

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0717479	<b>(X3) Date Survey Completed</b>  10/28/2024
<b>Name of Provider or Supplier</b>  Gulf Coast Pathologists Llc	<b>Street Address, City, State</b>  2631 McCormick Dr Suite 101, Clearwater, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Gulf Coast Pathologists LLC on 10/22/2024 - 10/28/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5300 Preanalytic Systems D5400 Analytic Systems
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 American Proficiency Institute (API) proficiency record review and interview with the Laboratory Director, the laboratory failed to retain documentation of signed attestation statements for two proficiency testing (PT) events (Microbiology 2nd Event 2024 and Hematology 2nd Event 2024) out of three events (Microbiology 2nd Event 2024 and Hematology 2nd and 3rd Event 2024) reviewed. Findings included: Record review of the laboratory's Quality Management Policy showed "Proficiency Testing Procedures" required documentation to include an attestation page with the analyst name. The procedure manual was signed by the Laboratory Director on 05/15/22. Review of the API instructions revealed testing personnel and the laboratory director must physically sign an attestation statement for all PT results</p>

	<p>and retain the signed statement (or a copy) for a minimum of 2 years. Review of proficiency records revealed the Microbiology 2nd Event 2024 and Hematology 2nd Event 2024 attestation records had not been signed by the lab director or testing personnel. On 10/22/2024 at 3:00 PM, the Laboratory Director confirmed the lack of signatures for the two proficiency testing events.</p>
<p><b>D5213</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing (PT) and interview with the Laboratory Director, the laboratory failed to evaluate ungraded results in microbiology proficiency testing for the 2nd Event 2024. Findings Included: Record review of the "API Proficiency Testing Performance Evaluation 2024 Microbiology - 2nd Event" revealed "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes." Record review of API proficiency testing evaluation revealed the laboratory had not performed a self evaluation for ungraded results for the following: Microbiology 2nd Event 2024 Parasitology - PAR - 05 and PAR - 09 - no consensus Molecular Bacti [sic] bacteriology - Urine Streptococcus pyrogenes - UTI - 06 - no appropriate peer group Molecular Resist. [sic] Resistance Genes - Urine CTX - M [sic] cefotaximase-Munich Group 1- UTI 06 - 07, 09, 10 - no appropriate peer group dfrA (Resistance gene) - UTI - 06, 07, 09, 10 - no appropriate peer group mecA (Resistance gene) - UTI - 06 - 10 - no appropriate peer group qnr [sic] quinolone-resistance - UTI - 06, 08 - 10 qnrA [sic] quinolone resistance gene A - UTI - 06 - no appropriate peer group sul [sic] sulfonamide - UTI - 06, 07, 09, 10 - no appropriate peer group vanA/B [vancomycin A and B] - UTI -06 - 10 - no appropriate peer group On 10/22/2024 at 3:05 PM, the Laboratory Director confirmed a self evaluation of ungraded results was not performed.</p>
<p><b>D5300</b></p>	<p><b>PREANALYTIC SYSTEMS</b> CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to complete a stability study for specimens delivered above -20 Celsius (C) to the laboratory before patient polymerase chain reaction (PCR) testing in Gastrointestinal (GI) and wound (see D5311).</p>
<p><b>D5305</b></p>	<p><b>TEST REQUEST</b></p>

CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have requisitions labeled with specimen collection dates and times for 5 (A-E) out of 5 patients reviewed. Findings included: Review of Patient requisitions revealed: Patient A was sent for H. pylori testing with no collection date and time. Patient B was sent for gastrointestinal pathogen panel testing with no collection date and time. Patient C was sent for Giardia and cryptosporidium testing with no collection date and time. Patient D was sent for Pancreatic Elastase testing with no collection date and time. Patient E was sent for H. pylori testing with no collection date and time. Review of the Molecular and Antibody policy revealed no information relating to specimen collection and specimen rejection for molecular specimens and antibody testing specimens. Review of Final patient reports revealed: Patient A specimen was collected and received in the lab on 9/16/2024 at 11:36 AM for H. pylori. Patient B specimen was collected and received in the lab on 10/2/2024 at 4:17 PM and 4:19 PM for gastrointestinal pathogen panel. Patient C specimen was collected and received in the lab on 10/2/2024 at 12:18 PM and 12:19 PM for Giardia and cryptosporidium. Patient D specimen was collected and received in the lab on 10/3/2024 at 4:36 PM and 4:40 PM for Pancreatic Elastase. Patient E specimen was collected and received in the lab on 8/20/2024 at 12:24 PM for H. pylori. On 10/23/2024 at 12:00 PM, the Laboratory Director confirmed specimen collection times and dates were not labeled for specimens that entered the laboratory.

