Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D1058546	06/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Silver Falls Dermatology Pc	1793 13th Street Se, Salem, OR	

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
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based upon review of Laboratory procedures manual and discussion with staff, the Laboratory failed to retain a copy of the Melan A procedure after it was retired. Findings include: 1. While reviewing stain Quality Control (QC) records, it was noted that the last Melan A QC was performed was January 11, 2018 by this lab. Upon discussion with staff about this assay, I was told the stain was no longer performed at this laboratory and it was being sent out since January 2018. I asked to see this lab's retired procedure for this stain but it could not be produced during survey.
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 laboratory policy and review of records, the Laboratory Director (LD) failed to follow Laboratory policy regarding bi-annual review. Findings include: 1. The Laboratory policy states that the LD will "faciliate quality control testing twice yearly". Review of records for bi-annual Histopathological slide peer review for 2016 and 2017 show one review of six (6) slides for 9/2015 - 9/2016 and one review of six (6) slides for 9/2016 - 9/2017. There were no peer review records available for 2018.

	2. The Laboratory policy also states "She will randomly select ten (10) slides to send to a Dermatologist of her choosing for a second review". Bi-annual Histopathological peer review records shows six (6) slides submitted once in 2016 and six (6) slides submitted once in 2017, not ten (10) slides twice in each year. There were no peer reviews available for my review for 2018.
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 review of error log records and discussion with staff, the laboratory failed to address critical Quality Assessment (QA) events, specifically patient slide misidentification. Findings include: 1. On 12/12/2017, two (2) different specimens were received by the lab for anatomical grossing and slide preparation. Slides were prepared on both patients but mislabeled as a single patient. Patient one had a diagnosis of a non-malignant fibroma. Patient two had a diagnosis of basal cell carcinoma (BCC), a malignant form of skin cancer (CA). Upon further investigation of the mislabeling, it was determined that the diagnoses were reversed and the patient originally diagnosed with the BCC did not have a malignant CA. 2. No QA assessment of mislabeling of patient slides or work up on either patient was documented nor was any mechanism to monitor slide mislabeling was put into place.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the procedure manuals and discussion with staff, no procedure for performing the Melan A stain could be produced. Findings include: 1. The laboratory discontinued performing the Melan A stain in January 2018 but failed to keep the retired procedure with date of discontinuation documented and available for review.
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: Based on review of temperature records and discussion with staff, the laboratory failed to monitor the temperature of water baths, refrigerators and an oven beginning 4/20/2018 to day of survey. Findings include: 1. The laboratory has three (3) water baths used to make histopathology slides from parafin blocks. The last time the temperature was recorded for any of the water baths was 4/20/2018. 2. The laboratory has three (3) refrigerators. Refrigerator #1 had temperature recordings up until 4/20/2018. Thereafter, no temperature was recorded. Refrigerator #2 had no temperature recordings at all since it was plugged in for use 2/26/2018. Chemical exposure badges for employee monitoring are stored in this refrigerator. Refrigerator #3 had no log available for review at the time of survey. 3. The laboratory has one small oven with an established temperature range of 65 degrees to 70 degrees farenheit. The oven has not been above 55 - 60 degrees according to temperature log records from 2/23/2018. The last recorded temperature taken was on 4/20/2018. (Total of forty (40) working days). The day of survey, upon inspection, it measured 60 degrees. When staff was asked why there had been no documentation of temperatures after 4/20/2018, I was told they were "too busy".
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 review of multiple documents while on site 6/4/2018 and interview with laboratory personnel, the Laboratory Director failed to fulfill her responsibilities. Findings include: 1. See D6079, D6084, D6093, D6103, D6106, D6107
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 review of competency assessment records and interview with staff on 6/4/2018, the Laboratory Director (LD)/Technical Supervisor (TS) failed to fulfill her responsibilities of competency assessment of testing personnel or delegating this responsibility to a qualified individual. Findings include: 1. Competency assessment of personnel performing anatomical grossing examination is currently being performed by unqualified staff members. 2. The LD/TS blanket signs off on the

