

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2004845	(X3) Date Survey Completed 02/26/2018
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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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to have the same identification numbers for the dermatopathology consultation report and the patient's specimen slide. The findings included: 2/26/18 at 10:45 AM, four Histopathology slides and final report for the patient review showed that; the slides were labeled with patient's name and the identification numbers as 18-213A and 18-213B (2 slides for each identification number) as was in requisition slip, while the final dermatopathology consultation report had same patient name but the slide identification numbers as 18-215A and 18-215B(2 slides for each identification number). During an interview on 2/26/18 at 11:00 AM, the laboratory director confirmed that; the slides were labeled with patient's name and the identification numbers as 18-213A and 18-213B (2 slides for each identification number) as was in requisition slip, while the final dermatopathology consultation report had same patient name but the slide identification numbers as 18-215A and 18-215B(2 slides for each identification number).</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general</p>

laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and the interview with the laboratory director, the laboratory failed to review assessment policies, procedures and reports to verify that the laboratory had a system in place to ensure continuous improvement. The findings included: Observation on February 26, 2018 revealed that; 1) The identification numbers for the dermatopathology consultation report did not match with the identification numbers on requisition slip and the specimen slides. Refer to D5203. 2) Quality control log did not include immunohistochemical (IHC) stains reactivity for the IHC stains performed on the test specimens. Refer to D5475. 3) The dermatopathology consultation reports did not include specimen source. Refer to D5805. During an interview on 2/26/18 at 12:30 PM, the laboratory director confirmed findings 1 to 3 and that, there was no quality assessment review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems.

D5475

CONTROL PROCEDURES

CFR(s): 493.1256(e)(3)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview, the laboratory failed to check the immunohistochemical (IHC) stains for reactivity for the IHC stains performed on the samples. 2/26/18 at 10:30 AM, four final consultation reports for Histopathology specialty from January 2018, slides, and "Hematoxylin and eosin control log" (H & E control log) review showed that; H& E control log did not include the IHC stain controls and there was no separate log for the IHC stain reactivity. The laboratory did not check the immunehistochemical stains for reactivity for the IHC stains performed on the samples. First three final consultation reports did not have the specimen slides or the control slides at the time of survey. The fourth report had the patient's specimen slides but no quality control slides at the time of survey. During an interview on 2/26 /18 at 12:15 PM, the laboratory director confirmed that; H& E control log did not include the IHC stain controls and there was no separate log for the IHC stain reactivity. The laboratory did not check the immunehistochemical stains for reactivity for the IHC stains performed on the samples. First three final consultation reports did not have the specimen slides or the control slides at the time of survey. The fourth report had the patient's specimen slides but no quality control slides at the time of survey.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have the specimen source for the dermatopathology consultation reports. The findings included: 2/26/18 at 11:30 AM, two dermatopathology consultation reports reviewed showed that; (1) Accession: C18-001(DR18-015-3) & (2) Accession: C18-002 (DR18-041), did not have the source of specimen. During an interview on 2/26/18 at 11:40 AM, the laboratory director confirmed that; dermatopathology consultation reports for Accession: C18-001(DR18-015-3) & Accession: C18-002 (DR18-041), did not have the source of specimen.