Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0980717	03/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arlington Center For Dermatology	711 East Lamar Suite 200, Arlington, TX	

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
D0000	Laboratory representatives were present at the entrance conference conducted 03/03 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 03/03 /2021. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
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 review of laboratory policy, Quality Control (QC) logs and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 4 of 4 days in 2019 (random review 09/2019), 5 of 5 days in 2020 (random review 12/2020) and 7 of 7 days in 2021 (random review 02/2021). Findings: 1. Review of laboratory policy "ROUTINE HEMATOXYLIN, EOSIN STAINING AND COVERSLIPPING" pages 11.2 and 11.3 revealed: "5. Quality Control A quality control slide will be stained and checked a histology technician or pathologist before staining any routine or re-cut cases. The result of the control will be recorded on the H&E Quality Control Log. Any discrepancies will be corrected, monitored and annotated on the QC log." The procedure failed to define the

	staining characteristics for intended reactivity for the H&E stain. 2. A random review in 2019, 2020 and 2021 of the H&E QC log revealed the following: The bottom of the log had a line stating: "Staining quality for all H&E stains today: Acceptable Not Acceptable (see notes attached)," each day stain quality was documented with the word "Acceptable" circled. The log did not specify if the word "Acceptable" was indicated for H&E intended reactivity to ensure predictable staining characteristics. The following dates were observed to be documented with "Acceptable" circled: 09/23 /2019 Random sampling of patient specimen numbers: A19-2553, A19-2554, A19-2555, A19-2556, A19-2557, A19-2558, A19-2559 09/24/2019 Random sampling of patient specimen numbers: A19-2576, A19-2577, A19-2578, A19-2579, A19-2580, A19-2581, A19-2582 09/25/2019 Random sampling of patient specimen numbers: A19-2590, A19-2591, A19-2592, A19-2593, A19-2594, A19-2595, A19-2596 09/26 /2019 Random sampling of patient specimen numbers: A19-2605, A19-2606, A19-2607, A19-2608, A19-2609, A19-2610, A19-2611 12/14/2020 Random sampling of patient specimen numbers: A20-3189, A20-3190, A20-3191, A20-3192, A20-3193, A20-3194, A20-3195 12/15/2020 Random sampling of patient specimen numbers: A20-3196, A20-3197, A20-3198, A20-3199, A20-3200, A20-3201, A20-3202 12/16 /2020 Random sampling of patient specimen numbers: A20-3206, A20-3207, A20-3208, A20-3209, A20-3210, A20-3211, A20-3212 12/17/2020 Random sampling of patient specimen numbers: A20-3222, A20-3223, A20-3224, A20-3225, A20-3226, A20-3227, A20-3228 12/18/2020 Random sampling of patient specimen numbers: A20-3235, A20-3236, A20-3237, A20-3238, A20-3239, A20-3240, A20-3241 02/01 /2021 Random sampling of patient specimen numbers: A21-182, A21-183, A21-184, A21-185, A21-186, A21-187, A21-188 02/02/2021 Random sampling of patient specimen numbers: A21-192, A21-193, A21-194, A21-195, A21-196, A21-197, A21-198 02/03/2021 Random sampling of patient specimen numbers: A21-203, A21-204, A21-205, A21-206, A21-207, A21-208, A21-209 02/04/2021 Random sampling of patient specimen numbers: A21-219, A21-220, A21-221, A21-222, A21-223, A21-224A, A21-224B 02/05/2021 Random sampling of patient specimen numbers: A21-236, A21-237, A21-238, A21-239, A21-240, A21-241 02/08/2021 Random sampling of patient specimen numbers: A21-242, A21-243, A21-244, A21-245, A21-246, A21-247, A21-248 02/09/2021 Random sampling of patient specimen numbers: A21-258, A21-259, A21-260, A21-261 A21-262, A21-263, A21-264 The laboratory failed to document the intended reactivity to ensure predictable H&E characteristics for the above dates. 3. During an interview on 03/03/2021 at 11:55 am, testing person-2 and the laboratory director confirmed the above findings.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i)

Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on review of CMS 209 form, laboratory logs, patient final test reports and confirmed in interview, the general supervisor failed to ensure gross examinations for patient specimens performed by testing persons were reviewed within 24 hours for 3 of 3 patient specimens in 2019 (random review 09/2019), 7 of 7 patient specimens in 2020 (random review 12/2020) and 11 of 11 patient specimens in 2021 (random review 02/2021). 1. Review of the CMS 209 form listed the laboratory director as the clinical consultant, general supervisor (GS), technical supervisor (TS) and testing person (TP). The form included one additional testing person (TP-2), who performed the gross examinations of specimens received from the laboratory director's private practice. TP-2 did not qualify as general supervisor or technical supervisor, requiring review within 24 hours. Gross examination included all documented physical examination/descriptions, including measurement of the specimen. 2. During an interview on 03/03/2021 at 10:25 am, TP-2 stated that grossing was reviewed by the laboratory director (TS/GS) during slide review. She also stated that occasionally the

