

|  |   |   |
|--|---|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D1014741        | <b>(X3) Date Survey Completed</b><br><br>12/15/2023 |
| <b>Name of Provider or Supplier</b><br><br>Auc Urologists, Llc   | <b>Street Address, City, State</b><br><br>3600 Sea Mountain Hwy, Little River, SC |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
|---------------------------|--|
| <b>D5473</b>              | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory records and interview with the Laboratory Manager the laboratory failed to test staining materials for intended reactivity of the Papanicolaou stain used for nongynecologic cytology slide preparations for each day of use in July 2023 and from September 2023 through November 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide records to document an assessment of the intended staining characteristics of the Papanicolaou stain which was used to stain nongynecologic cytology slide preparations in July 2023 and September 2023 through November 2023. 2. Records titled CYTOLOGY QUALITY CONTROL for July 2023 and September 2023 through November 2023 documented 914 nongynecologic cytology slide preparations were stained with the Papanicolaou stain in July 2023 and September 2023 through November 2023. The laboratory failed to document during this timeframe that the Papanicolaou stain was tested for intended staining characteristics on each day that the 914 nongynecologic cytology slide preparations were stained. 3. During an interview on December 12, 2023 at 11:00 AM these findings were confirmed by Laboratory Manager. Laboratory Manager stated during the interview: a. The Laboratory Director/Technical Supervisor A no longer reviewed specimen slides at this laboratory (Facility A) and the quality of the stain on the slides was not assessed at Facility A. b. The specimen slides were being evaluated at Facility B which was unable to provide the daily quality control records specific to the assessment of the quality of the Papanicolaou stain used at Facility A.</p> |