

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0036143	(X3) Date Survey Completed 06/06/2022
Name of Provider or Supplier University Health Service	Street Address, City, State 207 Fletcher Street, Ann Arbor, MI	
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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #1 (GS1), the laboratory failed to test staining materials for intended reactivity each day of use for peripheral blood smear testing for 2 (June 2020 to June 2022) of 2 years. Findings include: 1. A review of patient test records revealed patient 101294855 had a peripheral blood smear evaluated on 11/16/21. 2. The surveyor requested documentation of the staining characteristics assessments from June 2020 to June 2022 on 6/6/22 at 11:21 am and it was not made available. 3. A review of the laboratory's "PROCEDURE: 3.8 SLIDE SCANS (MANUAL SLIDE REVIEW) AND MANUAL DIFFERENTIAL COUNTS" revealed a lack of a process to document staining characteristics each day of use. 4. An interview on 6/6/22 at 11:23 am with GS1 revealed the laboratory did not establish a process for testing and documenting staining materials to ensure predictable staining characteristics.</p>
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p>

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor #1 (GS1), the Technical Consultant failed to assure personnel performing wet mount and potassium hydroxide (KOH) maintained their competency with the performance of direct observation of testing for 4 (Testing Personnel (TP) #25, #26, #27, and #28) of 28 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's competency assessments revealed a lack of documentation for TP #25, #26, #27, and #28 for the direct observation of testing for 2022. 2. An interview on 6/06/2022 at 9:53 am, the GS1 confirmed the direct observation for the testing personnel listed above was not included in the 2022 assessment.