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to complete a stability study for specimens delivered above -20 Celsius (C) to the laboratory before patient

polymerase chain reaction (PCR) testing for 44 patients in Gastrointestinal (GI) and 6 patients in wound from June 12, 2024 to October 28, 2024. Findings Included: Review of temperature logs revealed PCR room temperature for testing was 19 to 25 C. The temperature logs did not have the accession area listed as a recorded temperature for PCR specimen arrivals into the lab. Review of GI panel Validation Kit read, "store all wet reagents and specimens at -20 C." Review of GI panel Quantitative (Q)PCR Validation report signed on March 8th, 2024, by laboratory director on page 22 revealed the specimen stability study had no documentation of what collection tubes were used and what temperatures were used for 5 days. The following specimens were not documented in the study as positive and negative in collection tubes: Adenovirus Astrovirus Campylobacter (coli, jejuni, lari) Clostridium difficile c. difficile toxin A c. difficile toxin B Escherichia coli (VTEC) Shiga-toxin 1 Shiga-toxin 2 E. Coli)157 Norovirus GI Norovirus GII Rotavirus Salmonella spp. Sapovirus Shigella spp. Yersinia enterocolitica Review of Wound panel qPCR Validation report signed by laboratory director on April 5th, 2024 revealed the specimen stability study had no documentation of what collection tubes were used and what temperatures were used for 5 days. The following specimens were not documented in the study as positive and negative in collection tubes: Acinetobacter baumannii Bacteroides fragilis Candida albicans Candida dubliniensis Candida glabrata Candida krusei Candida parapsilosis Candida tropicalis Citrobacter braakii/freundii Citrobacter koseri Enterobacter cloacae Enterococcus spp. Escherichia coli Klebsiella aerogenes K. oxotyca/michiganensis -lactamase (blaKPC) -lactamase (CTX-M-Group 1) Metallo--lactamase (blaNDM) Fluoroquinolones Klebsiella pneumoniae Morganella morganii Mycoplasma genitalium Mycoplasma hominis Prevotella bivia Proteus mirabilis Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Staphylococcus epidermidis Staphylococcus saprophyticus Streptococcus agalactiae (Group B) Streptococcus pyogenes (Group A) Ureaplasma urealyticum Methicillin/Oxacillin (mecA) Sulfonamides Trimethoprim Review of the patient logs revealed 44 patients have been tested with the GI panel and 6 patients have been tested with the wound panel from June 12, 2024 to current. On 10/23/2024 at 1:00 PM, Testing Person M stated no specimen transportation procedure was created for PCR specimens delivered to the laboratory.

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on record review and interview, the laboratory failed to complete performance specifications which included accuracy, precision, analytical sensitivity including interfering substances, and reportable ranges for the following assays before patient testing: Cleartest Calprotectin diagnostic, Immunodiagnostic (IDK) Pancreatic Elastase Elisa, Streamline polymerase chain reaction (PCR) Gastrointestinal (GI) pathogen panel, and Streamline PCR Wound pathogen panel (see D5423). The laboratory failed to run positive controls for 2 (A and B) out of 2 patients reviewed for

Gastrointestinal (GI) pathogen panel and 1 (C) out 1 patient reviewed for Wound pathogen panel (see D5449).

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to complete performance specifications which included accuracy, precision, analytical sensitivity including interfering substances, and reportable ranges before testing 86 patients from June 12, 2024 to October 28, 2024 for the following assays: Cleartest Calprotectin diagnostic, Immunodiagnostic (IDK) Pancreatic Elastase Elisa, Streamline polymerase chain reaction (PCR) Gastrointestinal (GI) pathogen panel, and Streamline PCR Wound pathogen panel. Finding Included: Review of Food and Drug Administration (FDA) Classification website revealed the following tests were not listed on the website: Cleartest Calprotectin diagnostic, Immunodiagnostic (IDK) Pancreatic Elastase Elisa, Streamline polymerase chain reaction (PCR) Gastrointestinal (GI) pathogen panel, and Streamline PCR Wound pathogen panel. Review of Cleartest Calprotectin diagnostic test verification revealed no documentation of accuracy, precision, analytical sensitivity including interfering substances, and reportable range. Review of Immunodiagnostic (IDK) Pancreatic Elastase Elisa verification revealed no documentation of accuracy, precision, analytical sensitivity including interfering substances, and reportable range. Review of GI panel Quantitative (Q)PCR Validation report signed on March 8th, 2024, by the laboratory director revealed no documentation of what specimen type and collection tube was used for accuracy, precision, analytical sensitivity including interfering substances, and reportable ranges to identify the following pathogens: Adenovirus Astrovirus Campylobacter (coli, jejuni, lari) Clostridium difficile c. difficile toxin A c. difficile toxin B Escherichia coli (VTEC) Shiga-toxin 1 Shiga-toxin 2 E. Coli)157 Norovirus GI Norovirus GII Rotavirus Salmonella spp. Sapovirus Shigella spp. Yersinia enterocolitica Review of Wound panel qPCR Validation report signed by laboratory director on April 5th, 2024, revealed no documentation of what specimen type and collection tube was used for accuracy, precision, analytical sensitivity including interfering substances, and reportable ranges to identify the following pathogens: Acinetobacter baumannii Bacteroides fragilis Candida albicans Candida dubliniensis Candida glabrata Candida krusei Candida parapsilosis Candida tropicalis Citrobacter braakii/freundii Citrobacter koseri Enterobacter cloacae Enterococcus spp. Escherichia coli Klebsiella aerogenes K. oxotyca/michiganensis -lactamase (blaKPC) -lactamase (CTX-M-Group 1) Metallo--lactamase (blaNDM) Fluoroquinolones Klebsiella pneumoniae Morganella morganii Mycoplasma genitalium Mycoplasma hominis Prevotella bivia Proteus mirabilis Pseudomonas aeruginosa Serratia marcescens

