| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 42D2157906 | 08/28/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Musc Pathology Outreach Services | 173 Ashley Avenue, Charleston, SC | |

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 |
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| **D0000** | An announced CLIA Recertification survey was conducted on 8/28/2024. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with staff the laboratory failed to document twice annual accuracy in 2022 and 2023 for each test performed. a. The laboratory was asked to provide a policy for the performance of twice annual accuracy of histopathology and oral pathology. No policy was provided. b. The laboratory was asked to provide documentation of verification of accuracy. No documentation was provided. b. An interview with the Laboratory Director on 8/28/2024 at 2:10 PM confirmed these findings. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on record review and interview with testing personnel the laboratory failed to document the intended reactivity and predicted stain characteristics of Hematoxylin and Eosin each day of use. a. A review of the patient report MRN 001368435 revealed "Microscopic Description ...The hematoxylin and eosin stain quality was deemed appropriate; when pertinent, stains were performed using appropriate controls." b. An interview with testing number 3 (TP-3), as listed on the CMS-209, on 8/28/2024 at 4: 33 PM revealed stain quality is documented in the patient notes, and appropriate evaluation of stain quality is based on experience. |
| **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>Based on record review and interview with testing personnel the laboratory failed to document the intended reactivity of histopathology stains. a. A review of the patient report MRN 001368435 revealed "Microscopic Description ...The hematoxylin and eosin stain quality was deemed appropriate; when pertinent, stains were performed using appropriate controls." b. An interview with testing number 3 (TP-3), as listed on the CMS-209, on 8/28/2024 at 4:33 PM revealed stain quality is documented in the patient notes, a positive control slide is provided and evaluated for immunohistochemical stains; if it is determined the control slide quality is inadequate it will be sent back for repeat staining. |
| **D6128** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with staff the Technical Supervisor failed to document competency of 6 or 6 testing personnel in 2022 and 2023. a. The laboratory was asked to provide documentation of competency for testing personnel. No documentation was provided. b. An interview with the Laboratory Director on 8/28 /2024 at 2:10 PM confirmed these findings. |