specimen blocks were submitted along with the slides to the laboratory director for her review. During an interview on 11/05/2019 at 11:22 am, the laboratory director (TS/GS) stated that she reviewed the grossing during her slide review and reviewed the blocks during her morning rounds in the laboratory. 3. Review of laboratory daily QC log sheets revealed gross examinations were documented on the form and included on the bottom of the sheet the following statement: "All path performed on this page was grossed by (XX)". Review of patient test reports revealed gross examinations were documented and electronically signed by the TS/GS. There was no documentation of the TS/GS review of the tissue and blocks within 24 hours of the gross examinations for TP-2. The following are a random sampling of patients in 2019, 2020 and 2021: Specimen #: A19-2563 Patient final report date collected and received: 09/23/2019, QC log sheet included grossing examination, TP-2 name and date (09/23/2019) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 09/24/2019 Specimen #: A19-2580 Patient final report date collected and received: 09/24/2019, QC log sheet included grossing examination, TP-2 name and date (09/24/2019) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 09/25/2019 Specimen #: A19-2610 Patient final report date collected and received: 09/26/2019, QC log sheet included grossing examination, TP-2 name and date (09/26/2019) of processing /grossing Final report was electronically signed by laboratory director (TS/GS) on 10 /01/2019 Specimen #: A20-3184 Patient final report date collected and received: 12/14 /2020, QC log sheet included grossing examination, TP-2 name and date (12/14/2020) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 12/15/2020 Specimen #: A20-3195 Patient final report date collected and received: 12/14/2020, QC log sheet included grossing examination, TP-2 name and date (12/14/2020) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 12/15/2020 Specimen #: A20-3199 Patient final report date collected and received: 12/15/2020, QC log sheet included grossing examination, TP-2 name and date (12/15/2020) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 12/16/2020 Specimen #: A20-3184 Patient final report date collected and received: 12/14/2020, QC log sheet included grossing examination, TP-2 name and date (12/24/2020) of processing /grossing Final report was electronically signed by laboratory director (TS/GS) on 12 /15/2020 Specimen #: A20-3207 Patient final report date collected and received: 12/16 /2020, QC log sheet included grossing examination, TP-2 name and date (12/16/2020) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 12/17/2020 Specimen #: A20-3225 Patient final report date collected and received: 12/17/2020, QC log sheet included grossing examination, TP-2 name and date (12/17/2020) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 12/18/2020 Specimen #: A20-3241 Patient final report date collected and received: 12/18/2020, QC log sheet included grossing examination, TP-2 name and date (12/18/2020) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 12/21/2020 Specimen #: A21-187 Patient final report date collected and received: 02/01/2021, QC log sheet included grossing examination, TP-2 name and date (02/01/2021) of processing /grossing Final report was electronically signed by laboratory director (TS/GS) on 02 /02/2021 Specimen #: A21-188 Patient final report date collected and received: 02/01 /2021, QC log sheet included grossing examination, TP-2 name and date (02/01/2021) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 02/02/2021 Specimen #: A21-192 Patient final report date collected and received: 02/02/2021, QC log sheet included grossing examination, TP-2 name and date (02/02/2021) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 02/03/2021 Specimen #: A21-193 Patient final report

	date collected and received: 02/02/2021, QC log sheet included grossing examination, TP-2 name and date (02/02/2021) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 02/03/2021 Specimen #: A21-205 Patient final report date collected and received: 02/03/2021, QC log sheet included grossing examination, TP-2 name and date (02/03/2021) of processing /grossing Final report was electronically signed by laboratory director (TS/GS) on 02 /04/2021 Specimen #: A21-222 Patient final report date collected and received: 02/04 /2021, QC log sheet included grossing examination, TP-2 name and date (02/04/2021) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 02/05/2021 Specimen #: A21-240 Patient final report date collected and received: 02/05/2021, QC log sheet included grossing examination, TP-2 name and date (02/05/2021) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 02/08/2021 Specimen #: A21-242 Patient final report date collected and received: 02/08/2021, QC log sheet included grossing examination, TP-2 name and date (02/08/2021) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 02/09/2021 Specimen #: A21-245 Patient final report date collected and received: 02/08/2021, QC log sheet included grossing examination, TP-2 name and date (02/08/2021) of processing /grossing Final report was electronically signed by laboratory director (TS/GS) on 02 /09/2021 Specimen #: A21-260 Patient final report date collected and received: 02/09 /2021, QC log sheet included grossing examination, TP-2 name and date (02/09/2021) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 02/10/2021 Specimen #: A21-262 Patient final report date collected and received: 02/09/2021, QC log sheet included grossing examination, TP-2 name and date (02/09/2021) of processing/grossing Final report was electronically signed by laboratory director (TS/GS) on 02/10/2021 The laboratory did not ensure tissue and blocks were reviewed and documented within 24 hours by the TS/GS, as required. 4. During an interview on 03/03/2021 at 11:22 am, the laboratory director and TP-2 confirmed the above findings. Word Key: CMS- Centers for Medicare & Medicaid Services