Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2291258	07/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Summitmd Dermatology Chandler	5950 S Cooper Rd #4, Chandler, AZ	

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	An initial survey was performed on July 18, 2025. The facility was found to be NOT in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1219 - Condition: Histopathology
D5028	HISTOPATHOLOGY CFR(s): 493.1219 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. This CONDITION is not met as evidenced by: Based on surveyor review of Histopathology records and laboratory personnel interviews, the laboratory failed to establish QA policies and procedures and failed to document QA activities (Refer to D5291, D5391, D5791 and D5891); failed to establish policies for slide labeling (Refer to D5311); failed to ensure the Mohs test procedure included control procedures, corrective action procedures and test reporting procedures (Refer to D5403); failed to ensure the laboratory director approved, signed and dated the procedure manual prior to use (Refer to D5407); failed to ensure the ambient humidity of the lab where the cryostat is utilized and specimen processing occurred was monitored (Refer to D5413); failed to establish a maintenance protocol and perform and document maintenance for the microscope used to read patient slides (Refer to D5433); failed to ensure pathology (Mohs) test reports were signed by only qualified individuals who performed the examination and issued the diagnosis (Refer to D5607); failed to ensure name and address on final reports indicated the facility where testing was performed (Refer to D5805). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of established quality assessment (QA) policies and procedures for review and interview with the facility personnel on 7/18/25, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. No QA documentation was provided for review during the survey conducted on 7/18/25 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236. 2. The facility personnel interviewed on 7/18/25 at 9:00 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements. 3. The laboratory began patient testing in the subspecialty of Histopathology on 6/14 /24, and tested 50 patients from 6/14/24 through 7/18/25.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on lack of written policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures for labeling patient slides for Mohs. Findings include: 1. The laboratory performs the microscopic interpretation of patient slides in conjunction with the Mohs procedure under the subspecialty of Histopathology. The laboratory began patient testing on 6/14 /24 and tested 50 patients through the survey date of 7/18/25. 2. No evidence was presented for review to indicate the laboratory established policies and procedures for labeling Mohs slides. 3. The facility personnel interviewed on 7/18/25 at 8:35 AM confirmed the laboratory failed to establish a policy and procedure for labeling patient slides.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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 preanalytic systems specified at 493.1241 through 493.1242.

	This STANDARD is not met as evidenced by: Based on lack of established quality assessment (QA) policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the preanalytic systems requirements specified at 493.1241 through 493.1242. Findings include: 1. No QA documentation was provided for review during the survey conducted on 7/18/25 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the preanalytic systems requirements specified at 493.1241 through 493.1242. 2. The facility personnel interviewed on 7/18/25 at 9:00 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the preanalytic systems requirements. 3. The laboratory began patient testing in the subspecialty of Histopathology on 6/14/24, and tested 50 patients from 6/14/24 through 7/18/25.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 review of the Mohs test procedure and interview with the facility personnel, the Mohs test procedure failed to include control procedures, corrective action to take when control results fail and the laboratory's system for entering Mohs results in the patient record and reporting patient results. Findings include: 1. The laboratory performs the microscopic interpretation of patient slides in conjunction with the Mohs procedure under the subspecialty of Histopathology. The laboratory began patient testing on 6/14/24 and tested 50 patients through the survey date of 7/18/25. It is the practice of the laboratory to enter the Mohs test results into the patient's Electronic Health Record (EHR). 2. The Mohs test procedure failed to include control procedures for the Hematoxylin and Eosin (H&E) stain. 3. The Mohs test procedure failed to include corrective actions to take when the H&E stain fails or is unsatisfactory. 4. The Mohs test procedure failed to include the laboratory's system for entering and reporting results in the patient's EHR. 5. Interview with the facility personnel on 7/18

