Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 31D0105229	**(X3) Date Survey Completed** 09/05/2023
Name of Provider or Supplier Pilgrim Medical Center Inc	**Street Address, City, State** 393 Bloomfield Avenue, Montclair, NJ	
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 an office review of the CASPER reports 153 and 155 and Proficiency Testing (PT) provider reports, the laboratory failed to achieve a score of 80% or more for Endocrinology tests performed with the Wisconsin State Lab of Hygiene Proficiency Testing (WSLHPT) . The finding includes: 1) The laboratory scored 0% for Beta-Human Chorionic Gonadotropin (B-hCG) for the 1st event - 2023 with WSLHPT. 2) The laboratory scored 0% for B-hCG for the 2nd event- 2023 with WSLHPT.
D2100	ENDOCRINOLOGY

	CFR(s): 493.843(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on an office review of the CASPER reports 153 and 155 and Proficiency Testing provider reports, the laboratory failed to participate in Endocrinology Beta-Human Chorionic Gonadotropin (B-hCG) events 1 and 2, 2023 with Wisconsin State Lab of Hygiene Proficiency Testing (WSLHPT).
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in 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 an office review of the CASPER reports 153 and 155 and Proficiency Testing provider reports, the laboratory failed to achieve a score of 80% for Endocrinology tests. The finding includes: 1) The laboratory scored 0% for Beta-Human Chorionic Gonadotropin (B-hCG) for the 1st event - 2023 with Wisconsin State Lab of Hygiene Proficiency Testing (WSLHPT). 2) The laboratory scored 0% for B-hCG for the 2nd event- 2023 with WSLHPT.
D2154	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on an office review of the CASPER reports 153 and 155 and Proficiency Testing (PT) provider reports, the laboratory failed to attain an overall testing event score of at least 100 percent for D (Rho) typing prformed the findings include. 1. The laboratory scored 80% for D (Rho) Typing event 3, 2022 with American Association of Bioanalysts (AAB). 2. The laboratory scored 0% for D (Rho) Typing event 2, 2023 with AAB.
D2155	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(c)

	Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on an office review of the CASPER reports 153 and 155 and Proficiency Testing provider reports, the laboratory failed to participate in ABO and RHo(D) Groups, D (Rho) Typing with American Association of Bioanalysts (AAB) in event 2, 2023.
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 an office review of the laboratory's performance in Proficiency Testing (PT) surveys, the laboratory director failed to provide appropriate direction to the laboratory personnel to ensure that the PT surveys are performed satisfactorily and compliance with the CLIA regulations are maintained.