

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2157832	(X3) Date Survey Completed 05/13/2021
Name of Provider or Supplier Monmouth Medical Center Vantage Point	Street Address, City, State 100 Route 36 East, Suite 1m, West Long Branch, 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
D2001	<p>ENROLLMENT CFR(s): 493.801(a)(1)(2)(i)</p> <p>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Consultant (TC) the Laboratory failed ensure that the laboratory failed to notify Health and Human Services (HHS) of the approved PT program in which it participates at the time of survey. The findings include: 1) The Clinical Laboratory Improvement Amendment (CLIA) number on the PT evaluation sheet was 31D0114688. 2) The mailing address on the PT evaluation sheet was Monmouth Medical Center, Long Branch NJ, 07740-6303 3) The CLIA number of the laboratory performing the PT was 31D2157832 4) The address of the laboratory performing PT was Monmouth Medical Center Vantage Point, 100 Route 36 East Suite 18, West Long Branch. 5) The TC confirmed at 10:30 am on 5/13/21 that the laboratory failed to notify HHS of the approved PT program in which it participates.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:
Based on surveyor observation of the Quality Control (QC) vials and interview with the Technical Consultant (TC), the laboratory failed to put an appropriate expiration dates on the Coulter 4C-ES Cell QC reagents in use on the Beckman Coulter AcT diff 2 analyzer on the date of the survey. The findings include: 1. The Manufacturers Package Insert (MPI) stated "open vial stability is 31 days or open vial 20 times" 2. The laboratory wrote the open date 4/15/21 and the expiration date 5/25/21 on the Coulter 4C-ES Cell QC vials. 3. The TC confirmed on 5/13/21 at 11:00 am the laboratory failed to put appropriate expiration dates on the QC vials.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Consultant (TC) the Laboratory director failed ensure that the laboratory is enrolled in an Health and Human Services (HHS) approved proficiency testing program at the time of survey. The findings include: 1) The Clinical Laboratory Improvement Amendment (CLIA) number on the PT evaluation sheet was 31D0114688. 2) The mailing address on the PT evaluation sheet was Monmouth Medical Center, Long Branch NJ, 07740-6303 3) The CLIA number of the laboratory performing the PT was 31D2157832 4) The address of the laboratory performing PT was Monmouth Medical Center Vantage Point, 100 Route 36 East Suite 18, West Long Branch. 5) The TC confirmed at 10:30 am on 5/13/21 that the LD failed ensure that the laboratory was enrolled in an HHS approved proficiency testing program.