Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2121729	(X3) Date Survey Completed 05/29/2019
Name of Provider or Supplier Cronin Dermatology & Skin Cancer Center	**Street Address, City, State** 5530 Wisconsin Ave Ste 1418, Chevy Chase, 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
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 quality assurance (QA) record review and interview with the laboratory staff, the laboratory did not ensure that proficiency testing (PT) was performed at least twice annually. Findings: 1. The laboratory's PT is performed by sending completed slides out to another pathologist for review. Once returned, the results are compared to verify that the evaluations agree. 2. A review of QA records from 2018 to 2019 showed that one set of PT slides had been sent out in 2018, and one set had been sent out by the time of the survey in 2019. 3. During an interview on 5/29/19 at 10:30 AM, the laboratory staff confirmed that the laboratory did not ensure that PT was performed at least twice annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory did not perform and document quarterly sterilization tests on the autoclave. Findings: 1. The laboratory uses the "Steri-Dent Sterilizer Test" to check that the laboratory's autoclave is functioning properly. The test contains a test paper containing spores as well as an indicator. 2. During an interview at 9:30 AM, laboratory staff stated that the "Steri-Dent Sterilizer Test" is performed and mailed to the company every 3 months and the results are faxed to the laboratory once complete. 3. A review of "Sterilization Monitoring Service Quarterly Report Forms" showed that the last report present was from 6/2018. Laboratory staff stated that they had not realized that the "Steri-Dent Sterilizer Test" kits had expired and therefore had not been receiving the reports from the company. 4. During an interview on 5/29/19 at 10:30 AM, laboratory staff confirmed that required function checks had not been performed on the autoclave as required.
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 quality control (QC) and patient log record review and interview with laboratory staff, the laboratory did not ensure that daily stain QC was consistently documented, recording the quality of the staining characteristics of the Hematoxylin and Eosin (H&E) stain. Findings: 1. The laboratory performs H&E staining procedures to evaluate histopathology slides. Daily stain QC for H&E stains are recorded on the "Control Slide Log." 2. A review of daily stain QC logs from 26 days of testing from 1/9/18 to 4/24/18 showed that for 4 of 26 days patient testing was performed, but the results of the stain QC were not documented on the log sheet; and 3. A review of daily stain QC logs from 26 days of testing from 1/2/19 to 4/30/19 showed that for 2 of 26 days patient testing was performed, but the results of the stain QC were not documented on the log sheet. 4. During an interview on 5/29/19 at 10:30 AM, the laboratory staff confirmed that daily slide QC was not consistently documented.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 12/06/2017 for not maintaining records of quarterly reviews. The plan of correction stated that this would be corrected. Based on laboratory procedure manual and quality assurance (QA) record review and interview with laboratory staff, the

	laboratory failed to document the quarterly QA reviews as described in the laboratory's written procedures. Findings: 1. The laboratory's procedure manual states that, "The lab will perform a quarterly chart review" and that "This program will help minimize charting errors." A review of QA records showed that at the time of the survey, the "chart review and audit" was performed 2 times in 2019, and had not been performed in 2018. 2. During an interview on 5/29/19 at 10:30 AM, the laboratory staff confirmed that QA reviews were not performed as instructed in the laboratory's procedure manual.