Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0211849	02/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sona Dermatology	6500 Rock Spring Dr Ste 105, Bethesda, MD	

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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on quality control (QC) record review and interview with the histotechnologist, the laboratory failed to ensure that staining materials were tested for intended reactivity to ensure predictable staining characteristics when performing Hematoxylin and Eosin (H&E) and Toluidine Blue (T-Blue) staining of histopathology slides (D5473); failed to ensure that the results of all H&E and T-Blue stain QC were acceptable and that all control procedures were documented prior to reporting patient results (D5481); and failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283 (D5791).
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: Note: This is a repeat deficiency. The laboratory was cited during the recertification

	survey on 3/13/2018 for not recording the daily stain quality control, recording the staining characteristics of the Hematoxylin and Eosin stain and the Toluidine Blue stain. The plan of correction stated that this would be corrected. Based on quality control (QC) record review and interview with the histotechnician, the laboratory did not ensure that staining materials were tested for intended reactivity to ensure predictable staining characteristics when performing Hematoxylin and Eosin (H&E) and Toluidine Blue (T-Blue) staining of histopathology slides. Findings: 1. The laboratory documents daily slide QC for H&E and T-Blue stains on a "Mohs Frozen Section Daily Technical Quality Assurance Report". The form documents the date the QC was performed, whether it was "H&E" or "T-Blue" stain, the results of the evaluation of the slide's "Completeness," "Stain Quality," and "Technical Quality" ("Satisfactory" or "Unsatisfactory"), "Action taken for unsatisfactory marks," whether "Recuts" are needed, and records the identity of the testing person preparing the slides and the lab director's signature. 2. A review of "Mohs Frozen Section Daily Technical Quality Assurance Reports" from September 2019, and July and September, 2020 showed that on 9/4/2019 there was a log labeled "T-Blue" however the second log for 9/4/2019 was not labeled as to whether it was for "H&E" or "T-Blue" stain QC. 3. On 9/18/2019 both slide QC logs were labeled as "H&E" however there was no log labeled "T-Blue" for that date present at the time of the survey. 4. On 7/22/2020 a QC log labeled "H&E" was present, however the log labeled "T-Blue" had the date "8/22 /2020." A log documenting "T-Blue" stain QC for 7/22/2020 was not present at the time of the survey. 5. On 9/4/2020 both slide QC logs were labeled as "H&E" however there was no log labeled "T-Blue" for that date present at the time of the survey. 6. During the phone exit interview on 2/11/2021 at 10:15 AM, the histotechnician confirmed that results of slide stain QC were not documented each day of testing.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) record review and interview with the histotechnician, the laboratory did not ensure that the results of all Hematoxylin and Eosin (H&E) and Toluidine Blue (T-Blue) stain QC were acceptable and that all control procedures were documented prior to reporting patient results. Findings: 1. The laboratory documents daily slide QC for H&E and T-Blue stains on a "Mohs Frozen Section Daily Technical Quality Assurance Report". The form documents the date the QC was performed, whether it was "H&E" or "T-Blue" stain, the results of the evaluation of the slide's "Completeness," "Stain Quality," and "Technical Quality" ("Satisfactory" or "Unsatisfactory"), "Action taken for unsatisfactory marks," whether "Recuts" are needed, and records the identity of the testing person preparing the slides and the lab director's signature. 2. "Mohs Frozen Section Daily Technical Quality Assurance Reports" were reviewed from June through September of 2018, 2019, and 2020. 3. On 8/17/2018, H&E QC was marked "Unsatisfactory" for "Completeness." No comment was written for "Action taken for unsatisfactory marks", no "Recut" was requested, and there was no evaluation of the repeated QC documented. 4. On 7/15/2019, H&E QC was marked "Unsatisfactory" for "Completeness." A "Recut" was requested, however no evaluation of the repeated QC documented. 5. On 7/29/2019, H&E QC

	was marked "Unsatisfactory" for "Completeness." A "Recut" was requested, however no comment was written for "Action taken for unsatisfactory marks." 6. On 8/2/2019, T-Blue QC was marked "Unsatisfactory" for "Completeness." A "Recut" was requested, however no comment was written for "Action taken for unsatisfactory marks." 7. On 8/5/2019, H&E QC was marked "Unsatisfactory" for "Completeness." A "Recut" was requested, however no comment was written for "Action taken for unsatisfactory marks." 8. On 8/7/2019, T-Blue QC was marked "Unsatisfactory" for "Completeness." A "'Recut" was requested, however no comment was written for "Action taken for unsatisfactory marks." 9. On 8/30/2019, T-Blue QC was marked "Unsatisfactory" for "Completeness." A "Recut" was requested, however no comment was written for "Action taken for unsatisfactory marks." 10. On 9/25/2019, the T-Blue QC sheet was not signed by laboratory director under "Reviewed by," showing that slide QC was acceptable. 11. On 8/31/2020, the evaluation of T-Blue stain QC's "Completeness," "Stain Quality," and "Technical Quality" was not documented (marked "Satisfactory" or "Unsatisfactory"), however "Recuts" were requested for "Missing epidermis." The repeated QC was documented as "Satisfactory" for all three criteria. 12. During the phone exit interview on 2/11/2021 at 10:15 AM, the histotechnician confirmed that the laboratory did not ensure that the results of all H&E and T-Blue stain QC was acceptable and that all control procedures were documented prior to reporting patient results.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on laboratory procedure manual and document review and interview with the histotechnologist, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283 for Hematoxylin and Eosin (H&E) and Toluidine Blue (T-Blue) stained slides. Findings: 1. The procedure manual states that "Quality control and assurance programs are being developed to increase high quality laboratory work and identify failures when they occur", however a review of the procedure manual showed that the laboratory did not have a procedure for quality assurance. 2. A review of "Mohs Frozen Section Daily Technical Quality Assurance Reports" which document histopathology slide stain quality control (QC) from June through September of 2018, 2019, and 2020 showed that stain QC logs were not available for each day of patient testing. Cross-refer to D5473; and 3. Stain QC logs did not document the acceptability of the H&E and T-Blue stains, the reason "Recuts" were requested, the evaluation of repeated slide QC, and that the laboratory director had evaluated the quality of the stain. Cross-refer to D5481. 4. This was confirmed during the phone exit interview on 2/11/2021 at 10:15 AM.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 procedure manual review and interview with the histotechnician, the laboratory director failed to establish and maintain a quality assurance program to assure the quality of laboratory services provided and to identify failures in quality as they occur. Cross-refer to D5791.