Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1010918	06/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
City Medical	30581 Stephenson Hwy, Madison Heights, 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 2017, 2018, and 2019 provider performance testing reported to the CLIA database by the American Proficiency Institute (API) and review of the final program reports from API, the laboratory failed to achieve satisfactory performance for the "Cell I.D. or WBC Diff" in 5 of 7 testing events. Refer to D2130.
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 review of the CMS database and review of the American Proficiency Institute (API) final proficiency testing program reports, the laboratory failed to achieve satisfactory performance in 5 out of 7 consecutive proficiency testing events for the following hematology analyte: Cell Identification (ID) or White Blood Cell (WBC) Differential (Diff). Findings include: 1. Unsatisfactory performance in 5 out of 7 proficiency testing events constitutes subsequent unsuccessful proficiency testing performance. Cell ID or WBC Diff PT Event Score 1st event 2017 7% 2nd event 2017 67%, 3rd event 2017 53% 2nd event 2018 47% 1st event 2019 73%
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 review of the American Proficiency Institute (API) proficiency testing program reports, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: Failure to ensure that the proficiency testing samples were tested as required under subpart H. Refer to D6016
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 program reports, the laboratory director failed to ensure the laboratory successfully participated in a proficiency testing program as required under subpart H. Findings include: 1. Unsatisfactory performance in 5 out of the last 7 proficiency testing events for the Cell Identification (ID) or White Blood Cell (WBC) Differential (Diff) testing. Refer to D2016 and D2130.