

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0105229	(X3) Date Survey Completed 06/08/2021
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control Binder (QCB) and interview with the Testing Personnel (TP), the laboratory failed to follow their PM policy for "Quality Assurance Concurrent Testing using Anti D, Rh-Hr" for Rhesus (Rh) factor tests ran with Rh Immucor reagents from February 2019 to the date of survey. The finding includes: 1) The PM stated "When Changing lot numbers: Test old and new lots concurrently against respective quality control cells A2 (known as Rh negative) and Hemantigen (Known as positive). In addition, test a random Rh-negative patient against both lots. Reactivity should be the same." 2) The aforementioned procedure was last performed 2/2/19. The old lots are as follows: a) A2 Cell Lot number 112851 expired 2/8/19 b) Hematantigen lot number 16710 expired 2/8/19 3) The current lots are as follows: a) A2 Cell Lot number 112914 expires 6/25/21 b) Hematantigen lot number 16710 expires 6/25/21 4) Approximately 5,625 patients where run and reported. 5) The TP #1 on CMS form 209 confirmed on 6/8//21 at 11:05 am the above mentioned procedure was not followed.</p>