| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D2021788 | 03/13/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Gastroenterology Associates Of Tidewater | 661 Independance Pkwy, Suite 120, Chesapeake, VA | |

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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| **D0000** | An announced CLIA recertification survey was conducted at Gastroenterology Associates of Tidewater on March 13, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the tissue processor operations manual, procedures, instrument maintenance logs, patient log sheets, and an interview, the laboratory failed to document performance of weekly Tissue Tek VIP 6 maintenance according to their policy from February 11, 2019 to March 13, 2019 while reporting six hundred forty-eight (648) histopathology cases. Findings include: 1. Review of the Sakura Tissue-Tek Operations Manual revealed Care of the Equipment Maintenance Instructions in Section 6 that stated: "All the reagents should be replaced or exchanged on a weekly basis". 2. Review of the laboratory's procedure manual revealed a "Reagent Exchange and Warm Water Flush" procedure that stated: "all reagents are exchanged or replaced on a weekly basis". 3. Review of the laboratory's Sakura Tissue-Tek VIP instrument maintenance logs revealed no documentation of reagent replacement or exchange from 2/11/19 to 3/13/19. The inspector requested to review additional documentation of Xylene, Ethanol, and Formalin reagent replacement and exchange for the four (4) weeks outlined above. No records were available. 4. Review of the patient log sheets revealed 648 histopathology patient cases were processed utilizing the Sakura Tissue |

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| | Tek processing instrument for the 4 week timeframe outlined above. 5. In an exit interview with the laboratory director, practice manager, and primary histotechnician at 12:30 PM, the above listed findings were confirmed. |
| **D5433** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(1)<br><br>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of policies, equipment maintenance logs, and an interview, the laboratory failed to document histopathology microscope maintenance, according to their policy, during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's policy manual revealed an equipment maintenance policy that stated: "microscope preventative maintenance will be performed by Southern Microscope at least once every eighteen months". 2. Review of the laboratory's equipment maintenance records from 3/1/17 to 3/13/19, revealed one (1) service record for the Olympus Bx45 microscope (Serial Number 9G10675) performed on 2 /22/19. The inspector requested to review additional microscope maintenance documentation. The practice manager located a Southern Microscope service record dated 11/29/16. No other documentation was available. 3. In an exit interview with the laboratory director, practice manager, and primary histotechnician at 12:30 PM, the above listed findings were confirmed. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on a tour, review of the laboratory's procedure manual, equipment maintenance logs, available personnel training documentation, and an interview, the laboratory director (LD) failed to document a competency assessment for one (1) testing personnel (TP) after installation and validation of four (4) new Avantik equipment components were put in use for patient tissue testing on December 19, 2018 and up to the date of the survey on March 13, 2019. Findings include: 1. In a laboratory tour at |

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| | approximately 10:00 AM, it was revealed that the following four (4) new Avantik equipment components were being utilized for patient tissue processing: Sakura VIP6 Tissue Processor, EM8 Embedding Center, Leica RM2125 Rotary Microtome, and Leica XL Automatic Stainer. The practice manager stated: "we installed the new equipment in December 2018". 2. Review of the laboratory's procedure manual revealed a policy for personnel competency assessment. The policy stated: "the lab director will evaluate the competency of testing personnel when a new method is begun and semi-annually during the first year of employment. Thereafter, evaluation is done yearly." 3. Review of the maintenance logs for the 4 Avantik components outlined above revealed that TP A was the operator of the newly installed equipment from 12/19/18 to 3/13/19. See Personnel Code Sheet. 4. Review of the Avantik equipment Qualification and Validation Checklists for the 4 newly installed components listed above revealed no LD signature for the training documentation for Testing Personnel A as an operator of the instruments. The inspector requested to review the initial competency assessments for TP A for the equipment. The documentation was not available for review. 5. In an exit interview with the laboratory director, practice manager, and primary histotechnician at 12:30 PM, the above listed findings were confirmed. |