	"Histology Technician Competency Evaluations" without actually physically observing any of the listed events on the form according to staff interviewed. 2. The LD/TS has not delegated the TS duties to another qualified individual to perform competency assessment of grossing personnel in writing.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on inspection of the facility and interview with staff, the Laboratory Director failed to ensure a safe environment throughout the laboratory for all personnel. Findings include: 1. Highly flammable organic solvents including alcohol and Xylene are being stored on open shelves in the personnel office inside the lab. 2. Solvent fumes were evident when I walked into the office space. When I asked about the fumes, staff said the flammables cabinets, of which there are two (2), were full. Physical examination of both of these cabinets confirmed that they were indeed full.
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: Based on review of records and interview with staff, the Laboratory Director (LD) failed to ensure quality control (QC) testing was performed daily or whenever patient testing was performed. Findings include: 1.The last time the LD documented QC review on the monthly calendar kept in the log book for the Hematoxylin and Eosin (H&E) and Periodic Acid Schiff (PAS) stains according to on site records was 01/24 /2018. 2. QC on recut specimens is not consistently recorded in the space provided at the bottom of each daily log sheet used to request recuts. 5/29/2018 was randomly selected for review and did not have the slide number for QC on the document for either H&E or PAS. 3. According to the Laboratory's policy, grossing is to be reviewed within one day of gross assessment but no date, time or sign off of grossing review could be found on the patient report. Staff confirmed that their "AP Easy" program used to generate patient reports does not show date and time of grossing review. 4. See Dtag 6117 for further detail.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 upon review of Laboratory policy and procedures manual and discussion with staff at time of survey, there was no policy or procedure regarding competency assessment of staff. Findings include: 1. Staff members who perform high complexity anatomical grossing procedures are currently being assessed by unqualified staff members and not the Laboratory Director (LD) / Technical Supervisor (TS).
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: Based on review of the procedure manual for this laboratory and discussion with staff who use the manual, the Laboratory Director (LD) failed to review and sign the procedure manual used by laboratory staff members. Findings include: 1. A physical signature with date by the LD approving the procedure manual was not found during survey discovery 6/4/2018 or 6/11/2018. 2. Testing personnel (TP) confirmed that no signature or date of testing implementation for each test performed was available for my review.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of records and interview with staff, the Laboratory Director (LD) failed to provide employee job descriptions for two (2) testing personnel (TP) performing anatomical grossing, nor written designation of which testing procedures each TP is competent to perform. Findings include: 1. There was no job description available for review for TP performing gross anatomical assessment during investigation 6/4/2018. 2. There was no written document by the LD available for review during investigation designating which TP were approved to perform which test procedures or if supervision or LD review was required. 3. Findings were confirmed by staff during survey.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification

	requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based upon review of records and interview with staff, the Laboratory Director (LD), who serves as the Technical Supervisor (TS) failed to fulfill the duties of the TS. Findings include: 1. See D5413, D6079, D6093, D6117, D6120, D6122, D6123, D6124, D6126
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of daily and monthly Quality Control (QC) records and discussion with staff, the Technical Supervisor (TS) failed to ensure an ongoing QC program was being upheld and performed daily when patient testing was done. Findings include: 1. For Hematoxylin and Eosin (H&E) and Periodic Acid Schiff (PAS) staining for re-cut testing dated 4/16/2018 through 6/5/2018, QC was documented on re-cut log sheets only eleven (11) out of thirty six (36) days of patient testing for H&E stain and ten (10) out of thirty six (36) days of patient testing for PAS stain. 2. For routine H&E and PAS stains for initial staining, the calendar used by the Laboratory Director (LD) to record the daily QC for routine H&E and PAS staining has not been documented in writing since 01/24/2018 as of 6/04/2018. 3. In the PAS staining procedure, the detail indicating what the PAS QC slide(s) should look like, the H&E QC result is indicated rather than the PAS result. (Different colors) 4. The weekly QC stain change records for the automatic H&E stainer have not been kept in writing since 3/23/2018. 5. Discussion with staff confirmed that QC had not been documented as they were "too busy".
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 review of records and interview with staff, the Technical Supervisor (TS) failed to assess high complexity testing personnel competency or delegate in writing competency assessment duties to a qualied individual. Findings include: 1. The TS did not participate in the observation competency assessment of either of the two (2)

	personnel performing gross anatomical assessment. 2. The TS did not delegate such duties to a qualified individual. 3. See D6121, D6122, D6123, D6124, D6126
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based upon competency assessment reviews of two (2) high complexity testing personnel and discussion with staff, the Technical Supervisor (TS) failed to fulfill her responsibilities for competency assessment. Findings include: 1. The TS did not directly observe or assess the testing personnel performing gross anatomical examinations. 2. These findings were confirmed by staff.
D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based upon competency assessment reviews of two (2) high complexity testing personnel and discussion with staff, the Technical Supervisor (TS) failed to fulfill her responsibilities for competency assessment. Findings include: 1. The TS did not directly assess the recording and reporting of test results by testing personnel performing gross anatomical examinations. 2. These findings were confirmed by staff.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based upon competency assessment reviews of two (2) high complexity testing personnel and discussion with staff, the Technical Supervisor (TS) failed to fulfill her responsibilities for competency assessment. Findings include: 1. The TS did not directly observe daily Quality Control records for the testing personnel performing gross anatomical examinations. 2. These findings were confirmed by staff.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

	This STANDARD is not met as evidenced by: Based upon competency assessment reviews of two (2) high complexity testing personnel and discussion with staff, the Technical Supervisor (TS) failed to fulfill her responsibilities for competency assessment. Findings include: 1. The TS did not directly observe the testing personnel performing instrument maintenance. 2. These findings were confirmed by staff.
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 upon competency assessment reviews of two (2) high complexity testing personnel and discussion with staff, the Technical Supervisor (TS) failed to fulfill her responsibilities for competency assessment. Findings include: 1. The TS did not directly assess the problem solving skills of testing personnel performing gross anatomical examinations. 2. These findings were confirmed by staff.