Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2152458	09/29/2020
Name of Provider or Supplier	**Street Address, City, State**	
Village Dermatology	7575 San Felipe, Ste 300, Houston, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: I. Based on a review of the laboratory's polices, a review of the laboratory's Proficiency Testing records from 2018, 2019, and 2020, a review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of verifying the accuracy of Mohs slides at least twice annually in 2018. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing' revealed the following: "Six Mohs Cases are selected to be pulled and put on the slide trays and given to the dermatopathologist. They will evaluate the slides and list if they concur with the diagnoses. Frequency: January and July of the Calendar Year" 2. A review of the Proficiency Testing records for 2018, 2019, and 2020 revealed the following dates when an accuracy assessment was performed for Mohs

	slides: 2/7/19 6/25/19 1/9/20 7/24/20 3. A review of patient test records revealed the laboratory started patient testing on 8/21/18. 4. The laboratory was asked to provide documentation of verifying the accuracy of Mohs slides at least twice annually in 2018. No documentation was provided. 5. An interview with the MA/histotech on 9/29 /20 at 10:35 a.m. in the conference room, after review of the records, confirmed the above findings. II. Based on a review of laboratory's CMS 116 application, a review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for KOH (potassium hydroxide) preps in 2018 and 2019. Findings include: 1. A review of the laboratory's CMS 116 application (signed by the laboratory director on 9/17/20) revealed the laboratory performs 100 KOH preps annually. 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for the KOH preps in 2018 and 2019. 3. The laboratory was asked to provide documentation of performing the twice annual accuracy assessments. No documentation was provided. 4. An interview with the MA /histotech on 9/29/20 at 9:40 a.m. in the laboratory confirmed that the twice annual accuracy assessments were not done in 2018 and 2019 for KOH testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and staff interview, it was revealed that the laboratory failed to make available a written procedure for the laboratory personnel to follow for KOH (potassium hydroxide) preps. Findings include: 1. A review of the laboratory's policies revealed no documentation of a written procedure for KOH preps including the following: a) Requirements for patient preparation b) Microscopic examination c) Step-by-step performance of the procedure d) Preparation of slides and stains e) Control procedures to ensure quality of stain f) Corrective action 2. An interview with the MA/histotech on 9/29/20 at 9:40 a.m. in the laboratory revealed that the laboratory did not have a policy for KOH preps. This confirmed the above findings.
D5781	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Room Temperature logs for 2019 and 2020 and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the room temperature was documented outside the laboratory's acceptable range for 13 of 13 times from January 2019 to September 2020. Findings include: 1. A review of the laboratory's Room Temperature logs from January 2019 to September 2020 revealed the following acceptable temperature range: "Range 70F +/- 5F." 2. Further review of the Room Temperature logs for 2019 and 2020 revealed the following days where the documented room temperature was outside the laboratory's acceptable range: Date Recorded Temperature 10/22/19 61F 10/23/19 61F 10/28/19 61F 11/4/19 60F 11/5/19 62F 12/18/19 64F 6/3/20 64F 9/1/20 62F 9/8/20 60F 9/9/20 64F 9/15/20 63F 9/23/20 64F 9/29/20 60F 3. The laboratory was asked to provide documentation of performing corrective actions when the room temperature was outside of the acceptable range. No documentation was provided. 4. An interview with the MA/histotech on 9/29/20 at 9:50 a.m. in the conference room, after review of the records, confirmed the above findings.
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's records and staff interview, it was revealed the laboratory failed to have a quality assessment program that could identify and correct problems in analytic systems. Findings include: 1. The quality assessment program failed to identify that the laboratory did not have a written procedure for the laboratory personnel to follow for KOH (potassium hydroxide) preps. (refer to D5403) 2. The quality assessment program failed to identify that the laboratory did not have documentation of corrective actions when the room temperature was outside of the laboratory's acceptable range. (refer to D5781)
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assessment program, a review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assessment program identified failures in quality. Findings include: 1. The laboratory's quality assessment program failed to identify that the laboratory did not have a written procedure for the laboratory personnel to follow for KOH (potassium hydroxide) preps. (refer to D5403) 2. The laboratory's quality assessment program failed to identify that the laboratory did not have documentation of corrective actions when the room temperature was outside of the laboratory's acceptable range. (refer to D5781)
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel files, and staff interview, it was revealed the technical consultant failed to perform competency assessments on 2 of 2 testing personnel for moderate complexity testing- KOH (potassium hydroxide) preps. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 9/7/20) revealed the laboratory identified 2 testing personnel that performed KOH preps. 2. A review of the laboratory's personnel files revealed that there was no documentation of the technical consultant performing competency assessments for the 2 testing personnel (testing person #2 and testing person #3) performing KOH preps. 3. An interview with the MA/histotech on 9/29/20 at 10:05 a. m. in the laboratory revealed there was no documentation of competency assessments for the 2 testing personnel. This confirmed the above findings.