

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2280799	(X3) Date Survey Completed 02/07/2024
Name of Provider or Supplier Advanced Facial, Oral And Skin Surgery	Street Address, City, State 5060 Tennyson Parkway Suite 200, Plano, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, maintenance logs, and confirmed in interview, the laboratory failed to follow its own written policy for changing staining solutions for one of two staining solutions reviewed in February 2024. Findings Included: 1. Review of laboratory policy, "H & E Staining Procedure For Frozen Tissue Sections" (Approved by the Laboratory Director on 09/12/2014) revealed the following: "Quality Control: Stains are filtered daily and grossly examined for any evidence of contaminants or precipitates. Solutions are changed as follows: hematoxylin and eosin stains are changed weekly ..." 2. Review of laboratory daily maintenance logs (October 2023-January 2024) revealed the following weeks the laboratory failed to document hematoxylin solution changes weekly: a. 10/23/2023 - 10/27/2023 b. 12/04/2023 - 12/08/2023 c. 12/11/2023 - 12/15/2023 d. 12/18/2023 - 12/22/2023 e. 01/08/2024 - 01/12/2024 f. 01/22/2024 - 01/26/2024 The surveyor requested documentation of changing the hematoxylin solution for the above weeks, and none was provided. 3. During an interview in the facility breakroom on 02/07/2024 at 10:48 AM, the laboratory consultant confirmed the laboratory failed to follow its own written policy for changing staining solutions for one of two solutions reviewed in February 2024.</p>
D5403	PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory maintenance logs, procedure manual, CMS (Centers for Medicare and Medicaid Services)-116 form, and confirmed in interview, the laboratory failed to establish a written policy/procedure for Toluidine Blue staining for four of four months reviewed in February 2024 (October 2023-January 2024). Findings Included: 1. Review of laboratory daily maintenance logs (October 2023-January 2024) revealed the laboratory performed Toluidine Blue staining on patient specimens. 2. Review of laboratory policy and procedure manual, revealed the laboratory failed to establish a written policy/procedure for Toluidine Blue staining for 4 of 4 months (October 2023-January 2024) to include: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including interpretation of results. (4) Preparation of slides, solutions, controls, reagents, stains, and other materials used in testing. (5) Control procedures. (6) Corrective action to take when control results fail to meet the criteria for acceptability. 3. Review of CMS-116 form submitted at time of survey, revealed the laboratory performed 6,448 tests annually. 4. During an interview in the facility breakroom on 02/07/2024 at 11:22 AM, the laboratory consultant confirmed the laboratory failed to establish a written policy/procedure for Toluidine Blue staining for four of four months reviewed in February 2024 (October 2023-January 2024).

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 manufacturer's instructions, laboratory policy, maintenance logs, and confirmed in interview, the laboratory failed to define and document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides on each day of patient testing for four of four months reviewed in February 2024 (October 2023-January 2024). Findings Included: 1. Review of manufacturer's instructions for StatLab Hematoxylin and Eosin stains (Revised 01/15/2019) stated the following staining characteristics: " PRINCIPLE AND RESULTS: This kit is intended for use by laboratory professionals to stain routinely prepared paraffin embedded tissue specimens (in vitro) to identify nuclei and cytoplasm. Nuclei is stained blue, cytoplasm pink, and other tissue shades of pink." 2. Review of laboratory policy, "H & E Staining Procedure For Frozen Tissue Sections" (Approved by the Laboratory Director on 09/12/2014) revealed the following: "Principle: Thin tissue sections cut on the cryostat microtome are stained for nuclear and cytoplasmic detail ...Steps that follow remove excess stain and elements, then counterstaining with eosin reveals cytoplasmic elements." The laboratory failed to document H & E intended reactivity to ensure predictable staining characteristics. 3. Review of laboratory daily maintenance logs (October 2023-January 2024) revealed the laboratory failed to document H & E intended reactivity to ensure predictable staining characteristics for four of four months reviewed. The surveyor requested the above documentation of intended H & E staining reactivity, and none was provided. 4. During an interview in the facility breakroom on 02/07 /2024 at 10:54 AM, the laboratory consultant confirmed the laboratory failed to define and document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides on each day of patient testing for four of four months reviewed in February 2024 (October 2023-January 2024).