Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>31D0105229 | (X3) Date Survey Completed<br>10/01/2025 |
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| Name of Provider or Supplier<br>Pilgrim Medical Center Inc | Street Address, City, State<br>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 |
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| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation of the laboratory reagents, refrigerator, water dispenser and interview with the Testing Personnel (TP), the laboratory failed to ensure protection from biohazardous materials from 8/2/23 to 10/1/25. The finding includes: 1. The office water dispenser was located in an area where laboratory testing was performed. 2. The TP #1 as listed on the CMS 209 form confirmed on 10/1/25 at 11: 15 am, the laboratory did not ensure protection from biohazardous material. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) and interview with the Testing Personnel (TP), the laboratory failed to have a QC policy for Rhesus factor (Rh) testing performed with the Immucor Inc Anti-D Tube method from 8/2/23 to 10/1/25. The finding includes: 1. The laboratory used Panoscreen vials 1, 2 and 3 as QC. 2. There was no policy on how to use the above mentioned QC. 3. |

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| | There was no policy on how to document and monitor the above mentioned QC. 4. TP #1 as listed on the CMS form 209 confirmed on 10/1/25 at 10:55 am, the laboratory did not have a QC policy for Rh testing. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;<br><br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to document QC for Rhesus factor (Rh) Immucor Inc Anti-D Tube method on each day of patient testing from 8/2/23 to 10/1/25. The finding includes: 1. There was no documented evidence TP performed QC for Rh tests on each day of patient testing. 2. Approximately 5000 patient tests were performed and reported annually. 3. TP #1 as listed on the CMS 209 form confirmed on 10/1/25 at 11:35 am, the laboratory did not perform daily QC for Rh tests. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.<br><br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory did not establish a Quality Control Verification (QCV) procedure for verifying new lots of QC used for Rhesus factor (Rh) tests from 8/2/23 to 10/1/25. The findings include: 1. The laboratory did not establish a procedure for performing QCV on new lots of QC material that included the frequency, acceptability and rejection criteria. 2. TP #1 listed on the CMS 209 form confirmed on 10/1/25 at 11:10 am, the laboratory did not establish a detailed QCV procedure. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) material and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure a Quality Control (QC) and Quality Assurance (QA) program were established and maintained to assure the quality of laboratory services from 8/2/23 to 10/1/25. The finding includes: 1. The laboratory failed to establish a QC policy for Rhesus factor (Rh) testing. Cross refer D5401. 2. The laboratory did not perform QC for Rhesus factor (Rh) on each day of patient testing. Cross refer D5449. 3. QC |

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| | material was not verified before use. Cross refer D5469. 4. The laboratory did not establish a Quality Control Verification (QCV) procedure for verifying new lots of QC used for Rhesus factor (Rh) tests. Cross refer D5791. 5. TP #1 listed on CMS 209 form confirmed on 10/1/25 at 11:10 am, the QA and QC programs were not established and maintained. |
| **D6168** | TESTING PERSONNEL<br>CFR(s): 493.1487<br><br>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor review of the Testing Personnel (TP) files and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure Testing Personnel were qualified to perform Rhesus factor (Rh) testing from January 2025 to 10/1/25. The finding includes: 1. Surveyor review of TP files revealed that five out of five TP listed on the CMS 209 form did not meet the academic requirements to qualify them to perform Rh testing. 2. The TP #1 listed on CMS form 209 confirmed on 10/1/25 at 11:30 am, all TP did not meet the academic requirements to perform Rh testing.. |
| **D6171** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1489(b)<br><br>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified |

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| | laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Testing Personnel (TP) files and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure Testing Personnel were qualified to perform Rhesus factor (Rh) testing from January 2025 to 10/1/25. The finding includes: 1. Surveyor review of TP files revealed that five out of five TP listed on the CMS 209 form did not meet the academic requirements to qualify them to perform high complexity testing. 2. The TP #1 listed on CMS form 209 confirmed on 10/1/25 at 11:30 am, all TP did not meet the academic requirements to perform high complexity testing. |