	/2025 at 8:30 AM confirmed the Mohs test procedure lacked information regarding control procedures for the H& E stain, corrective action processes for the H&E stain, and the laboratory's system for entering and reporting patient test results in the EHR.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the Mohs test procedure on 7/18/25 and interview with the facility personnel, the laboratory director failed to approve, sign and date the Mohs test procedure before use. Findings include: 1. The laboratory began patient testing in conjunction with the Mohs procedure on 6/14/24 and tested 50 patients through the survey date of 7/18/25. 2. The 'Mohs Section Procedure' failed to include the approval, signature and date of the current laboratory director. 3. The facility personnel interviewed on 7/18/25 at 8:30 AM acknowledged that the Mohs Section Procedure was not approved, signed and dated by the current laboratory director before use.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 lack of humidity records for review and interview with the facility personnel, the laboratory failed to monitor and document the ambient humidity of the room where the cryostat is utilized to process dermatopathology specimens on 14 out of 14 testing dates between 6/14/24 and 7/18/25. Findings include: 1. The laboratory failed to monitor and record the ambient humidity of the room where the cryostat is used each day of patient testing. The laboratory performed patient testing on 14 days between 6/14/24 and 7/18/25 and tested 50 patients during that timeframe. 2. The laboratory's policy titled, 'Temperature and Humidity Monitoring' states, "To ensure that the cryostat is operating under manufacturer recommended temperature and humidity ranges....Record the room temperature, humidity and cryostat temperature while cryostat is turned on." 3. The facility personnel interviewed on 7/18/25 at 9:15 AM confirmed the laboratory failed to monitor and document the ambient humidity of the area where Mohs specimens are processed each day of patient testing, and stated that the laboratory utilizes a mobile Mohs service in which the cryostat is brought to the laboratory only on each day of testing.
D5433	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of a microscope maintenance policy, lack of maintenance records for the microscope and interview with the facility personnel, the laboratory failed to establish a microscope maintenance policy that includes specific routine maintenance procedures, as well as scheduled preventative maintenance procedures, and failed to perform microscope maintenance on 14 out of 14 testing dates from 6/14/24 through 7 /18/25. Findings include: 1. The laboratory failed to establish a microscope maintenance policy, including routine and preventative maintenance for one microscope that is used for patient testing. 2. The laboratory failed to perform and document microscope maintenance activities from 6/14/24 through 7/18/25. The laboratory used the microscope to read patient slides on 14 days during that time period. 3. Facility personnel interviewed on 7/18/25 at 9:15 AM acknowledged that no microscope maintenance policy was established by the laboratory and no maintenance activities were performed from 6/14/24 through 7/18/25 on the microscope that is used to read patient slides. 4. The laboratory performs testing in the subspecialty of Histopathology, and tested 50 patients during the timeframe indicated above.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f) (d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. This STANDARD is not met as evidenced by: Based on review of tissue pathology reports for Mohs maintained in the laboratory's electronic medical record (EMR) and interview with the facility personnel, four out of four Mohs test reports reviewed during the survey were electronically signed by individuals who were not qualified to perform the microscopic examination of slides, report diagnostic findings and report the final diagnosis of histopathology/Mohs specimens. Findings include: 1. The laboratory performs Mohs testing in the subspecialty of Histopathology, and performed testing on 50 patients from 6/14/24 through 7/18/25. 2. Four out of four Mohs test reports reviewed during the survey indicated the test reports were not signed by the individual who performed the examination and issued the diagnosis, and instead were electronically signed by individuals who were not qualified to perform the microscopic examination of slides, report diagnostic findings and report the final diagnosis, as evidenced by the following Mohs case numbers: 080624-02, 120324-04, 010725-01, and 030425-03 were electronically signed by a Nurse Practitioner (NP). 3. The facility personnel interviewed on 7/18/25 at 8:45 AM confirmed the tissue pathology reports indicated above were not signed by the individual who performed the examination and made the

