| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 05D0864483 | 11/18/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Gastroenterology Of The East Bay | 2510 Webster St, 2nd Flr, Berkeley, CA | |

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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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the Microscope [Olympus BX43, serial number OJ48121], review of laboratory records, the lack of records in 2022, and interview with laboratory personnel, it was determined that the laboratory failed to verify at least twice each calendar year the accuracy of biopsy pathology reported by two Testing Persons. Findings included: a. Laboratory Pathology Reports documented Testing Personnel in 2022, as follows: Date ID Testing Person ---------- 4/04/22 PX22 - 815 Dr. ML 6/24/22 PX22 - 1638 Dr. RS b. Records for peer review of pathology reported in 2022 documented one review for Dr. ML and one review for Dr. RS. The laboratory failed to have additional records of review in 2022 for these two Testing Persons. c. Laboratory personnel affirmed (11/18/25 at 5:00 PM) the aforementioned lack of additional records for peer review and that the Testing Persons reported pathology in 2022, as follows: Testing Person Month/Year Volume ---------- Dr. ML April 2022 82 reports Dr. RS May 2022 218 reports d. The reliability and quality of pathology results reported by Dr. ML and Dr. RS in 2022 could not be assured during this Survey. . |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or |

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| | examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on the deficiencies cited, review of written policy/procedures, and interview with Laboratory Personnel, it was determined certain elements were missing in the written policy/procedures pertaining to peer review of histopathology testing, documenting Stain quality, and test records documenting the testing person. Findings included: a. The written policy/procedure failed to specify at least twice annual peer review of pathology reported by each Testing Person during the calendar year. See D5217. b. The written policy/procedure failed to specify documenting Stain Quality by Testing Persons reporting pathology. See D5473. c. The written policy/procedure failed to specify that the identity of each Testing Person must be documented in the test records. See D5787. . |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the Leica Autostainer XL (serial number 1481), review of laboratory records, the lack of records, and interview with laboratory personnel, it was determined that the laboratory Testing Personnel failed to document the quality of the staining. Findings included: a. Laboratory Pathology Reports randomly selected for this Survey documented slides were stained and read, as follows: Date ID ---------- 3/09/22 PX22 - 560 4/04/22 PX22 - 815 10/19/22 PX22 - 2810 2/14/23 PX23 - 450 5/26/23 PX23 - 01575 12/05/23 PX23 - 03425 2/29/24 PX24 - 570 7/08/24 PX24 - 1825 10/22/24 PX24 - 2935 2/11/25 PX25 - 376 6/16/25 PX25 - 1610 8/14/25 PX25 - 2300 b. Laboratory personnel affirmed (11/18/25 at 5:00 PM) staining slides with H & E (Hemotoxylin & Eosin) and that requests for special stains were sent out. c. The laboratory failed to have records documenting the Testing Person's assessment of the quality of the Stain(s) for slides being reported. d. And thus, the reliability and quality of stained slides could not be assured. The Testing Personnel issued 7,000 Pathology Reports annually (CMS116 CLIA Application, 10 /28/25). . |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, the lack of records, and interview with |

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| | laboratory personnel, it was determined the laboratory failed to document the Testing Person grossing each biopsy sample. Findings included: a. Laboratory Personnel Reports (CMS209, CLIA and LAB116, CDPH; 10/30/25) named five Testing Persons performing Grossing, classified as High complexity testing. b. Laboratory Pathology Reports randomly selected for this Survey documented biopsy Gross descriptions, as follows: Date ID ---------- 3/09/22 PX22 - 560 4/04/22 PX22 - 815 10/19/22 PX22 - 2810 2/14/23 PX23 - 450 5/26/23 PX23 - 01575 12/05/23 PX23 - 03425 2/29/24 PX24 - 570 7/08/24 PX24 - 1825 10/22/24 PX24 - 2935 2/11/25 PX25 - 376 6/16/25 PX25 - 1610 8/14/25 PX25 - 2300 c. The laboratory failed to have records documenting which Testing Person performed the Grossing of each sample. d. Laboratory personnel affirmed (11/18/25 at 5:00 PM) the aforementioned findings and lack of records. e. The laboratory issued 7,000 pathology reports with multiple Gross descriptions annually (CMS116 CLIA Application, 10/28/25) with no records of which Testing Person did the Grossing. . |