

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0941513	(X3) Date Survey Completed 07/07/2023
Name of Provider or Supplier Harford Gastroenterology Associates Histology Lab	Street Address, City, State 2214 Old Emmorton Rd Suite 100a, Bel Air, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to ensure that the attestation worksheet was printed and signed by the appropriate laboratory personnel. Findings: 1. Review of the College of American Pathology (CAP) histopathology (HQBX1) PT records for the last event of 2021 through the first event of 2023 (4 events) were reviewed. The attestation worksheet for three of the four events had not been signed and dated by the appropriate laboratory personnel and the worksheet for one of the four events was not available. 2. During the validation survey on 07/07/2023 at 11:15 AM, the LD confirmed that the attestation worksheet had not been signed by the appropriate laboratory personnel and that one event was not available.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test</p>

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.

This STANDARD is not met as evidenced by:

Based on review of the quality control (QC) staining logs, patient slides, policy and procedure manuals, and interview with the laboratory director (LD), the laboratory's procedure manual did not include an interpretation of the abbreviations used on the staining logs and patient slides. Findings: 1. The laboratory's QC staining logs for the evaluation of the stains include abbreviations of the types of stains used each day of patient testing. The patient slides include abbreviations of the type of stain used on each slide. 2. Neither the worksheet nor the policy and procedure manual identified the meaning of the abbreviations used on the slides. 3. During the validation survey on 07/07/19 at 11:15 AM, the LD confirmed that the abbreviations used on the QC staining logs and patient slides were not identified in the policy and procedure manuals.

D6175

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual, room temperature and humidity chart, and interview with the laboratory director (LD), the testing personnel (TP) failed to follow the laboratory's procedures for labeling slides and documenting the minimum and maximum (Min/Max) temperature/humidity for the room and refrigerator on weekends and holidays. Findings: 1. The "Labeling of Slides / Slide Identification" procedure lists the following labeling instructions: "1st Line: Specimen Class + Last two of current year + Accession # 2nd Line: Specimen Designation + Block Designation 3rd Line: Stain/Procedure (left justify) 4th Line: Date (left justify)" 2. Observation of a labeled patient slide with the LD showed the following: 1st Line: HGA LAB (name of lab), 2nd Line: Specimen Class + Last two of current year + Accession #, 3rd Line: Specimen Designation + Block Designation + Stain, and 4th Line: patient's last name, first name and middle initial if needed. The LD confirmed that the TP were not labeling the slide based on the approved policy

and procedure manual. 3. The quality control section of the "Routine Staining of Tissue-Mounted Slides" procedure had been updated and approved on 6/8/23 by the LD. Section 5.1 was updated to include the refrigerator temperature. Section 5.1.1 was updated with the following statement: "This includes monitoring of minimum and maximum temp/humidity on weekends and holidays." 4. The LD explained that a "Min/Max" thermometer had been added to the room and refrigerator. The "Min/Max" readings of the thermometers are to be recorded after a weekend or holiday on the "Room Temperature/Humidity Chart" worksheet and then the thermometers are to be reset. Review of the "Room Temperature/Humidity Chart" for June 2023 showed that after the implementation of the updated procedure on 6/8/23 the "Min/Max" values had not been documented after each weekend as required. 5. During the validation survey on 07/07/23 at 11:15 AM, the LD confirmed that the TP were not labeling the slide based on the approved policy and procedure manual and that the updated "Min/Max" temperature procedures had not been followed by the TP as required.