

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0609327	(X3) Date Survey Completed 09/23/2019
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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
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must 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 follow survey performed on 09/23/2019, review of the patient testing logs and interview with the laboratory office manager, the laboratory director failed to 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. The findings included: a. During the follow up survey performed on 09/23/2019, the laboratory patient testing logs indicated a second testing personnel reviewing dermatopathology tissue slides during September 2019. b. The initials DrY indicated that on September 13, 2019 a second testing personnel performed three tissue dermatopathology tissue slide reviews. 0-61 Left Ear 0-62 Left Dorsal hand 0-63 Left top shoulder c. The laboratory had no documentation of initial training or competency for the testing personnel DrY. d. The laboratory had no documentation of policy or procedures for documenting testing personnel training and competencies. e. The laboratory office manager confirmed by interview on 09/23/2019 that the laboratory director had not performed an initial training and competency assessments on the testing personnel DrY. f. The laboratory reports on the CMS-116 performing approximately 2500 dermatopathology tissue slides reviews annually.</p>

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 a follow up visit, review of the laboratory policies and procedures and staff interview on September 23, 2019, the laboratory director failed specify, in writing, the responsibilities and duties of 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. The findings included: a. The laboratory performs dermatopathology tissue slide reviews. The patient log book indicated that the testing personnel (DrY), performed patient testing and diagnosis based off of differential slide reviews during 2018 and 2019. b. Upon review of the patients medical records, for slide ID # M-6 performed on 08/23/2019, and 0-65 performed on 09/16/2019, indicated that testing personnel (DrY) performed the patient testing and patient diagnosis report. d. The laboratory office manager confirmed by interview on September 23, 2019, that the individual listed on the patient logs (DrY) was a dermatopathologist and reads his own patients dermatopathology slides, but that the laboratory director reviews the slides prior to releasing the patient reports. e. The laboratory had no documentation that the laboratory director had authorized testing personnel (DrY) to perform patient testing; 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. f. The laboratory office manager confirmed by interview on September 23, 2019 at approximately 10:15 a.m. that the laboratory director had not specified in writing the responsibilities and duties of testing personnel (DrY). g. The laboratory reports performing approximately 2500 dermatopathology patient slide reviews annually.