Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2161303	09/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Capstone Pathology Plc	3260 N Hayden Road Suite 207, Scottsdale, AZ	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs from 2/01/2024 through 9/12/2024 and interview with the testing personnel (TP-1), the laboratory failed to define criteria for the room temperature and ambient humidity that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. Findings include: 1. The laboratory processes histopathology specimens using the Leica ASP 300s Tissue Processor and the Leica Autostainer XL, and stores/utilizes histology stain reagents. 2. No documentation was presented for review from 2/01/2024 though 9/12/2024 to indicate the laboratory established acceptable ranges for the room temperature and the ambient humidity of the laboratory. The criteria must be consistent with the manufacturer's instructions, if provided. 3. The TP-1 interviewed on 9/12/2024 at 12:08 PM confirmed the laboratory failed to define criteria for the room temperature and ambient humidity of the laboratory during the timeframe indicated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation of histopathology stain reagents and interview with the testing personnel (TP-1), the laboratory used the stain reagents, Hematoxylin and Eosin, past the expiration dates for 173 days during 2024. Findings include: 1. The laboratory performs the Hematoxylin and Eosin (H&E) stain on patient slides, with an approximate annual test volume of 3,500. 2. During the survey conducted on September 12, 2024, direct inspection of the Hematoxylin reagent, lot #011122, indicated an expiration date of 1/11/24. The laboratory used the expired stain reagent on approximately 173 days of testing. 3. During the survey conducted on September 12, 2024, direct inspection of the Eosin reagent, lot #155272, indicated an expiration date of 8/31/24. The laboratory used the expired stain reagent on approximately 7 days of testing. 4. TP-1 interviewed on 9/12/24 at 12:20 PM confirmed the Hematoxylin and Eosin stain reagents were expired and were in use at the time of the inspection.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on review of written quality control procedures for histology stains and interview with the testing personnel (TP-1), the laboratory failed to determine the positive and negative control procedures for the Alcian blue/PAS and Giemsa stains based upon the performance specifications established by the laboratory. Findings include: 1. The laboratory performs testing in the subspecialty of Histopathology, with a reported annual test volume of 3,500. 2. The laboratory performs the histology stains, Alcian blue/PAS and Giemsa, on certain tissues, if warranted and ordered by the physician who issues the diagnosis. It is the practice of the laboratory to use previously tested patient specimens as positive and negative tissue controls for these stains. 3. No documentation was presented for review during the survey to indicate the laboratory determined the control procedures for both positive and negative controls based upon the performance specifications established by the laboratory for each stain. The control procedures must include the frequency, type and number of control materials used for each stain. 4. The laboratory failed to produce documentation to indicate that each control tissue used by the laboratory between February 1, 2024 and September 11, 2024 was verified by the laboratory for intended reactivity (both positive and negative) prior to using it as a control tissue in conjunction with patient testing. 5. The TP-1 interviewed on 9/12/2024 at 11:00 AM confirmed the laboratory failed to determine control procedures for the stains indicated above.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's microscope maintenance policy and interview with the testing personnel (TP-1), the laboratory failed to perform and document annual maintenance of the microscope during 2023. Findings include: 1. The laboratory's maintenance policy for the microscope states, "Yearly: Electrical checks will be performed and recorded. Perform maintenance per manufacturer recommendations. Optics are evaluated and cleaned." 2. The laboratory failed to provide evidence of annual maintenance for the microscope from 2023. 3. TP-1 interviewed on 9/12/2024 at 12:15 PM confirmed the laboratory failed to provide documentation of annual maintenance from 2023 for the microscope used by the laboratory to read patient slides. 4. The laboratory's reported annual test volume in the subspecialty of Histopathology is 3,500.
D5787	TEST RECORDS CFR(s): 493.1283(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). This STANDARD is not met as evidenced by: Based on review of pathology reports and interview with the testing personnel (TP-1), one out of four pathology reports failed to include the correct identity of the individual who performs the gross description on pathology specimens. Findings include: 1. The laboratory performs the gross description on gastrointestinal (GI) specimens under the specialty of Pathology, with an approximate annual test volume of 3,500. 2. One out of four pathology reports (C24-000010) reviewed during the survey incorrectly listed the individual who performed the gross description as "C.C.". 3. The CMS-209, Laboratory Personnel Form submitted during the survey conducted on September 12, 2024 did not include a testing personnel with the initials, C.C. The facility personnel stated that no person with the initials "C.C." ever worked at the laboratory. 4. TP-1 interviewed on 9/12/24 at 11:30 AM confirmed the pathology report indicated above failed to include the correct identity of the testing personnel who performed the gross description and confirmed that "C.C." was not a current or former employee of the laboratory.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The

	laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) records and interview with the testing personnel (TP-1), the laboratory's QA processes failed to monitor, identify and correct errors found in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory's QA procedures failed to include an ongoing mechanism to monitor, identify and correct errors with: acceptable ranges for the room temperature and humidity (see D5413 for findings); the use of expired stain reagents (see D5417 for findings); establishment of quality control material used for the Ab/PAS and Giemsa stains (see D5425 for findings); annual maintenance of the microscope (see D5433 for findings); and ensuring test records show the correct personnel who performs the gross description on patient specimens (see D5787 for findings). 2. TP-1 interviewed on 9/12/24 at 12:30 PM confirmed the laboratory's QA process at the time of the survey was not effective to monitor, identify and correct errors found in the analytic systems specified in 493.1251 through 493.1283.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test results maintained in Laboratory Information System (LIS) and interview with the testing personnel (TP-1), the laboratory failed to have a system in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry to final report destination, in a timely manner. Findings include: 1. No documentation was presented for review during the survey conducted on 9/12/2024 to indicate the laboratory has a system in place to ensure the accuracy of patient-specific data and patient test results that are entered into the LIS (LABdivus) and electronically sent to the ordering entity. 2. TP-1 interviewed on 9/12/2024 at 11:25 AM confirmed the laboratory failed to have a system in place to verify the accuracy of patient-specific data and patient test results that are entered into the LIS and electronically sent to the ordering entity.
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 laboratory's pathology reports and interview with the testing personnel (TP-1), the laboratory failed to include the microscopic description for specimen 'B' on one out of four pathology reports; the laboratory failed to include the Alcian blue/PAS test result on one out of three pathology reports; and the laboratory failed to include the correct test report date on one out of four pathology reports. Findings include: 1. One out of four pathology reports reviewed during the survey (Accession # C24-000020) failed to include the test result for the microscopic examination of specimen B. The laboratory received and examined two specimens, A (Duodenum, second part) and B (Stomach, antrum), for this case. 2. One out of three pathology reports reviewed during the survey (Accession# C24-000020) failed to include the test result for the Alcian blue/PAS stain which was performed on specimen B. 3. One out of four pathology reports reviewed during the survey (Accession# C24-001410) failed to include the correct test report date. The pathologist who examined the tissue and issued the diagnosis electronically signed the pathology report on 9/09/24 at 1:04 PM. The 'reported' date listed on the pathology report is 9/08/2024. 4. The TP-1 interviewed on 9/12/2024 at 11:40 AM confirmed the pathology reports referenced above failed to include the microscopic description of tissue B, failed to include the test result of the Alcian blue/PAS stain performed on specimen B, and failed to include the correct test report date as indicated above. 5. The laboratory performs testing under the specialty of Pathology with a reported annual test volume of 3,500.