

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0105229	(X3) Date Survey Completed 11/16/2018
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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure the FR included all required information for tests performed from 11/1/16 to the date of the survey. The findings include: 1. The FR did not have the address of the laboratory where tests were performed. 2. The FR did not have the "Test Report Date". 3. The FR did not have units and interpretation for analytes on the FR. 4. The FR did not have the name of all tests performed. 5. The TP #1 listed on CMS form 209 confirmed on 11/16/18 at 2:10 pm that the laboratory did not have required information on the FR.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that quality assessment programs are established and</p>

maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on lack of a Quality Assessment (QA) policy and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that a QA program was established from 11/1/16 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 11/16/18 at 1:50 pm that the laboratory did not have a QA program.