| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 21D0898621 | 12/10/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Gastroenterology Specialists Of Frederick | 85 Thomas Johnson Court Ste B, Frederick, 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 |
|---|---|
| **D3043** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(7)<br><br>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of the patient slides and interview with the laboratory director (LD) and histology tech during the onsite revisit survey conducted on 12/10/19, the laboratory failed to ensure that patient slides were retained and available for the required 10 year period. Findings: 1. On 11/15/19 the "Stain Quality Assurance Log" showed that patient 893-A/B was reviewed and reported. The LD explained that 893-A /B indicated that there were two slides read, 893-A and 893-B. When the slides were pulled for review it was determined that slide 893-B was missing. 2. During the onsite revisit survey on 12/10/19 at 2:00 PM the LD and histology tech confirmed that patient slide 893-B was not available at the time of the survey. II. Based on review of the quality control (QC) slides and interview with the laboratory director and histology tech during the onsite revisit survey conducted on 12/10/19, the laboratory failed to ensure that QC slides were retained and available for the required 10 year period. Findings: 1. On 10/25/19 the "Stain Quality Assurance Log" showed that slides 1/3 and 3/3 for Helicobacter Pylori (HPY) had been reviewed and found acceptable. When the slides were pulled for review it was determined that the 2/3 HPY slide was missing. 2. On 11/13/19 and 11/15/19 the "Stain Quality Assurance Log" showed that slides for HPY had been reviewed and found acceptable. When the slides were pulled for review it was determined that there were 3 slides labeled 1/4, 2 /4 and 4/4. The slide labeled 3/4 was missing. 3. During the onsite revisit survey on 12 |

| | |
|---|---|
| | /10/19 at 2:00 PM the histology tech confirmed that the two of the QC slides were not available at the time of the survey. |
| **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:<br>Based on record review and interview with the laboratory director, the laboratory failed to ensure that written quality control (QC) policies were established to ensure accurate and reliable testing of patient specimens for histology. Findings: 1. During interview with the laboratory director on the afternoon on the day of survey, the director stated that in order to ensure a QC slide meets the laboratory's criteria of acceptability for staining characteristics or, if appropriate, positive reactivity, additional control slides are added to staining events to increase the chances that at least one control slide will stain as expected for each specific specialty or immunohistochemistry stain. 2. The laboratory did not have a written procedure for performing this method of QC analysis and evaluating and analyzing results of the quality control testing when multiple tissue was used to check the ability of each stain to produce expected patterns of reactivity and there were no references for the reliability of using multiple control slides to guard against control failure. 3. During the interview on 12/10/19 at 2:00 PM the laboratory director confirmed that the laboratory did not investigate and document the investigation when QC failures occurred if at least one tissue reacted as expected. |