Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2132375	05/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Franks Dermatology	4220 North Rodney Parham #320, Little Rock, AR	

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	This is the initial CLIA certification survey of the laboratory. At the time of the survey the laboratory was not in compliance with the following conditions of participation: D5300 - Preanalytic Systems D5400 - Analytic Systems D6076 - Laboratory Director (High Complexity)
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: Through lack of documentation and interviews with laboratory staff, it was determined the laboratory failed to verify the accuracy of frozen sections at least twice annually. Survey findings include: A. The surveyor requested documentation of twice annual consultation or quality assurance records for frozen section examinations. None was provided by the laboratory. The laboratory has been in operation for 11 months (June 2017). B. In an interview, at 9:17 a.m. on 5/11/2018, laboratory employee #2 (as listed on the Personnel Identification Worksheet) stated that no consultation slides had been sent out since the laboratory started testing and no slides had been sent out for quality assurance review.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.

	1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through a review of the laboratory policies and procedures, a review of the patient log, a review of patient final reports, observations made during a tour of the laboratory, and interviews with laboratory staff, it was determined the laboratory did not meet preanalytic systems requirements as evidenced by: D5311 - The laboratory did not ensure specimen preservation until the time of testing
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: Through a review of the laboratory policies and procedures, a review of the patient log, a review of patient final reports, observations made during a tour of the laboratory, and interviews with laboratory staff, it was determined the laboratory did not ensure specimen preservation until the time of testing which has the potential to affect all histopathology slides reviewed. Survey findings follow: A. The laboratory policies and procedures failed to include procedures for the use of fixative in patient samples to prevent autolysis (destruction) of the tissue sample. B. At 10:05 a.m. on 5 /11/2018 laboratory employee #2 (as listed on the Personnel Identification Worksheet) stated that tissue samples are stored refrigerated between qauze soaked in saline until the tissue can be processed. C. Final reports and the patient log for ten patients were reviewed. Nine of ten patients were not processed on the day of the surgical procedure. Pathology #18-1736 Procedure Date 4/25/2018, Process Date 4/30/2018 (processed five days after the sample was obtained); Pathology #18-1669 Procedure Date 4/19/2018, Process Date 4/23/2018 (processed four days after the sample was obtained); Pathology #18-1537 Procedure Date 4/12/2018, Process Date 4/16/2018 (processed four days after the sample was obtained); Pathology #18-1385 Procedure Date 4/4/2018, Process Date 4/9/2018 (processed five days after the sample was obtained); Pathology #18-1186 Procedure Date 3/22/2018, Process Date 3/26/2018 (processed four days after the sample was obtained); Pathology #18-1163 Procedure Date 3/21/2018, Process Date 3/26/2018 (processed five days after the sample was obtained); Pathology #18-0940 Procedure Date 3/8/2018, Process Date 3/8/2018 (the same day the sample was obtained); Pathology #18-0802 Procedure Date 2/28/2018, Process Date 3/5/2018 (processed five days after the sample was obtained); Pathology #18-0827 Procedure Date 3/1/2018, Process Date 3/5/2018 (processed four days after the sample was obtained); and Pathology #18-0564 Procedure Date 2/14/2018, Process Date 2/15/2018 (processed one day after the sample was obtained). D. During a tour of the laboratory, at 10:05 a.m. on 5/11/2018, the surveyor observed nine patient samples in the refrigerator. The samples were stored between pieces of gauze, in petri dishes. Samples observed were as follows: 18-1993A dated 5/10/2018; 18-

	1992 dated 5/10/2018; 18-1970 dated 5/9/2018; 18-1990 dated 5/10/2018; 18-1968-A dated 5/9/2018; 18-1980-A & B dated 5/10/2018; 18-1991 dated 5/10/2018; 18-1966-A dated 5/10/2018, and 18-1961-A dated 5/10/2018.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through a review of laboratory procedures,a review of cryostat temperature log, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to meet analytic systems requirements as evidenced by: D5403 - the procedure manual failed to include procedures for specimen acceptability, specimen rejection, specimen labeling, or specimen storage D5407 - the laboratory director failed to approve, sign, and date the procedure manual. D5413 - the laboratory failed to monitor temperatures to ensure reliable test system operation D5473 - the laboratory failed to document the quality of the Hematoxylin and Eosin stain each day of use
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: Through a review of laboratory procedures and interviews with laboratory staff, it was determined the procedure manual failed to include procedures for specimen acceptability, specimen rejection, specimen labeling, or specimen storage. Survey findings include: A. In an interview at 9:17 a.m on 5/11/2018, laboratory employee #2

