Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0718028	01/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Gabrail Cancer Center	4875 Higbee Ave Nw, Canton, OH	

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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interviews with the Chief Operations Officer (COO) and Testing Personnel (TP) #3, the laboratory failed to achieve a proficiency testing (PT) score of 80% (percent) for the analytes creatinine (creat) in the first PT event in 2019 and phosphorus (phos) and total iron binding capacity (TIBC) in the third PT event in 2019, all in the specialty of Chemistry. Patient creat, phos and TIBC testing had the potential to be affected by this deficient practice during the first and third quarters in 2019. Findings Include: 1. Review of the laboratory's 2019 American Proficiency Institute (API) Chemistry PT documentation, provided on the date of the inspection, revealed the following unsatisfactory analyte testing scores: First PT Event 2019 Creat; 40% unacceptable; CH-02, CH-03, CH-05 Third PT Event 2019 Phos; 60% unacceptable; CH-11, CH-12 TIBC; 20% unacceptable; CH-11, CH-13, CH-14, CH-15 2. The COO and TP#3 confirmed the unsatisfactory PT scores for the analytes indicated above. The interviews occurred on 01/16/2020 at 3:01 PM.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the

	proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and interviews with the Chief Operations Officer (COO) and Testing Personnel (TP) #3, the laboratory failed to conduct and document appropriate training activities and employ the technical assistance necessary to correct the unacceptable problems associated with creatinine (creat), phosphorus (phos) and total iron binding capacity (TIBC) proficiency testing (PT) failures in 2019, all in the specialty of Chemistry. Patient creat, phos and TIBC testing had the potential to be affected by this deficient practice during the first and third quarters in 2019. Findings Include: 1. Review of the laboratory's 2019 American Proficiency Institute (API) Chemistry PT documentation, provided on the date of the inspection, revealed the following unsatisfactory analyte testing scores: First PT Event 2019 Creat; 40% unacceptable; CH-02, CH-03, CH-05 Third PT Event 2019 Phos; 60% unacceptable; CH-11, CH-12 TIBC; 20% unacceptable; CH-11, CH-13, CH-14, CH-15 2. Review of the laboratory's 2019 "API Analyte Testing Form - Chemistry" PT review and corrective action records did not find any investigation, technical assistance and TP training activities documented for the unsatisfactory analyte PT scores listed above. The laboratory only retested the samples after receiving the API Performance Summary. 3. The Inspector requested the laboratory's documented investigation, technical assistance and TP training activities for the PT failures listed above from the COO and TP#3. The COO and TP#3 confirmed the unsatisfactory PT scores for the analytes indicated above, the laboratory did not conduct any further activities other than repeat testing after receiving the API Performance Summary, as documented on the respective "API Analyte Testing Form - Chemistry" records, did not investigate, document and implement any corrective actions and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 01 /16/2020 at 3:01 PM.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interviews with the Chief Operations Officer (COO) and Testing Personnel (TP) #3, the laboratory failed to achieve a proficiency testing (PT) score of 80% (percent) for the analyte red blood cell count (RBC) in the second PT event in 2019, in the specialty of Hematology. Patient RBC testing had the potential to be affected by this deficient practice during the third quarter in 2019. Findings Include: 1. Review of the laboratory's 2019 American Proficiency Institute (API) Hematology/ Coagulation PT documentation, provided on the date of the inspection, revealed the following unsatisfactory analyte testing scores: Second PT Event 2019 RBC; 60% unacceptable; PNT-06, PNT-07 2. The COO and TP#3 confirmed the unsatisfactory PT scores for the analyte indicated above. The interviews occurred on 01/16/2020 at 3:01 PM.
D2128	HEMATOLOGY CFR(s): 493.851(e)

