| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 21D0712129 | 07/30/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Allaway And Parousis Urology Md Pa | 12234 Williams Road, Cumberland, MD | |

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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| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the operator's manual, the endocrinology records and interview with the laboratory manager, the laboratory failed to perform the method validation on the new analyzer that was received in the laboratory prior to testing patient specimens. Findings: 1. The "Method Validation Policies and Procedures" in the operators manual states "Before using the FastPack System to test patients, validate the test(s) you plan to perform to demonstrate that, in your laboratory setting, the instrument meets the manufacturer's specifications for accuracy, precision and reportable range." 2. The "Method Validation Policies and Procedures" require the user to follow the procedures and document the results on the worksheets labeled "PSA Validation Worksheet", "Step 1: Verify Reportable Ranges", and "Step 2: Verify Accuracy and Precision." 3. The laboratory received a replacement endocrinology analyzer on 01/22/18. The endocrinology records show that only a calibration was performed for prostatic specific antigen (PSA). There were no records showing that the required "Method Validation Policies and Procedures" had been performed on the new analyzer prior to reporting patient test results. 4. During the survey on July 30, 2019 at 12:45 PM the laboratory manager confirmed that the "Method Validation Policies and Procedures" had not been performed on the new analyzer prior to reporting patient test results. |

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| **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 the laboratory director, the laboratory did not maintain the documentation of the acceptability of the quality control (QC) slide (s) with each batch of stained slides received from the processing laboratory.<br>Findings: 1. The histopathology records that were reviewed only included documentation of the QC of the stains for the month of July 2019. 2. The laboratory director stated that the laboratory that performs the staining of the slides requires the laboratory that is interpreting the slides to return the documentation of the stain QC of the slides as part of their quality assurance program. 3. During the survey on July 30, 2019 at 12:45 PM the laboratory director confirmed that the documentation of the QC of the stains was not available in the laboratory where the slides were being interpreted. |