

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0718028	(X3) Date Survey Completed 01/29/2018
Name of Provider or Supplier Gabrail Cancer Center	Street Address, City, State 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	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Supervisor (LS), the laboratory failed to attain a proficiency testing (PT) score of at least 80 percent of acceptable responses for the analyte creatinine for the second testing event of 2017. Findings Include: 1. Review of six of the laboratory's 2016 and 2017 American Proficiency Institute (API) Chemistry PT records, provided on the date of the inspection, revealed a creatinine analyte testing score of 20% for the second testing event of 2017. 2. The LS confirmed the laboratory did not achieve a PT analyte testing score of at least 80% for creatinine and received a score of 20% for the analyte creatinine for the second testing event of 2017. The interview occurred on 01/29/2018 at 10:44 AM.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Supervisor (LS), the</p>

laboratory failed to verify the accuracy of ungraded triglyceride and low density lipoprotein (LDL) results not assigned a proficiency testing (PT) score. Findings Include: 1. Review of six of the laboratory's 2016 and 2017 American Proficiency Institute (API) Chemistry PT records, provided on the date of the inspection, revealed the submitted triglyceride and LDL results for sample CH-01 in the first testing event of 2017 were not graded by API. 2. The Surveyor requested the laboratory's API PT verification documentation of the ungraded triglyceride and LDL results for sample CH-01 in the first testing event of 2017 from the LS. The LS was unable to provide any verification documentation for the ungraded PT results on the date of the inspection. The interview occurred on 01/29/2018 at 10:44 AM.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Laboratory Supervisor (LS), the laboratory failed to document evaluation activities of ungraded and unacceptable proficiency testing (PT) results. Findings Include: 1. Review of six of the laboratory's 2016 and 2017 American Proficiency Institute (API) Chemistry PT records, provided on the date of the inspection, revealed the submitted triglyceride and LDL results for sample CH-01 in the first testing event of 2017 were not graded by API and the Alanine Aminotransferase (ALT) result for sample CH-09 in the second testing event of 2016 was unacceptable. Documentation of the laboratory's result evaluations were not found. 2. The Surveyor requested the laboratory's API PT evaluation documentation of the ungraded triglyceride and LDL results and the unacceptable ALT result from the LS. The LS was unable to provide any evaluation documentation for the ungraded and unacceptable PT results on the date of the inspection. The interview occurred on 01/29/2018 at 10:44 AM.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Lab Supervisor (LS), the Technical Consultant (TC) failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing (PT) samples for testing personnel (TP) #1, who routinely performed the testing in the laboratory, in 2016. Findings Include: 1. Review of six out of six of the laboratory's 2016 and 2017 API Chemistry PT records, provided on the date of the inspection, did not find that TP#1 participated in any chemistry PT testing in 2016. 2. The Surveyor requested the laboratory's 2016 documentation indicating that TP#1 tested previously analyzed specimens, internal blind samples or external PT in 2016 from the LS. The LS confirmed that TP#1 did not participate in testing previously

analyzed specimens, internal blind samples or external PT activities in 2016, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/29/2018 at 10:45 AM.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Lab Supervisor (LS), the Technical Consultant (TC) failed to evaluate and document the 12 month competency assessments of testing personnel (TP) #1 and TP#2, who were responsible for moderate complexity testing procedures on the newly installed chemistry and hematology analyzers. Findings Include: 1. Review of the laboratory's "Lab Personnel Evaluation" policy and procedure, provided on the date of the inspection, found instructions to assess the competency of testing personnel semiannually during the first year. 2. Review of the laboratory's instrument installation records revealed the ACE Axcel Chemistry analyzer was installed in 11/2016 and the Beckman Coulter AcT 5Diff AL Hematology analyzer was installed in 12/2016 with documented training by the manufacturer's of both analyzers on 12/12/2016 for TP#1 and TP#2. 3. Review of the laboratory's 2017 and 2018 competency assessment records, provided on the date of the inspection, did not find the 12 month competency assessment documentation for TP#1 and TP#2 who tested patient samples on the newly installed Chemistry and Hematology analyzers since 12/2016. 4. The Surveyor requested the laboratory's ACE Axcel Chemistry analyzer and Beckman Coulter AcT 5Diff AL Hematology analyzer 12 month competency assessment documentation for TP#1 and TP#2 from the LS. The LS confirmed that TP#1 and TP#2 did not have their 12 month competency assessments conducted, as required, on the newly installed Chemistry and Hematology analyzers and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/29/2018 at 8:53 AM.