| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 19D0994686 | 03/14/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Tulane University Health Sciences Center | 1430 Tulane Avenue, 86-79, Room 6524, New Orleans, LA | |

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 |
|---|---|
| **D0000** | A Certification Survey was performed on March 14, 2019 at Tulane University Health Sciences Center, CLIA ID # 19D0994686. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| **D5601** | HISTOPATHOLOGY<br>CFR(s): 493.1273(a)(f)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on record review and interview with personnel, the laboratory failed to document the performance of a control slide for Hematoxylin and Eosin (H&E) staining for five (5) of eighty seven (87) days reviewed. Findings: 1. Review of the laboratory's "Quality Control" policy and procedure revealed "Daily QC will be performed on all stains using the Special Stain/IHC Control Slide Reactivity Form to ensure that the staining process was performed successfully and that the lab is obtaining the correct results." 2. Review of the laboratory's H&E quality control records for May 2018 through August 2018 revealed the laboratory did not document the staining acceptability for the following five (5) days: May 4, 2018: total of 133 slides processed May 18, 2018: total of 173 slides processed May 25, 2018: total of 130 slides processed July 12, 2018: total of 273 slides processed August 30, 2018: total of 180 slides processed 3. In interview on March 14, 2019 at 11:35 am, Personnel 2 stated the evaluating pathologist did not document the H&E stain quality |

| | |
|---|---|
| | on the laboratory's quality control form for the identified dates. II. Based on record review and interview with personnel, the laboratory failed to document the performance of a control slide with known reactivity for Special stains for three (3) of twelve (12) patients reviewed. Findings: 1. Review of the laboratory's "Quality Control" policy and procedure revealed "Daily QC will be performed on all stains using the Special Stain/IHC Control Slide Reactivity Form to ensure that the staining process was performed successfully and that the lab is obtaining the correct results." 2. Review of random selection of patients and quality control records revealed the laboratory did not document the performance of quality control for the following patients: May 24, 2018: Patient 1: AFB and Fite May 25, 2018: Patient 2: Phh3 February 22, 2019: Patient 3: CD31 3. In interview on March 14, 2019 at 11:59 am, Personnel 2 stated the laboratory did not document the quality control for the identified patients. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, and interview with personnel, the laboratory's Quality Assurance (QA) monitors failed to identify and correct quality issues. Findings: 1. Review of the laboratory's "Quality Control" procedure revealed "The lab supervisor is responsible for review of QC and documentation of corrective action. The medical director of the lab will review the all QC forms at least monthly and will provide technical assistance to the supervisor as needed." 2. Review of the laboratory's quality control and patient records identified the following issues: a) The laboratory failed to document the performance of a control slide for Hematoxylin and Eosin (H&E) Staining for five (5) of eighty seven (87) days reviewed. Refer to D5601 I. b) The laboratory failed to document the performance of a control slide with known reactivity for Special stains for three (3) of twelve (12) patients reviewed. Refer to D5601 II. 3. In interview on March 14, 2019, Personnel 2 confirmed the laboratory's QA monitors did not identify the cited issues. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5601. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES |

| | |
|---|---|
| | CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures. Refer to D5793. |