Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2033975	10/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Springville Dermatology And Diagnostics	732 N Main Street, Springville, UT	

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
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 lack of documentation, patient test records review, and interview with staff, the laboratory failed to document each day of testing Hematoxylin and Eosin (H&E) and Periodic Acid Shiff (PAS) stain for intended reactivity for 16 of 16 test days reviewed. Findings include: 1. Patient test records review included documentation patient biopsy specimens were received on: 12/05/2017 03/08/3018 06/06/2018 11/01 /2018 12/13/2018 12/21/2018 02/05/2019 03/19/2019 04/26/2019 05/10/2019 06/28 /2019 07/08/2019 08/02/2019 08/27/2019 09/09/2019 10/01/2019 2. Stain Quality control records for H &E stains failed to include documentation the laboratory evaluated H & E stain quality each day staining was performed from December 2017 to October 2019. 3. In an interview conducted on 10/15/2019 at approximately 5:15 P. M. the laboratory manager stated they did not record H & E stain quality each day slides were stained. The laboratory performed approximately 11,000 specimen processing and staining per year.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with

	each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on patient test records review, lack of documentation and confirmation by staff, the laboratory failed to document quality control performance for each batch of Immunohistochemical stains for 1 of 2 Mart-1 stain batches reviewed. The laboratory performed Mart 1 staining approximately twice weekly. Findings include: 1. Patient test records review included Mart -1 staining for specimen SDL-19-2073 received on 04/26/2019. 2. Mart 1 staining records review included searching for specimen SDL-19-2073 from the Monday after receipt to May 1, 2019. The specimen was not located in the batch tests that included positive and negative quality control slides. 3. In an interview with staff on 10/15/2019 at approximately 4:45 P.M. staff confirmed they could not confirm quality control performance for the batch specimen SDL-19-2073 was in.
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: Based on testing locations observed, new test's verification records review, training and competency records review, and interview with staff, the director failed to ensure testing compliance was maintained for test locations that were not at the same address as stated on the CLIA certificate, (See D6079); failed to ensure new test's verification was approved prior to testing patient specimens, (See D6086); and failed to ensure new testing personnel received gross analysis training and demonstrated they could accurately and reliable report the gross analysis tests, (See D6102).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on direct observation and interview with the laboratory staff, the director failed to assure compliance with applicable regulations to perform gross analysis testing at

	the same location as is stated on the CLIA certificate. The laboratory performed approximately 11,000 gross analysis of dermatopathology specimens per year. Findings include: 1. The laboratory CLIA certificate is located at 732 South Main Street. The location gross analysis testing is performed is at approximately 520 South Main Street in a strip mall office. 2. In a visit to the off-site location on 10/10/2019 at approximately 5:15 P.M., the laboratory manager guided the surveyor to the location where gross analysis is performed along with specimen fixation, embedding, cutting and staining including Immunohistochemical staining. 3. In an interview with the laboratory manager on 10/10/2019 at approximately 2:30 P.M. the manager stated the laboratory perfomed gross analysis testing at a location other than the CLIA certificate stated address. CLIA certificates are issued for each location tests are performed. The laboratory did not have a CLIA certificate for the location where gross analysis tests were performed.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on new test verification studies review, lack of documentation, and confirmation by staff, the director failed to approve the accuracy and precision studies for 2 of 2 differential stains added since the last survey, Periodic Acid Schiff (PAS) stain and Gomori Methenamine Silver (GMS) stain. Findings include: 1. The laboratory director failed to approve the accuracy and precision studies for PAS and GMS fungal element differential stains. 2. In an interview conducted on 10/10/2019 at approximately 5;15 P.M. the laboratory manager confirmed the stain verification study failed to include the director's signature and date as approval.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of documentation and confirmation by staff, the director failed to ensure one of one new testing person received training for gross analysis testing and had demonstrated they could perform gross analysis and histopathology specimen preparation prior to performing patient testing. The laboratory performed 11,000 histopathology specimen gross analyses per year. Findings include: 1. The laboratory lacked documentation one new testing person (test person C) was trained and evaluated for gross analysis prior to testing patient testing. 2. In an interview with staff on 10/10/2019 at approximately 4:30 P.M. staff confirmed the laboratory did not document training and demonstration new testing personnel could perform all testing operations reliably to provide and report accurate gross analysis results.

D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory manager, the technical supervisor failed to evaluate one testing person (test person B) annually for two of two years of testing 2017 and 2018. Findings include: 1. The laboratory lacked competency evaluations for staff members from October 2017 to October 2019. 2. In an interview with staff on 10/10/2019 at approximately 4:15 P.M. the laboratory manager confirmed the laboratory did not perform competency evaluations for gross analysis personnel.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory manager, the technical supervisor failed to evaluate one new testing person semiannually the first year of testing. Findings include: 1. The laboratory lacked competency evaluations for staff members from October 2017 to October 2019. 2. In an interview with staff on 10 /10/2019 at approximately 4:15 P.M. the laboratory manager confirmed the laboratory did not perform competency evaluations for the new gross analysis testing person (test person C).
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 personnel transcript review, lack of documentation, and interview with staff, one of three testing personnel failed to have qualifying documentation to perform high complexity gross analysis testing. (See 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 personnel transcript review, lack of documentation, and interview with staff, one of three testing personnel failed to have qualifying documentation to perform high complexity gross analysis testing. Findings include: 1. Test person C college

	transcript failed to include documentation it was an official transcript and the name of the school bestowing the bachelor's degree. 2. In an interview with staff on 10/15 /2019 by e-mail staff confirmed the transcript was not an official transcript.