

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2128778	(X3) Date Survey Completed 03/28/2018
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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
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on interview with the laboratory director on the day of survey, the laboratory failed to have documentation of verification of accuracy for histopathology slide reviews. Findings Include. a. The laboratory performs histopathology slide review for dematopathology. b. The laboratory failed to perform and document testing personnel's competency for accuracy for histopathology slide review. c. This deficient practice was affirmed by interview with the laboratory director on March 28, 2018 at approximately 2:15pm. d. The laboratory performs approximately 130 patient histopathology slide reviews annually.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the laboratory director on March 28,2018, the laboratory failed to include a quality assessment policy or procedure of how it will monitor and assess the general</p>

	<p>laboratory system requirements in accordance to 493.1231 through 493.1236. Findings include: a. The laboratory policy manual did include a policy or procedure regarding performing quality assessments for general performance. b. The laboratory did not have documentation of quality assessments that were performed regarding patient reports and records for completion and accuracy. c. The laboratory did not have documentation regarding competency assessments for preanalytical, analytic and postanalytical accuracy for testing performed or verification of accuracy of testing personnel performance. d. This deficient practice was affirmed by the laboratory director on March 28, 2018 at approximately 2:45 pm. e. The laboratory performs approximately 130 histopathology slide reviews annually.</p>
<p>D5601</p>	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's patient histopathology log book, patient pathology reports and Quality Control (QC) logs, on March 28, 2018, the laboratory failed to provide documentation of control slide review or documentation of quality of slide stain review for each day of patient testing. Findings include: a. The laboratory sends its specimens to an outside laboratory for slide preparation. Upon return of the slides to the laboratory, the laboratory did not assess the quality of the stained slide prior to releasing patient results. b. A random selection of patients records performed for the following years had no documentation stain quality or QC slides: 2017 2018 Patients: #6, #7, #8 #2,#3,#4, #5 c. This deficient practice was affirmed by interview with the laboratory director on March 28, 2018 apt approximately 3:00 pm. d. The laboratory records on the CMS-116 performing approximately 130 histopathology slide reviews annually.</p>
<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient testing records, the laboratory policy and procedure manual, the laboratory failed to provide a mechanism for verification of testing personnel accuracy for performing histopathology slide reviews. Findings include a. See Dtag 2003</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy and procedure manual on March 28, 2018; the laboratory failed to include policies or procedures regarding monitoring and assessment of personnel who are performing preanalytical, analytic and post analytical processes. Findings include: a. The laboratory policy manual does not include a process for monitoring of personnel performing preanalytic and postanalytic activities for patient specimen processing and retention of patient records or reports. b. The laboratory Policy's do not include how verification of accuracy of testing personnel are performed or evaluated. See Dtag 2003 c. This deficient practice was affirmed by the laboratory director by interview on March 28, 2018 at approximately 3:30 pm. d. The laboratory has three staff who package label and complete testing requisitions. These staff also file the slides and reports for retention. The laboratory records performing approximately 130 histopathology slides annually.