Staphylococcus aureus Staphylococcus epidermidis Staphylococcus saprophyticus Streptococcus agalactiae (Group B) Streptococcus pyogenes (Group A) Ureaplasma urealyticum Methicillin/Oxacillin (mecA) Sulfonamides Trimethoprim Review of Patient reports revealed the following from Jun 12,2024 to present: A. 21 patients have been tested with Immunodiagnostic (IDK) Pancreatic Elastase Elisa. B. 15 patients have been tested with Cleartest Calprotectin diagnostic. C. 44 patients have been tested with Streamline PCR GI panel testing. D. 6 patients have been tested with Streamline PCR wound panel testing. On 10/23/2024 at 1:00 PM, the laboratory director confirmed performance specifications were not completed for Cleartest Calprotectin diagnostic, Immunodiagnostic (IDK) Pancreatic Elastase Elisa, Streamline PCR Gastrointestinal (GI) pathogen panel, and Streamline PCR Wound pathogen panel.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Director, the laboratory failed to document all weekly maintenance for the Leica CV5030 Robotic Coverslipper, Leica ST5020 Multistainer, and the Leica Bond used for preparing slides for histopathology testing for two out of two years (2022-2024) reviewed. Findings included: Record review of the "Leica CV5030 Maintenance Log" revealed the weekly maintenance consisted of: New bath xylene, Cycle needle/brush, Clean gripper/rings, and Check Suction cup. Record review of the "Leica CV5030 Maintenance Log" revealed the weekly maintenance was not documented on the following weeks of testing: 01/09/23 - 01/13/23, 02/20/23 - 02/24/23, 03/20/23 - 03/24/23, 04/10/23 - 04/14/23, 08/28/23 - 09/01/23, 09/18/23 - 09/22/23, 11/27/23 - 12/01/23, 12/11/23 - 12/15/23, 01/15/24 - 01/19/24, 01/29/24 - 2/02/24, 06/17/24 - 06/21/24, 07/01/24 - 07/05/24, and 09/23/24 - 09/27/24. Record review of the "Leica Stainer ST5020 Maintenance Log" revealed the weekly maintenance consisted of: Clean wells, Check water hose, and Check Oven. Record review of the "Leica Stainer ST5020 Maintenance Log" revealed the weekly maintenance was not documented on the following weeks of testing: 01/09/23 - 01/13/23, 1/30/23 - 2/03/23, 02/27/23 - 03/03/23, 03/20/23 - 03/24/23, 04/10/23 - 04/14/23, 08/28/23 - 09/01/23, 09/18/23 - 09/22/23, 11/27/23 - 12/01/23, 12/11/23 - 12/15/23, 01/15/24 - 01/19/24, 01/29/24 - 02/02/24, 02/12/24 - 02/16/24, 04/13/24 - 04/17/24, 06/17/24 - 06/21/24, 07/01/24 - 07/05/24, and 09/23/24 - 09/27/24. Record review of the "Leica Bond Maintenance Guidelines" instrument manual revealed the weekly maintenance consisted of: Clean slide staining assemblies, Check Covertile clamps, Restart processing modules, Wipe the main robot aspirating probe, Check wash blocks and mixing station - clean or replace if necessary, Clean covers, doors (where fitted) and lid, Clean ID imager, and Clean handheld barcode scanner. Record review of the "Leica Bond Maintenance Log" revealed the weekly maintenance was not documented on the following weeks of testing: 01/09/23 - 01/13/23, 01/23/23 - 01/27/23, 02/06/23 - 02/10/23, 02/27/23 - 03/03/23, 03/06/23 - 03/10/23, 03/27/23 - 03/31/23, 04/03/23 - 04/07/23, 04/10/23 - 04/14/23, 08/28/23 - 09/01/23, 11/20/23 - 11/22/23, 12/11/23 - 12/15/23, 01/29/24 - 02/02/24, 06/17/24 - 06/21/24, 07/01/24 - 07/05/24, and 09/23/24 - 09/27/24. On 10/23/2024 at 11:50 AM, the Laboratory Director confirmed that not all weekly

maintenance had been documented for the equipment used in histopathology slide preparation.

