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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D2046668 | (X3) Date Survey Completed 08/31/2018 |
| Name of Provider or Supplier Russell O Schub Pa | Street Address, City, State 8875 Centre Park Drive Ste D, Columbia, 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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| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: I. Based on standard operating procedure manual (SOPM) review and interview with the laboratory staff, the laboratory did not ensure that there was an approved policy for transporting completed patient histopathology slides from the pathology service laboratory to the laboratory for testing. Findings: 1. The laboratory utilizes a pathology service to make and stain histopathology slides from patient biopsy specimens collected in their endoscopy center. 2. During an interview at 10:00 AM on the day of the survey, the testing person who reads the slides stated that, "the slides are sometimes delivered to my home and then I bring them here to read." and; 3.</p> |

During an interview at 10:15 AM, the representative from the pathology service confirmed that patient slides are sometimes delivered to the laboratory and other times delivered to the home of the testing person who reads the slides. The pathology service staff confirmed that the SOPM did not have an approved procedure for the current practice of transporting patient histopathology slides from the pathology service laboratory to the laboratory for testing.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

I. Based on standard operating procedure manual (SOPM) and quality assurance record review and interview with laboratory staff, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings: 1. The laboratory's SOPM was reviewed. The procedure, "Pathology Reports" states that "Pathology reports will be signed out within 2 business days of receipt of the specimen." 2. A review of "Surgical Pathology Annual Quality Assurance" reports from 2016 and 2017 showed that under "Turn-Around-Time" the "Average final diagnosis turn-around (days)" in 2016 was 3.89 and in 2017 it was 3.87. 3. During an interview on 8/31/18 at 12:15 PM, a representative from the pathology service which makes the slides stated that it was the goal of the pathology service to process the patient biopsy specimens and to return the patient slides to the laboratory for testing in 2 days and that it was not a measure of the amount of time it took for the pathologist to finalize the pathology report. The pathology service representative stated that the procedure needed to be rewritten to reflect the current practice of the laboratory. II. Based on standard operating procedure manual (SOPM) and quality assurance record review and interview with laboratory staff, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings: 1. The laboratory's SOPM was reviewed. The procedure, "Quality Assurance Program Surgical Pathology" states that "Cases with a diagnosis of malignancy for the patient may be shown to a second pathologist or sent-out for expert second opinion prior to release of the case" and that "An annual QC report is generated to look for trends." 2. A review of "Surgical Pathology Annual Quality Assurance" reports from 2016 and 2017 showed that there was no annual report tracking trends in the cases sent out for second opinion available at the time of the survey. 3. During an interview on 8/31/18 at 12:15 PM, a representative from the pathology service which makes the slides confirmed that the laboratory does not currently create a report which documents any differences in diagnosis on cases sent out for second opinion.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on laboratory procedure manual and record review and interview with laboratory staff, the laboratory director (LD) failed to follow the established quality assurance (QA) program to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. The laboratory summarizes its annual quality assurance (QA) activities in their "Surgical Pathology Annual Quality Assurance" report. The report documents the laboratory's "Specimen Deficiency Report," "Turn-Around-Time," "Amended Reports," "Addended Reports," "Total Cases Submitted" for the year as well as a record of the number of cases "Submitted for QC" and how many "Agreed" or "Disagreed," and a record of "Malignancies reported." 2. A review of "Surgical Pathology Annual Quality Assurance" reports from January, 2016 to June, 2018 showed that the annual report for "January 1, 2016 - December 31, 2016" was signed by the LD on 7/28/18; and 3. The annual report for "January 1, 2017 - December 31, 2017" was signed by the LD on 7/28/18. 4. During an interview on 8/31/18 at 12:15 PM, the laboratory staff confirmed that the LD did not ensure that the QA program was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.