

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0914293	<b>(X3) Date Survey Completed</b>  08/22/2019
<b>Name of Provider or Supplier</b>  Memorial Health Partners Foundation, Inc	<b>Street Address, City, State</b>  3905 Hixson Pike, Suite 103, Chattanooga, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the proficiency testing (PT) records for 2018-2019 and an interview with the lead lab tech, the laboratory failed to continue enrollment in an approved proficiency testing program for the Mycology and Parasitology specialties. (Refer to D2001).</p>
<b>D2001</b>	<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 a review of proficiency testing (PT) records for 2018-2019 and an interview</p>

with the lead lab tech and 5 mid-level practitioners (NPs), the laboratory failed to continue enrollment in an approved proficiency testing program for Mycology and Parasitology specialties from the 2nd event 2018 through the 2nd event 2019. Findings include: 1. Review of the American Proficiency Institute (API) Performance Summary for 2018 Hematology/Coagulation 3rd event revealed no scores for PT for Mycology and Parasitology in Vaginal Wet Preparation (VWP) and VWP (KOH) for the 2nd/3rd events 2018. 2. Review of the API 2018 Order Confirmation and Packing Slip revealed no PT shipment of Provider Performed Microscopy (PPM) VWP & VWP (KOH) kits for the 2nd/3rd events 2018. 3. Review of the API 2019 Order Confirmation revealed no PT shipment of PPM VWP & VWP (KOH) kits for the 1st /2nd events 2019. 4. In an interview, August 22, 2019, at approximately 10:30 AM, the lead lab tech confirmed the laboratory cancelled enrollment per corporate guidance for all waived and PPM PT beginning the 2nd event 2018 and beyond in an approved proficiency testing program for the Mycology and Parasitology specialties for 2018-2019. 5. In 5 of 5 interviews, August 22, 2019, at Noon, confirmed the lab's NPs continued to perform and report VWP & VWP (KOH) on patients for the past two years in 2017-2019.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of employee personnel records for 2017-2019 and interview with the quality manager, the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency for 5 of 5 mid-level practitioners (NPs) performing and reporting Vaginal Wet Preparations (VWP) and VWP (KOH) for 172 patients from September 1, 2017- August 22, 2019 . The findings include: 1) Review of 5 of 5 NP's employee personnel records for 2017-2019 did not reveal documentation of the six required criteria of competency for VWP & VWP (KOH) that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills. 2) An interview with the quality manager on August 22, 2019 at 11:30am confirmed 5 of 5 NP testing personnel evaluated during 2017, 2018, and 2019 were not evaluated using the six criteria for competency required by Centers for Medicare and Medicaid (CMS).

**D6069**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(a)

Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

This STANDARD is not met as evidenced by:

Based on review of patient testing records and an interview with the quality manager, testing personnel (TP) number one failed to report the laboratory order accurately on a complete blood count (CBC) without white blood cell (WBC) automated differential (diff) on February 9, 2018. Findings include: 1. Review revealed a patient, CBC without WBC diff (Correct Procedural Terminology - CPT 85027), ordered on February 9, 2018. 2. Review revealed the same patient's CBC report included a WBC diff (CPT 85025) included in the patient's record. 3. In an interview, August 22, 2019, at 1:30pm, the quality manager confirmed it was common practice to include all CBC results in the patient's record on February 9, 2018.