

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0950359	(X3) Date Survey Completed 08/17/2018
Name of Provider or Supplier Thomas Health Hematology Oncology At Tmh	Street Address, City, State 401 Division Street Suite 100, South Charleston, WV	
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
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Policy and Procedure Manual and Quality Control records for Hematology, the Laboratory Director did not ensure the analytic systems quality assessment was effective. Findings: 1. Three levels of Hematology 4C Control were performed daily for the Coulter Act Diff 2. However, the low level 4C control values results frequently had a notation of "Does not report low ranges because of high SD's". within the Coulter evaluation reports. 2. There was a repeated problem with error code x indicating bubbles were present in the Coulter ACT Diff line on dates, 1/28/18, 1/29/18, 1/30/18, 1/31/18 and other dates throughout 2017 and 2018 for RBC, Hgb, Hct, MCV, MCH, MCHC, RDW and platelet parameters. The director did initial the control review but added no comment on quality control assessment.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the</p>

type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory testing personnel training and competency records and interview with Technical consultant #2 (TC2), the laboratory director did not ensure ALL personnel received initial training and demonstrate reliability to perform testing prior to reporting patient test results. Findings include: 1. The first record of initial training and competency for testing personnel 2 (TP2) was dated 5/08/2018. However, records show that testing personnel #2 (TP2) began testing and reporting patient test results in January 2018. 2. At approximately 11:30 AM on 8/17/2018, the TC stated that initial training records for TP#2 were not available.

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 personnel competency records and interview with technical consultant (TC) and Office Manager (OM), the laboratory did not evaluate the competency of testing personnel with an employee meeting the qualifications of moderate complexity technical consultant found under 493.1409. Findings include: 1. Personnel competency annual review covering the laboratory elements referenced in 493.1413 (b)(8) (i-vi) was found for testing personnel 1 (TP1) and 2 (TP2). However, the validator signature for (TP2) was the OM who does not meet the qualification in 493-1409. 2. All competency assessment validation forms had the name of Thomas Memorial Hospital instead of the laboratory under this CLIA number - THS Physician Partners, Inc. 3. At approximately 10:30 AM on 8/17/18, the TC2 agreed with the finding that he (TC2) or TC1 or the Laboratory Director should conduct and approve all testing personnel annual competency assessments.