**D5449**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to run positive controls for 2 (A and B) out of 2 patients reviewed for Gastrointestinal (GI) pathogen panel and 1 (C) out 1 patient reviewed for Wound pathogen panel. Findings Included: Review of the test menu for the GI Pathogen Panel revealed the following 17 targets: Adenovirus Astrovirus Campylobacter (coli, jejuni, lari) Clostridium difficile c. difficile toxin A c. difficile toxin B Escherichia coli (VTEC) Shiga-toxin 1 Shiga-toxin 2 E. Coli)157 Norovirus GI Norovirus GII Rotavirus Salmonella spp. Sapovirus Shigella spp. Yersinia enterocolitica Review of the test menu for the Wound Pathogen Panel revealed the following 36 targets: Acinetobacter baumannii Bacteroides fragilis Candida albicans Candida dubliniensis Candida glabrata Candida krusei Candida parapsilosis Candida tropicalis Citrobacter braakii/freundii Citrobacter koseri Enterobacter cloacae Enterococcus spp. Escherichia coli Klebsiella aerogenes K. oxotyca/michiganensis -lactamase (blaKPC) -lactamase (CTX-M-Group 1) Metallo--lactamase (blaNDM) Fluoroquinolones Klebsiella pneumoniae Morganella morgani Mycoplasma genitalium Mycoplasma hominis Prevotella bivia Proteus mirabilis Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Staphylococcus epidermidis Staphylococcus saprophyticus Streptococcus agalactiae (Group B) Streptococcus pyogenes (Group A) Ureaplasma urealyticum Methicillin/Oxacillin (mecA) Sulfonamides Trimethoprim Review of Molecular plate face sheets revealed no documentation on how many positive controls were run for Gastrointestinal (GI) pathogen panel and Wound pathogen panel. Patient A and B were run on 10/3/2024 for GI panel with no documentation of 17 positives target controls and Patient C was run on 9/10/2024 for wound panel with no documentation of 36 positives target pathogen controls. Review of the policy and procedure for Molecular Interpretation of Results, signed by the laboratory director on 4/23/2024, showed: "b. Positive Controls (PC) i. Should always be on the "G" rows. ii. Is run on each patient. The positive control contains all of the assay components for a single pathogen." On 10/23/2024 at 10:00 AM, the Molecular Laboratory Supervisor confirmed not all positive controls were run for the GI pathogen panel on 10/3/2024 and not all positive controls were run for the Wound pathogen panel on 9/10/2024.

**D5601**

**HISTOPATHOLOGY**

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control

procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with the Laboratory Director, the laboratory failed to have negative quality control (QC) slides for Immunohistochemical (IHC) stains for two out of two years (2022 - 2024). The total number of positive control slides without a separate negative slide was 1760. Findings Included: Record review of the Clinical Laboratory Improvement Amendment application, signed and dated by the Laboratory Director on 10/22/24 revealed the laboratory performed the following IHC stains: Cluster of Differentiation(CD) 117, Ki - 67 ( cell proliferation marker), Smooth Muscle Actin (SMA), S-100 (marker for nerve sheath tumors and melanomas), MLH1(mismatch repair protein), PMS2 ( postmeiotic segregation increased 2), MSH2 (mismatch repair protein), MSH6 (mismatch repair protein), Chromagranin, Synaptophysin, CD56, Cytokeratin(CK) 7, CK20, Cytomegalovirus (CMV), Heliobacter pylori (H. pylori), Gastrin, Melan A, Human Melanoma Black 45 (HMB45), SOX - 10 (melanoma marker), Mucin 2 (MUC2), Mucin 5AC (MUC5AC), p16 INK4a (Human papillomavirus cancer marker), AE1/3 ( cocktail of antibodies to identify epithelial cells and tumors), Pin4 ( prostate cancer marker), CD44, and Giemsa. Record review of the "Stain/Processing Quality Log" revealed that IHC QC acceptability was documented daily. Record review of the "Stain Processing Quality Log" revealed a statement all use internal positive and negative controls. On 10/23/2024 at 2:55 PM, observation of Patient #2 and Patient #3's slides revealed the laboratory put a positive control and the patient's specimen on the same slide. On 10/23/2024 at 3:00 PM, the Laboratory Director stated the laboratory only used one piece of tissue for the positive and negative controls.