Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0372910	04/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Skin & Vein Center	305 N Leroy Street, Fenton, MI	

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
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: . Based on procedure review and interview with an office staff member, the laboratory failed to follow their written procedure for the Mohs' "Quality Control System" for one (S18-51) of nine patient charts audited. Findings include: 1. Review of the "Quality Control System" procedure states that "The mapping is completed on a Mohs Pathology Report with time in and time out recorded for each stage performed". 2. Record review for one of nine patient charts audited revealed the "time in and time out" were not recorded for stage II on the Mohs' map. 3. During the exit interview on April 3, 2019 at approximately 2:30 PM, an office staff member acknowledge the time in and time out were not documented on the Mohs' map for stage II.
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: . Based on procedure manual review, observation, and interview with an office staff member, the laboratory director failed to approve, sign, and date the "Laboratory Procedure Manual" and the "Mohs Protocol Manual" annually for two (April 2017 to

	April 2019) of two years as stated on the signature page. Findings include: 1. Review of the "Laboratory Procedure Manual" and the "Mohs Protocol Manual" revealed on the signature page that the Laboratory Director is to review the manuals annually. 2. On April 3, 2019 at 9:26 and 11:47 AM during a review of the procedure manuals the surveyor observed the manuals had not been reviewed, signed, and dated by the Laboratory Director for two of two annual reviews. 3. During the exit interview on April 3, 2019 at approximately 2:30 PM, the office staff member confirmed the manuals were not reviewed annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with an office staff member, the laboratory failed to perform and document the daily maintenance for the Microm HM525 cryostat histopathology instrument for three (July 25, 2018, October 17, 2018, and January 23, 2019) of 24 days of Mohs' procedures performed. Findings include: 1. Record review of the "Cryostat Log" and the "Per Use Laboratory Cleaning" log revealed there was no documentation on the log to show that the maintenance had been performed prior to patient Mohs' specimen testing on the following days: a. July 25, 2018 b. October 27, 2018 c. January 23, 2019 2. During the exit interview on April 3, 2019 at approximately 2:30 PM, an office staff member acknowledged the maintenance had not been performed and documented prior to testing patient specimens.
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 record review and interview with an office staff member, the laboratory failed to document the intended quality of the Hematoxylin and Eosin (H & E) stain each day of Mohs' testing for four (S18-04, S18-08, S18-10, and S18-13) of nine patient charts audited. Findings include: 1. Record review for four of nine patient charts audited revealed there was no documentation on the "H&E Stain Quality Control" log to show the quality of the stain was acceptable and recorded as follows: a. S18-04 b. S18-08 c. S18-10 d. S18-13 2. During the exit interview on April 3, 2019 at approximately 2:30 PM, an office staff member acknowledged the quality of the H & E stain was not documented on days of patient testing.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with an office staff member, the laboratory failed to perform and document media checks for the "Troy Biological's Dermatophyte Test Medium (DTM)" with each new batch, lot, or shipment for the ability to support growth of yeast for two (April 2017 to April 2019) of two years reviewed. Findings include: 1. Record review for two years of the DTM media revealed for five new batches, lots or shipments of media there was no documentation to show the ability to support growth for yeast (Candida albicans) was performed as follows: a. May 2017 - Lot 1615315 b. October 2017 - Lot 1632207 c. November 2017 - Lot 1704514 d. January 2018 - Lot 1713101 e. July 2018 - Lot 1810013 2. During the exit interview on April 3, 2019 at approximately 2:30 PM, an office staff member confirmed the test media was not checked for the ability to support yeast growth.
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 record review and interview with an office staff member, the laboratory failed to ensure 1) the name and address of the laboratory location performing the Mohs' tissue examination for nine of nine cases reviewed and 2) the reference biopsy # and the slide case # were incorrect and/or not recorded on the Mohs' map for five of nine cases reviewed. Findings include: 1. Record review of the Mohs' map revealed for nine of nine cases reviewed the name and address of the testing location where the Mohs' surgery took place was not recorded on the Mohs' map as follows: a. Mohs' report - S17-018 b. Mohs' report - S18-04 c. Mohs' report - S18-08 d. Mohs' report - S18-10 e. Mohs' report - S18-13 f. Mohs' report - S19-62 g. Mohs' report - S18-31 h. Mohs' report - S18-51 2. Record review of the Mohs' map revealed the map was missing the "Ref. biopsy #" and/or "Slide Case #" for five of nine cases reviewed as follows: a. S18-04 - "Slide Case #" not recorded on Mohs' map b. S18-08 - "Slide Case #" was incorrect on Mohs' map c. S18-10 - "Slide Case #" was incorrect on Mohs' map d. S18-13 - "Slide Case #" not recorded on Mohs' map e. S18-31 - "Ref. biopsy#" and "Slide case #" not recorded on Mohs' map 3. During the exit interview

	on April 3, 2019 at approximately 2:30 PM, an office staff member acknowledged the name and address of the testing location and the "Ref. biopsy #, and "Slide Case #" were absent or incorrect on the Mohs' map.