

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0881396	(X3) Date Survey Completed 01/08/2019
Name of Provider or Supplier Memorial Health Partners Foundation, Inc	Street Address, City, State 210 Walmart Drive, Soddy Daisy, TN	
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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to maintain satisfactory participation in two out of three events during 2018 for the automated Complete Blood Count (CBC), resulting in the first unsuccessful proficiency testing (PT) occurrence for the automated (CBC) (Refer to D2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive</p>

events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of Proficiency Testing (PT) records for 2018 and interview with practice management representative, the laboratory failed to participate in events two and three for CBCs resulting in a zero score for the two events and unsuccessful performance. Findings include: 1. The PT performance summary for CBCs indicated a zero score for events two and three of 2018. 2. An interview with the practice management representative at 11:45 AM on January 8, 2019 confirmed the PT performance summary for CBCs indicated a zero score for events two and three of 2018 resulting in the first unsuccessful performance,

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on a review of CBC Quality Control (QC) records for September and October 2018 and interview with the practice management, the records indicated three lot numbers in use for those two months, according to the report documented and signed by the laboratory director, had expired August 27, 2018. Findings include: 1. Lot numbers (089800; 079800; 069800) used in SEPTEMBER and OCTOBER UNTIL 10-30-18 with an expiration date 8-27-18. 2. An interview with the practice management representative at 11:00 AM on January 8, 2019 confirmed hematology lot numbers (089800; 079800; 069800) used in SEPTEMBER and OCTOBER UNTIL 10-30-18 with an expiration date 8-27-18.