

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2069519	(X3) Date Survey Completed 08/13/2019
Name of Provider or Supplier Skin Cancer & Cosmetic Dermatology Center	Street Address, City, State 2358 Lifestyle Way, Suite 212, Chattanooga, TN	
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
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) policy for monitoring competency of testing personnel, a lack of competency policy on initial and semi-annual competencies, and an interview with the lead histotech determined the laboratory failed to have a competency policy for performing on initial and semi-annual competency checks for the two year period of 2017-2019. The findings include: 1) A review of the Quality Assessment policy for the laboratory stated, "At least annually" for annual competency checks for each testing person will be performed. 2) There was no policy available to show initial and semi-annual competency checks were to be performed for the two year period of 2017-2019. 3) Interview with the lead histotech, on August 14, 2019, at 12:35 pm, confirmed the laboratory failed to have a QA policy for Personnel Assessment to show initial and semi-annual competency checks were to be performed for the two year period of 2017-2019.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare Services personnel report (CMS 209), review of the laboratory's employee competency evaluations and upon interview with the lead histotech determined the Technical Consultant failed to perform and document a semi-annual competency evaluations for testing personnel #7 and #8 who began laboratory testing in Mycology (Potassium Hydroxide - KOH) and Parasitology (Scabies) on March 26, 2018 during the past two years. The findings include: 1. Review of the CMS 209 revealed 9 of 9 testing personnel reporting with 2 of 2 new testing personnel (#7 and #8) who began laboratory testing in Mycology (Potassium Hydroxide - KOH) and Parasitology (Scabies) on March 26, 2018. 2. Review of the laboratory's semi-annual competency evaluations for testing personnel #7 and #8 who began laboratory testing in Mycology (Potassium Hydroxide - KOH) and Parasitology (Scabies) on March 26, 2018 did not reveal the TC's signature/approvals. 3. An interview with the lead histotech at approximately 12:30pm, at August 13, 2019, confirmed that semi-annual competency evaluations were missing the TC's signature /approvals for testing personnel #7 and #8 who began laboratory testing in Mycology (Potassium Hydroxide - KOH) and Parasitology (Scabies) on March 26, 2018 during the past two years.

D6068

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare Services personnel report (CMS 209), review of the laboratory's procedure manual policy on Potassium Hydroxide (KOH) Examination, Provider Provided Microscopy Log (PPMLog), patient records and upon interview with the lead histotech determined the testing personnel #5 (NM) failed to document a KOH patient result in the PPMLog on May 16, 2018. The findings include: 1. Review of the CMS 209 revealed 5 of 5 testing personnel reporting laboratory testing in Mycology (Potassium Hydroxide - KOH) and Parasitology (Scabies) during 2018-2019. 2. Review of the laboratory's procedure manual policy on Potassium Hydroxide (KOH) Examination (Lab.P.212, Revised 4/16 /2019, Section 9.2.3 stated: "Results are reported utilizing the Provider-Provided Microscopy Log (Lab.F.111) additionally the results are noted in the patients EMR." 3. Review of Patient #5 (#609774, 5/16/2018) revealed in PPMLog for Scabies testing, but did not reveal the KOH result. The patient report for Patient #5 (#609774, 5/16/2018) was not ordered or reported in the EMR until 5/30/2018 with a KOH and Scabies result. 4. An interview with the lead histotech at approximately 11:30am, at August 13, 2019, confirmed testing personnel #5 (NM) failed to document a KOH patient result in the PPMLog on May 16, 2018.