	diagnosis, and instead signed by individuals who are not qualified to perform the microscopic examination, report diagnostic findings and report the final diagnosis of Histopathology specimens.
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. This STANDARD is not met as evidenced by: Based on lack of established quality assessment (QA) policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the analytic systems requirements specified at 493.1251 through 493.1283. Findings include: 1. No QA documentation was provided for review during the survey conducted on 7/18/25 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic system requirements specified at 493.1251 through 493.1283. 2. The facility personnel interviewed on 7/18/25 at 9:00 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems requirements. 3. The laboratory began patient testing in the subspecialty of Histopathology on 6/14/24, and tested 50 patients from 6/14/24 through 7/18/25.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, one out of three test reports failed to include the correct laboratory name and address where the testing was performed. Findings include: 1. The laboratory performs the microscopic interpretation of patient slides in conjunction with the Mohs procedure under the subspecialty of Histopathology. The laboratory began patient testing on 6/14 /24 and tested 50 patients through the survey date of 7/18/25. 2. One out of three test reports reviewed during the survey (#120324-04) failed to include the correct laboratory name and address where the testing was performed. 3. At the time of the survey conducted on 7/18/25, the laboratory name and address listed in the CLIA database for CLIA# 03D2291258 was SummitMD Dermatology Chandler, 5950 S. Cooper Rd. #4, Chandler, AZ 85249. 4. The test report indicated above listed the resulting lab as "Sun City West Dermatology, 13940 W Meeker Blvd. Ste. 135, Sun

	City West, AZ 85375-4492." 5. The facility personnel interviewed on 7/18/25 at 8:45 AM confirmed that the laboratory name and address listed on the test report referenced above was not correct.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 lack of established quality assessment (QA) policies and procedures for review of and interview with the facility personnel, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the postanalytic systems requirements specified at 493.1291. Findings include: 1. No QA documentation was provided for review during the survey conducted on 7/18/25 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the postanalytic systems requirements specified at 493.1291. 2. The facility personnel interviewed on 7/18/25 at 9:00 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the postanalytic systems requirements. 3. The laboratory began patient testing in the subspecialty of Histopathology on 6/14/24, and tested 50 patients from 6/14/24 through 7/18/25.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on lack of established QA policies and procedures, lack of QA documentation from 6/14/24 through 7/18/25 and interview with the facility personnel, the laboratory director failed to ensure that QA programs are established and maintained to assure the quality of laboratory services provided in the subspecialty of Histopathology and to identify failures in quality as they occur. Findings include: 1. The laboratory began testing on 6/14/24 in the subspecialty of Histopathology. The laboratory performed and reported 50 Mohs test results from 6/14/24 through the survey date of 7/18/25. 2. The laboratory director failed to ensure QA policies and procedures were established, and QA activities were performed and documented for all aspects of the Mohs testing process (general, preanalytic, analytic and postanalytic) from 6/14/24 through 7/18/25. See D5291, D5391, D5791 and D5891 for specific findings. 3. The facility personnel interviewed on 7/18/25 at 9:45 AM acknowledged that the laboratory director failed to ensure QA programs were established and maintained for the Mohs test results reported by the laboratory.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)

	(e)(13) 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 lack of competency documentation for laboratory personnel and interview with the facility personnel, the laboratory director failed to establish a policy and procedure for monitoring the competency of the Mohs technician, and the laboratory failed to assess the competency of one Mohs technician from 6/14/24 through 7/18/25. Findings include: 1. The laboratory has one (1) Mohs technician (Histotech) who is responsible for the labeling, processing and staining of Mohs specimens. 2. The laboratory failed to provide evidence of an established policy and procedure to assess the competency of the Mohs technician. 3. The laboratory failed to assess the competency of one (1) Mohs technician from 6/14/24 through the survey date of 7/18 /25. 4. The facility personnel interviewed on 7/18/25 at 9:45 AM confirmed the lack of policy or procedure for performing and documenting competency for the Mohs technician, and confirmed that competency of the Mohs technician was not assessed during the timeframe indicated above. 5. The laboratory began patient testing on 6/14 /24 in the subspecialty of Histopathology and tested 50 patients from 6/14/24 through 7/18/25.