record the specimen receipt time into the laboratory for the Mohs' tissue specimens for 13 of 17 final Mohs' maps reviewed. Findings include: 1. A record review for 13 of 17 final Mohs' maps reviewed in the patients electronic medical record (EMR) system revealed the laboratory did not record the specimen receipt time into the laboratory for the tissue specimen on the Mohs' map as follows: a. specimen M20-010 - collected on 1/17/2020 b. specimen M20-046 - collected on 3 /20/2020 c. specimen M20-083 - collected on 5/29/2020 d. specimen M20-0133 - collected on 7/22/2020 e. specimen M20-0176 - collected on 9/16/2020 f. specimen FVA20-0275 - collected on 11/18/2020 g. specimen FVA21-0005 - collected on 1/07 /2021 h. specimen FVA21-0279 - collected on 5/27/2021 i. specimen FVA21-0353 - collected on 7/08/2021 j. specimen FVS21-0001 - collected on 8/17/2021 k. specimen FVS21-0058 - collected on 9/22/2021 l. specimen FVS21-0079 - collected on 10/06 /2021 m. specimen FVS21-0123 - collected on 10/20/2021 2. An interview on 11/02 /2021 at 1:30 pm, the LL confirmed the final Mohs' maps did not contain the time of receipt into the laboratory for the Mohs' tissue specimens.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Liaison (LL), the laboratory failed to 1) monitor and evaluate the Quality Assurance chart review semi-annually for 1 (2020) of 2 years reviewed and 2) monitor and evaluate the "Quality Assurance Checklist" annually for 1 (2020) of 2 years reviewed. Findings include: 1. Record review revealed a lack of documentation for the semi-annual Quality Assurance chart review for 5 cases 2/year for 1 (2020) of 2 years reviewed. 2. Record review revealed a lack of documentation for the annual "Quality Assurance Checklist" for 1 (2020) of 2 years reviewed. 3. A interview on 11/02/2021 at 1:50 pm, the LL confirmed the semi-annual and annual quality assurance tasks had not been performed and documented.