Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1069404	04/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
98 Point 6 Emergicenter	1540 Lake Lansing Road Suite 203, Lansing, MI	

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 review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the specialty of Hematology. Findings include: Review of the CMS database and the API proficiency testing reports showed unsatisfactory performance for 4 of 5 proficiency testing events. Refer to D2131. ***Repeat Deficiency from 4/20/2022 and 1/11/2023 surveys***
D2131	HEMATOLOGY

	CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on review of the CMS database and review of the American Proficiency Institute (API) final proficiency testing reports, it was determined the laboratory failed to achieve satisfactory performance for the specialty of hematology for 4 (3rd event 2021, 1st and 3rd events 2022, and 1st event 2023) of 5 testing events. Findings include: Unsatisfactory performance for 4 of 5 testing events constitutes subsequent unsuccessful performance for the specialty of hematology. Specialty of Hematology PT Event Score 3rd event of 2021 66% 1st event of 2022 33% 3rd event of 2022 66% 1st event of 2023 0% ***Repeat Deficiency from 4/20/2022 and 1/11/2023 surveys***
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The Laboratory Director failed to ensure the laboratory successfully participated in a proficiency testing program as required under Subpart H. Refer to D6016. ***Repeat Deficiency from 1/11/2023 survey***
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: . Based on review of the CMS database and review of the American Proficiency Institute (API) proficiency testing reports, the director failed to ensure the laboratory successfully participated in a proficiency testing program as required under subpart H. Findings include: The laboratory failed to achieve satisfactory performance for the specialty of Hematology for 4 of 5 proficiency testing events as follows: Specialty of Hematology PT Event Score 3rd event 2021 66% 1st event 2022 33% 3rd event 2022 66% 1st event 2023 0% ***Repeat Deficiency from 1/11/2023 survey***