	(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and interviews with the Chief Operations Officer (COO) and Testing Personnel (TP) #3, the laboratory failed to conduct and document appropriate training activities and employ the technical assistance necessary to correct the unacceptable problems associated with the red blood cell count (RBC) proficiency testing (PT) failure in 2019, in the specialty of Hematology. Patient RBC testing had the potential to be affected by this deficient practice in the third quarter in 2019. Findings Include: 1. Review of the laboratory's 2019 American Proficiency Institute (API) Hematology PT documentation, provided on the date of the inspection, revealed the following unsatisfactory analyte testing score: Second PT Event 2019 RBC; 60% unacceptable; PNT-06, PNT-07 2. Review of the laboratory's 2019 "API Analyte Testing Form - Hematology" PT review and corrective action records did not find any investigation, technical assistance and TP training activities documented for the unsatisfactory analyte PT score listed above. The laboratory only retested the samples after receiving the API Performance Summary. 3. The Inspector requested the laboratory's documented investigation, technical assistance and TP training activities for the PT failures listed above from the COO and TP#3. The COO and TP#3 confirmed the unsatisfactory PT scores for the analytes indicated above, the laboratory did not conduct any further activities other than repeat testing after receiving the API Performance Summary, as documented on the respective "API Analyte Testing Form - Hematology" record, did not investigate, document and implement any corrective actions and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 01/16/2020 at 3:01 PM.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interviews with the Chief Operations Officer (COO) and Testing Personnel (TP) #3, the laboratory failed to document the evaluation of the American Proficiency Institute (API) proficiency testing (PT) results when results were not graded or found to be unacceptable for four out of six chemistry and 1 out of six hematology PT events in 2018 and 2019. All patient testing performed in the second and third quarter in 2018 and all of 2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 2018 and 2019 API chemistry and hematology PT records did not find any indication of PT result investigations and evaluations for an ungraded ALT PT result (CH-01) in the first PT event of 2019 and for the unacceptable PT results as follows: Third event of 2018 LDL (low density lipoprotein) analyte score of 80%; CH-14 First event of 2019 Creatinine (creat) analyte score of 40%; CH-02, CH-03, CH-05 Second event of 2019

