

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2063582	(X3) Date Survey Completed 01/15/2019
Name of Provider or Supplier Family Dermatology PC	Street Address, City, State 929 S Tamiami Trail Unit 201, Osprey, FL	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of employee competency records, policy manual, and interview with the Laboratory Director, the laboratory failed to perform competency evaluations for the Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel #B (same person for all titles) who perform histopathology testing for 2 (2017-2018) years reviewed. Findings Included: Review of employee competency records found no competency evaluations performed on the Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel #B (same person for all titles). Review of policy manual revealed the absence of a competency procedure. Interview on 01/15/2019 at 11:30 AM the Office Manager confirmed that there were no documented competency evaluations for the Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel #B (same person for all titles).</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observations, record review, and interview with the Office Manager, the</p>

laboratory failed to ensure Eosin Y Stain Solution and Hematoxylin Stain Solutions were removed from use after the expiration date. Findings Included: Observations on 01/15/2019 at approximately 9:30 AM revealed an open container of Eosin Y Stain Solution(Lot#1630818) with an expiration date of 11/9/2018. Also revealed was an open container of Hematoxylin Stain Solution (Lot#1632602) with an expiration date of 11/2018. Record review of the accession log revealed that 10 patients were tested on November 16, 2018, 14 patients were tested on November 30, 2018, 10 patients were tested December 14, 2018, 1 patient tested December 15, 2018, 7 patients were tested December 20, 2018, 5 patients were tested December 21, 2018, 12 patients were tested January 4, 2019, and 12 patients were tested January 12, 2019. Interview on 01/15/2019 at 10:30 AM the Office Manager confirmed the expired reagents had been used for testing but new reagents had been ordered. Observation during the tour at approximately 9:30 AM revealed the shipment of new reagents had been received but not taken out of boxes.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of the procedure manual and interview with the Laboratory Director, written job description for the Laboratory Director, Clinical Consultant, Technical Supervisor, the General Supervisor, and the Testing Person #B were missing from the procedure manual. Findings Included: Review of the procedure manual revealed that job descriptions were missing for Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, and the Testing Person #B. In an interview on 01/15 /2019 at 11:50 AM, the Laboratory Director confirmed the job descriptions for the Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, and the Testing Person #B were missing from the procedure manual.