Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0480592	03/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Surgi Center	8230 Walnut Hill Ln Suite 808, Dallas, 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	An announced recertification survey was conducted 03/31/2023. The laboratory was found out of compliance with the following conditions: 493.1487 Laboratories performing high complexity testing; Testing Personnel
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 review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records, and confirmed in interview, the laboratory failed to verify the accuracy of non-regulated potassium hydroxide (KOH) preparations at least twice annually for 1 of 1 testing events in 2021 and 2 of 2 testing events in 2022. The findings include: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed KOH preparations. 2. Review of the laboratory's proficiency testing records for 2021 and 2022 revealed the laboratory failed to verify the accuracy of KOH preparations at least twice annually for 1 of 1 testing events in 2021 and 2 of 2 events in 2022. The surveyor requested documentation of twice annual accuracy assessments for KOH preparations for 2021 and 2022. None were provided. 3. During an interview on 03/31/2023 at 11:20 a.m., Testing Person 3 confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when

	appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient test records, and confirmed in interview, the laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least 2 unique patient identifiers for 35 of 35 slides from January 2023 (random sampling). The findings include: 1. Review of the laboratory policy titled "Permanent Paraffin Sectioning Technique" revealed: "Principle: A tissue specimen is placed in fixative as soon as possible after biopsy. The tissue is processed through a series of graded alcohols, xylene, and paraffin. Finally, the specimen is embedded in a paraffin block; thin sections are cut, mounted on slides, and then prepared for staining ... Procedure ... 4. Once the block has solidified, it is placed in the object holder of the microtome and properly oriented. Sections of 4-6 microns are cut, floated on a warm water bath, and picked up on glass slides labeled with patient information. 5. Slides are incubated for 30 minutes in the slide dryer at 70 degrees. Slides are then removed from the drying oven and allowed to cool to room temperature. 6. Slides are then stained and coverslipped [sic] ..." The laboratory policy did not include labeling instructions to reliably identify patients using unique patient identifiers to distinguish between specimens. Refer to D5403. 2. A random review of patient slides from January 2023 revealed 35 slides labeled with the only a patient last name, medical record number (MRN), date of service, site, and sections. The laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least 2 unique patient identifiers. 3. During an interview on 03/31/2023 at 12:09 p.m., Testing Person 2 and Testing Person 3 confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of the Centers for Medicare and Medicaid (CMS)- 116 form, laboratory policies, and confirmed in interview, the laboratory failed to have a written procedure available to testing personnel for performing potassium hydroxide (KOH) preparations. The findings include: 1. Review of the CMS-116 form submitted at survey revealed the laboratory performed KOH preparations. 2. Review of the laboratory policy and procedure manual revealed no standard operating procedure (SOP) for KOH preparations. The surveyor requested documentation of a written procedure for KOH preparations. None was provided. 3. During an interview on 03/31 /2023 at 11:32 a.m., Testing Person 3 confirmed the above findings. II. Based on review of laboratory records, laboratory policies, and confirmed in interview, the laboratory failed to have a written procedure available to testing personnel for performing immunohistochemical (IHC) stains. The findings include: 1. Review of laboratory records submitted at survey revealed the laboratory performed IHC stains on the Leica Bond Max automatic staining system. 2. Review of the laboratory policy and procedure manual revealed no standard operating procedure (SOP) for performing

	IHC stains. 3. During an interview with Testing Person 3 on 03/31/2023 at 11:11 a.m., the surveyor requested documentation of a written procedure for IHC stains with staining characteristics defined. None was provided. During another interview with Testing Person 3 on 03/31/2023 at 12:09 p.m., the surveyor requested documentation of a written procedure for IHC stains with staining characteristics defined. None was provided. The laboratory was unable to provide a SOP with staining characteristics defined for IHC stains. This confirmed the above findings.
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 review of laboratory policy and confirmed in interview, the laboratory failed to ensure their sectioning procedure included instructions for labeling histopathology (Mohs) slides. The findings include: 1. Review of the laboratory policy titled "Permanent Paraffin Sectioning Technique" revealed: "Principle: A tissue specimen is placed in fixative as soon as possible after biopsy. The tissue is processed through a series of graded alcohols, xylene, and paraffin. Finally, the specimen is embedded in a paraffin block; thin sections are cut, mounted on slides, and then prepared for staining ... Procedure ... 4. Once the block has solidified, it is placed in the object holder of the microtome and properly oriented. Sections of 4-6 microns are cut, floated on a warm water bath, and picked up on glass slides labeled with patient information. 5. Slides are incubated for 30 minutes in the slide dryer at 70 degrees. Slides are then removed from the drying oven and allowed to cool to room temperature. 6. Slides are then stained and coverslipped [sic] ..." The policy failed to include instructions for labeling histopathology (Mohs) slides. The surveyor requested documentation of instructions for slide labeling. None was provided. 2. During an interview on 03/31/2023 at 12:09 p.m., Testing Person 2 and Testing Person 3 confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from

	the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient records, and confirmed in interview, the laboratory failed to ensure 4 of 10 patient KOH preparation results (random review) were transcribed accurately to the final test report in 2022 (March through June). The findings include: 1. Review of the laboratory policy and procedure manual revealed no standard operating procedure (SOP) for KOH preparations. Refer to D5401. 2. A random review of KOH patient final reports from 2022 (March through June) revealed the laboratory failed to accurately transcribe the following patient results: 03/29/2022 MRN: 05804 KOH Log: "+" Final Report: "Examination of the slide showed: no hyphae" 04/20/2022 MRN: 06368 KOH Log: "+" Final Report: "Examination of the slide showed: branching hyphae" 05/23/2022 MRN: 06547 KOH Log: "+" Final Report: "Examination of the slide showed: budding yeast and branching hyphae" 06/29/2022 MRN: 00755 KOH Log: "+" Final Report: "Examination of the slide showed: branching hyphae" The laboratory failed to accurately transcribe results of KOH preparations to the final reports. 3. During an interview on 03/31/2023 at 12:09 p.m., Testing Person 3 confirmed the above findings. Key: KOH-potassium hydroxide
D5805	TEST REPORT CFR(s): 493.1291(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 confirmed in interview, the laboratory failed to include the name and address of the testing facility for 9 of 9 Mohs maps (random review) in January 2023. The findings include: 1. A random review of patient test reports from January 2023 revealed the following 9 Mohs maps missing the name and address of the testing facility: 01/19/2023 MRN: 73354, 07448, 70427, 05908, 07459, 03582, 70427, 03582, 60522 2. During an interview on 03/31/2023 at 12:09 p.m., Testing Person 2 and Testing Person 3 confirmed the above findings.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

	This CONDITION is not met as evidenced by: Based on review of CMS (Centers for Medicare and Medicaid Services)- 209 form, personnel records, and confirmed in interview, the laboratory failed to ensure 1 of 3 testing persons (TP3) met the requirements to perform high complexity testing. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control

	values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicaid and Medicare (CMS)- 209 form, personnel records, and confirmed in interview the laboratory failed to ensure 1 of 3 testing personnel (TP3) were qualified to perform high complexity testing (grossing). The findings include: 1. Review of the CMS-209 form revealed 3 Testing Persons performed high complexity testing. 2. Review of personnel records for TP3 revealed no documentation of the minimum educational requirements to qualify as a testing person for high complexity. 3. During the exit interview on 03/31/2023 at 1:38 p.m., Testing Person 2 confirmed the above findings.