	Total iron binding capacity (TIBC) analyte score of 80%; CH-06 Red blood cell count (RBC) analyte score of 60%; PNT-06, PNT-07 Third event of 2019 Phosphorus (phos) analyte score of 60%; CH-11, CH-12 TIBC analyte score of 20%; CH-11, CH-13, CH-14, CH-15 2. The Inspector requested the laboratory's 2018 and 2019 API ungraded and failed PT result investigation and evaluation documentation for the sample numbers indicated above from the COO and TP#3. The COO and TP#3 stated they repeated the respective testing on the unacceptable samples and verified the results were within acceptable ranges after receiving the API Performance Summary, as documented on the respective "API Analyte Testing Form - Chemistry" and "API Analyte Testing Form - Hematology" records, however, they did not investigate, document and implement any corrective actions so as to prevent unacceptable results in the future and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 01/16/2020 at 3:01 PM.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and an interview with the Chief Operations Officer (COO) and Testing Personnel (TP) #3, the laboratory failed to review the effectiveness of their quality assessment program for ungraded and unacceptable proficiency testing (PT) results in the general laboratory systems. This deficient practice had the potential to affect all chemistry and hematology test results reported in 2018, 2019 and through 01/16/2020. Findings Include: 1. Review of the laboratory's "Monthly Quality Assurance Checklist" for 2018 and 2019, provided on the date of the inspection, revealed a completed checklist for each month; however there were no problems or corrective actions indicated. 2. Further review of the laboratory's 2018 and 2019 quality assessment documentation did not find record of the ungraded, unacceptable and/or unsatisfactory PT sample results in the respective months of each occurrence as follows: Third event of 2018; September 2018 LDL (low density lipoprotein) CH-14; analyte score of 80% First event of 2019; February 2019 Creatinine (creat) CH-02, CH-03, CH-05; analyte score of 40% Alanine aminotransferase (ALT) CH-01; ungraded PT result; false analyte score of 100% Second event of 2019; June 2019 and July 2019 Total iron binding capacity (TIBC) CH-06; analyte score of 80% Red blood cell count (RBC) PNT-06, PNT-07; analyte score of 60% Third event of 2019; September 2019 Phosphorus (phos) CH-11 and CH-12; analyte score of 60% TIBC CH-11, CH-13, CH-14, CH-15; analyte score of 20% 3. The Inspector requested the laboratory's quality assessment documentation of the ungraded, unacceptable and/or unsatisfactory PT analyte scores from the COO and TP#3. The COO and TP#3 confirmed that the "Monthly Quality Assurance Checklist" was the only quality assessment documentation and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 01/16/2010 at 3:15 PM.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and an interview with Testing Personnel (TP) #3, the laboratory failed to label the set of three out of three secondary containers of solution and stain with their lot numbers, which were utilized for manual peripheral smear staining procedures. All patient manual peripheral smear staining procedures in 2018, 2019 and through 01/16/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Direct observation, on 01/16/2020 at 3:55 PM, of the manual peripheral smear staining station in the hematology area, found a filled set of 3 secondary containers labeled with the following contents and their expiration dates, however the lot number were not indicated: container #1 Methanol container #2 Xanthene Dye container #3 Thiazine Dye 2. The Inspector requested documentation of what the lot numbers were of each of the three secondary containers labeled as Methanol, Xanthene Dye and Thiazine Dye from TP#3. TP#3 confirmed that the three secondary staining containers were not labeled with each of their respective lot numbers and was unable to provide the requested documentation on the date of the inspection, however stated that they were filled from larger stock bottles of which indicated the lot numbers. The interview occurred on 01/16/2020 at 3:55 PM.
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 record review and interviews with the Chief Operations Officer (COO) and Testing Personnel (TP) #3, the laboratory failed to have an adequate system in place to ensure the reference ranges for each chemistry analyte tested and reported were accurate and consistent between the instrument printouts, the laboratory information system (LIS) and the electronic medical record (EMR) for both male and female patients. This deficient practice had the potential to affect all chemistry test result interpretations in 2018, 2019 and through 01/16/2020. Findings Include: 1. Review of 2 of 2 of the laboratory's patient test records and their corresponding test reports for both a male and a female patient indicated the following analyte reference ranges: Male Instrument LIS/EMR Approved Printout Printouts Ranges LDH 100-190 80-285 80-285 BUN 6-20 7-18 7-18 Creat 0.9-1.3 0.7-1.3 0.7-1.3 Ca 8.5-10.2 8.5-10.5 8.5-10.5 Tbili 0.3-1.2 0.0-1.5 0.0-1.5 ALT 5-30 10-40 10-40 ALB 3.5-5.2 3.5-5.0 3.5-5.0 ALP 44-147 35-123 35-123 AST 7-31 5-34 5-34 Female Instrument LIS/EMR Approved Printout Printouts Ranges UA 2.6-6.0 3.5-7.2 3.5-7.2 LDH 100-190 80-285

	80-285 BUN 6-20 7-18 7-18 Creat 0.60-1.10 0.6-1.2 0.6-1.2 Ca 8.5-10.2 8.5-10.5 8.5-10.5 Tbili 0.3-1.2 0.0-1.5 0.0-1.5 ALT 5-30 5-35 7-35 ALB 3.5-5.2 3.5-5.0 3.5-5.0 ALP 44-147 35-123 35-123 AST 7-31 5-34 5-34 UA; uric acid LDH; lactate dehydrogenase BUN; blood urea nitrogen Creat; creatinine Ca; calcium Tbili; total bilirubin ALT; alanine aminotransferase ALB; albumin ALP; alkaline phosphotase AST; aspartate aminotransferase 2. The COO and TP#3 confirmed that there have been occasions when the instrument printout is provided to the physician before their review of the final test report in the EMR. This further confirmed that the reference ranges for the above mentioned analytes were inconsistent between the instrument printout and the LIS/EMR/the reference ranges approved by the Laboratory Director. Additionally, the ALT reference range is inconsistent between the instrument printout, the LIS/EMR and the approved reference ranges approved by the Laboratory Director. The interviews occurred on 01/16/2020 at 4:07 PM.