

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0718028	(X3) Date Survey Completed 04/28/2022
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with the sole Testing Personnel (TP), the laboratory failed to successfully participate in a Proficiency Testing (PT) program for the non-waived glucose testing performed under the subspecialty of routine chemistry. All patients who had glucose testing in this laboratory from the first testing event of 2022 to current date had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to achieve a PT score of 80% (percent) for the analyte glucose in the first PT event in 2022 in the specialty of Chemistry. (Refer to D2087)</p>

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 an interview with the sole Testing Personnel (TP), the laboratory failed to achieve a proficiency testing (PT) score of 80% (percent) for the analyte glucose in the first PT event in 2022 in the specialty of chemistry. All patients tested for glucose from the first testing event in 2022 to current date had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "QUALITY ASSURANCE PROCEDURE MANUAL FOR ACE AXCEL", approved by the Laboratory Director via signature and date on 01/03/2022 and provided on the date of the inspection found the following statement: "Unsuccessful or unsatisfactory Proficiency testing events are to be reported to the lab manager and lab director. Retests on the specific test are to be done and the corrective action taken needs to be documented on the API form....". 2. Review of the laboratory's 2022 American Proficiency Institute (API) Chemistry PT documentation, provided on the date of the inspection, revealed the following unacceptable analyte testing scores: First PT Event Chemistry-Core Glucose = 60% (CH-04, CH-05) 3. Review of the submitted API forms and documentation of the laboratory's API Analyte Testing Form - Chemistry revealed two out of five unacceptable glucose results in the testing event indicated above. The TP confirmed the unacceptable glucose PT score via an electronic email on 05/09/2022 at 2:06 PM.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the sole Testing Personnel (TP), the Technical Consultant (TC) failed to evaluate and document the competency of one out of one TP in 2021 assuring their competency was maintained in order to perform moderately complex routine chemistry and hematology testing procedures and report the test results promptly, accurately, and proficiently. All testing conducted by the sole TP for two out of two test systems conducted in 2021 to date of inspection had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Lab Personnel Evaluation" policy and procedure, provided on the date of the inspection, found the following instructions for TP competency assessments: "1. All Laboratory personnel will be evaluated by the laboratory supervisor and the laboratory director. 2. All laboratory personnel will be evaluated... annually..." 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 04/18/2022, revealed one TP listed and credentialed to perform moderately complex chemistry and hematology testing procedures. 3. Review of the laboratory's 2021 competency assessment records did not find the competency assessment for the sole TP. The Inspector requested the sole TP's 2021 competency assessment from the TP. The TP confirmed, via an electronic

email on 05/09/2022 at 2:06 PM, that their 2021 competency assessment was not completed as required.