

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1022768	(X3) Date Survey Completed 09/17/2021
Name of Provider or Supplier Gi Associates Of Maryland	Street Address, City, State 3510 Old Washington Rd, Suite 201, Waldorf, 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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual, annual quality assurance (QA) report, and "Send-Out Log" and interview with the laboratory consultant (LC), the laboratory failed to document all slides sent to extra-departmental facilities on the "Send-Out Log" to ensure tracking and follow-up for potentially overdue slides. Findings: 1. Section "6. Release of Slides or Blocks" of the laboratory's procedure manual stated that any slide that was sent out was to be logged onto a "Send-Out Log" form. The "Send-Out Log" was also used to document return of the slides. 2. The procedure stated that "Periodic review of the "Send-Out Log" is performed to identify materials which have not been returned in a timely manner. When material is overdue, the organization receiving the material is contacted to expedite the return of materials." 3. Every six months, the laboratory ran an annual QA report that showed the cases sent out for extra-departmental consultation. The annual QA report from 05/01/2020-12/31/2020 showed a single extra-departmental consultation for part F of accession number GM20-221. The annual QA report from 01/01/2021-06/30/2021 showed a single extra-departmental consultation for part A of accession number GM21-740. 4. The laboratory had a single "Send-Out Log" that contained two entries, neither of which were GM20-221 or GM21-740. 5. The Laboratory Information System (LIS) showed which slides from GM20-221 were sent out and to whom, but did not contain any notes as to if and when the slides were received back into the laboratory. The slides</p>

that were documented as having been sent out were found in the slide storage box. 6. The LIS showed which slides from GM21-740 were sent out, to whom they were sent, and notes on when the slides were received back at the laboratory. 7. During the exit interview on 09/17/2021 at 10:45 AM, the LC confirmed that the laboratory was not documenting all patient slides sent out to extra-departmental facilities on the "Send-Out Log" to be able to track and follow-up on potentially overdue slides.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of the final test report and interview with the laboratory consultant (LC), the laboratory's final test report failed to include the correct suite number in the address where the testing was performed. Findings: 1. The laboratory's final test report listed the testing laboratory's address with "Suite 200." The CLIA Certificate of Registration listed the laboratory's address with "Suite 201." 2. During the initial survey on 09/17/2021 at 9:40 AM, the LC confirmed that the final test report had an incorrect suite number listed.