	(as listed on the Employee Identification Worksheet) stated that the laboratory only performs frozen section tissue examinations. B. The laboratory policy and procedure manual included a policy titled, "Frozen Sections" A review of the "Frozen Sections" policy revealed the only pre-analytic procedure states, "Specimen is worked up by nurse and slide prepared". C. The "Frozen Sections" policy did not have procedures for specimen acceptability, specimen rejection, specimen labeling, or specimen storage. D. At 9:27 a.m. on 5/11/2018 an additional "Frozen Section Procedure" was faxed from another laboratory and presented to the surveyor as further laboratory procedures. The faxed "Frozen Section Procedure" did not include specimen acceptability, specimen rejection, specimen labeling, or specimen storage. E. In an interview at 10:17 a.m. on 5/11/2018, laboratory employee #2 stated that there were no additional written procedures available.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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: Through a review of laboratory procedures and interviews with laboratory staff, it was determined the laboratory director failed to approve, sign, and date the procedure manual. Survey findings follow: A. The laboratory policy and procedure manual and procedures within the manual did not include the director's signature or the date the procedure was put in use. B. At 9:27 a.m. on 5/11/2018 an additional "Frozen Section Procedure" was faxed from another laboratory and presented to the surveyor as further laboratory procedures. The faxed "Frozen Section Procedure" was not signed or dated by the laboratory director. C. In an interview at 10:17 a.m. on 5/11/2018, laboratory employee #2 stated that there were no additional written procedures available.
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: Through a review of the "Frozen Section Procedure", a review of cryostat temperature log, and interviews with laboratory staff, it was determined the laboratory failed to monitor temperatures to ensure reliable test system operation. Survey findings include: A. The "Frozen Section Procedure" states, "Make sure the cryostat is at proper operating temperature -20 degrees Celsius to -30 degrees Celsius." B. The cryostat temperature log used to monitor the daily operating temperature of the cryostat states the acceptable range of the cryostat is +5 [which is above freezing] to -30 Celsius. C. In an interview at 9:27 a.m. on 5/11/2018, laboratory employee #2 (as listed on the Personnel Identification Worksheet) confirmed the range used to evaluate

	the daily temperature of the cryostat was +5 to -30 degrees Celsius [which is not consistent with the laboratory procedure].
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: Through a review of the laboratory procedures, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document the quality of the Hematoxylin and Eosin (H and E) stain each day of use which has a potential to affect all histopathology slides reviewed. Survey findings include: A. A review of laboratory procedure for frozen sections failed to include a policy for documenting the quality of H and E staining of the slides. B. The surveyor requested documentation of stain quality but none was provided. C. In an interview, at 10:17 a.m. on 5/11/2018, laboratory employee #2 (as listed on the Personnel Identification Worksheet) confirmed the laboratory failed to document slide and stain quality each day of testing.
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: Through a review of the patient test logs and the patient final reports from the medical record, as well as interviews with laboratory staff, it was determined the test reports failed to include the test report date on nine of ten records reviewed. Survey findings follow: A. Patient test logs included the following samples and dates of processing: Pathology #18-1736 processed 4/30/2018; Pathology #18-1669 processed 4/23/2018; Pathology #18-1537 processed 4/16/2018; Pathology #18-1385 processed 4/9/2018; Pathology #18-1186 processed 3/26/2018; Pathology #18-1163 processed 3/26/2018; Pathology #18-0940 processed 3/8/2018; Pathology #18-0802 processed 3/5/2018; Pathology #18-0827 processed 3/5/2018; and Pathology #18-0564 processed 2/15/2018. B. Final reports from ten patient medical records were reviewed. Nine of ten final reports included "Read Dates" which were before the samples were processed. The following read dates were incorrect and were before the samples were processed to be read: Pathology #18-1736 Read Date 4/25/2018 (five days before the sample was processed); Pathology #18-1669 Read Date 4/19/2018 (four days before the

	sample was processed); Pathology #18-1537 Read Date 4/12/2018 (four days before the sample was processed); Pathology #18-1385 Read Date 4/4/2018 (five days before the sample was processed); Pathology #18-1186 Read Date 3/22/2018 (four days before the sample was processed); Pathology #18-1163 Read Date 3/21/2018 (five days before the sample was processed); Pathology #18-0940 Read Date 3/8/2018 (the date the sample was processed); Pathology #18-0802 Read Date 2/28/2018 (five days before the sample was processed); Pathology #18-0827 Read Date 3/1/2018 (four days before the sample was processed); and Pathology #18-0564 Read Date 2/14/2018 (one day before the sample was processed). C. In an interview at 9:56 a.m. on 5/11 /2018, employee #2 confirmed that the read date on the final report is not correct.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Through a review of the laboratory policies and procedures, a review of cryostat temperature log, a review of the patient log, a review of patient final reports, lack of documentation, observations made during a tour of the laboratory, and interviews with laboratory staff, it was determined the laboratory director failed to provide overall management and direction of the laboratory as evidenced by: D6082 - laboratory director failed to ensure test systems provide quality services in all phases of testing D6093 - the laboratory director failed ensure that the quality control programs are established D6106 - the laboratory director failed to ensure that an approved procedure manual is available to all personnel
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Through a review of the laboratory policies and procedures, a review of cryostat temperature log, a review of the patient log, a review of patient final reports, lack of documentation, observations made during a tour of the laboratory, and interviews with laboratory staff, it was determined the laboratory director failed to ensure test systems provide quality services in all phases of testing. Survey findings follow: D5311 - did not ensure specimen preservation until the time of testing D5413 - the laboratory failed to monitor temperatures to ensure reliable test system operation D5473 - the laboratory failed to document the quality of the Hematoxylin and Eosin (H and E) stain each day of use
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality control 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: Through a review of laboratory procedures, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed ensure that the quality control programs are established . Survey findings include: D5473 - the laboratory failed to document the quality of the Hematoxylin and Eosin stain each day of use which has a potential to affect all histopathology slides reviewed
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Through a review of laboratory procedures and interviews with laboratory staff, it was determined the laboratory director failed to ensure that an approved procedure manual is available to all personnel for any aspect of the testing process. Survey findings follow: D5403 - the procedure manual failed to include procedures for specimen acceptability, specimen rejection, specimen labeling, or specimen storage D5407 - the laboratory director failed to approve, sign, and date the procedure manual