Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0718028	10/04/2023
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. 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 automated white blood cell (WBC) differential (diff) testing performed under the specialty of Hematology. This deficient practice had the potential to affect 1179 out of 1179 patient WBC diff testing performed in this laboratory between the first and second PT testing events of 2023. Findings Include: 1. The laboratory failed to achieve a PT score of 80% (percent) for WBC diff testing in the first PT event in 2023 in the specialty of Hematology. (Refer to D2121) 2. The laboratory failed to achieve satisfactory performance for the same analytes; white

	blood cell (WBC) differential (diff) and percent monocyte in two consecutive events for first and second PT events in 2023, in the specialty of Hematology. (Refer to D2130)
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, phone and electronic mail (email) interviews with the sole Testing Personnel (TP), the laboratory failed to achieve a proficiency testing (PT) score of 80% (percent) for white blood cell (WBC) differential (diff) in the second PT event in 2023, in the specialty of Hematology. This deficient practice had the potential to affect 1179 out of 1179 patient WBC diff testing performed in this laboratory between the first and second PT testing events of 2023. Findings Include: 1. Review of the laboratory's second American Proficiency Institute (API) Hematology /Coagulation PT testing event of 2023 documentation, provided for the PT desk review, revealed the following unsatisfactory analyte testing scores: Second PT Event 2023 WBC diff; 56% % mono; 60%; DXH-07, DXH-09 % lymph; 40%; DXH-06, DXH-07, DXH-08 % neut; 20%; DXH-06, DXH-07, DXH-08, DXH-09 % eos; 60%; DXH-07, DXH-08 2. Review of the laboratory's PT evaluation documentation revealed the laboratory ran the PT event samples under the incorrect software version and also ran them in the quality control (QC) mode under "other" as the source when API instructed the PT samples to be run in the QC mode under "patient" as the source. 3. Further review of the laboratory's PT evaluation documentation found the following statements: "QC, machine operation, calibrations and start up logs were all reverified by the lab director. At random 15 patient results were pulled from the month of Mar - Aug 2023 prior to the 2nd event...'(the Laboratory Director)' seen no discrepancies and determined the API failures had no effect on patient results...API advised that if samples were run under the correct source they would have passed." 4. The TP confirmed the unsatisfactory PT scores for the analytes indicated above. The interviews occurred on 07/28/2023 at 12:57 PM. % mono; percent monocyte % lymph; percent lymphocyte % neut; percent neutrophil % eos; percent eosinophil
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review, phone and electronic mail (email) interviews with the sole Testing Personnel (TP), the laboratory failed to achieve satisfactory performance for the same analyte, white blood cell (WBC) differential (diff) and percent monocyte, in two consecutive events for first and second PT events in 2023 in the specialty of Hematology. This deficient practice had the potential to affect 1179 out of 1179 patient WBC diff testing performed in this laboratory between the first and second PT testing events of 2023. Findings Include: 1. Review of the laboratory's second American Proficiency Institute (API) Hematology/Coagulation PT testing event of

	2023 documentation, provided for the PT desk review, revealed the following unsatisfactory analyte testing scores: First PT Event 2023 WBC diff; 76% % mono; 0%; Second PT Event 2023 WBC diff; 56% % mono; 60%; 2. Review of the laboratory's PT evaluation documentation revealed the laboratory ran both the first and second PT event samples under the incorrect software version and also ran them in the quality control (QC) mode under "other" as the source when API instructed the PT samples to be run in the QC mode under "patient" as the source. 3. Further review of the laboratory's PT evaluation documentation found the following statements: "QC, machine operation, calibrations and start up logs were all reverified by the lab director. At random 15 patient results were pulled from the month of Mar -Aug 2023 prior to the 2nd event...'(the Laboratory Director)' seen no discrepancies and determined the API failures had no effect on patient results...API advised that if samples were run under the correct source they would have passed." 4. The TP confirmed the unsatisfactory PT scores for the analytes indicated above. The interviews occurred on 07/28/2023 at 12:57 PM. % mono; percent monocyte