Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0040942	01/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Umd Health Services Laboratory	615 Niagara Ct, Duluth, MN	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate an unacceptable Hematology proficiency testing (PT) result for 1 analyte in 2018. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 01/17/19 at 10:05 a.m. The laboratory performed PT using the College of American Pathologists (CAP) PT provider. 2. The laboratory received an unacceptable PT result from CAP in 2018 for the analyte listed below. Hematology Event Sample Test Lab CAP result FHI-B FHI-06 HGB* 10.4 10.5-12.2 3. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 4. In an interview on 01/17/19 at 11:30 a.m., the GS confirmed a documented investigation of the unacceptable results was not performed. * Note HGB Hemoglobin
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the

	laboratory failed to perform and document required Hematology analyzer maintenance. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 01/17/19 at 10:05 a.m. 2. An Abbott Cell-Dyn Emerald hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Semi-annual piston lubrication was required by the manufacturer and established in the Cell Dyn Emerald Checklist laboratory equipment maintence record. 4. Documentation of the semi-annual piston lubrication was not found in laboratory records for the timeframe reviewed, May 2017 - December 2018. The laboratory was unable to provide the missing documentation upon request. 5. In an interview on 01/17/19 at 1: 05 p.m., the GS confirmed the semi-annual piston lubrication was not documented.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to check each lot and shipment of Microbiology media for sterility prior to or concurrent with use. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 01/17/19 at 10:05 a.m. 2. The Strep Culture QC procedure, quality control record and media receipt log indicated a visual examination and ability to support growth check was required and performed prior to use of new lots and shipments of media. The procedure did not include a requirement to check each lot and shipment of media for sterility. 3. Sterility check documentation was not found during review of laboratory records. The laboratory was unable to provide documentation of sterility checks upon request. 4. An Individualized Quality Control Plan (ICQP) to remove the requirement to check each lot and shipment of media for sterility was not found in laboratory records. The laboratory was unable to provide an IQCP for media quality control upon request. 5. In an interview on 01/17/19 at 1:25 p. m., the GS confirmed sterility checks were not performed on new lots or shipments of media.
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 document review and interview with laboratory personnel, the technical consultant (TC) failed to evaluate required Hematology competency assessment

	elements for all testing personnel (TP) in 2017. Required elements include; 1) Direct observation of test performance, 2) Monitoring the recording and reporting of test results, 3) Review of intermediate test results or worksheets and records, 4) Direct observation of instrument maintenance, 5) Assessment of test performance with previously analyzed specimens, and 6) Assessment of problem solving skills. Findings are as follows: 1. The laboratory performed Manual Differential testing under the Hematology specialty as confirmed by the General Supervisor (GS)during a tour of the laboratory on 01/17/19 at 10:05 a.m. The GS confirmed all TP performed this test. 2. The 2017 Hematology competency assessment record for 1 of 2 tenured TP reviewed on date of survey was incomplete. See below. The laboratory was unable to provide the missing documentation upon request. Manual Differential TP Missing elements GS 1, 2, 3, 4, 5, 6 3. In an interview on 01/17/19 at 11:25 a.m., the GS confirmed the Manual Differential portion of his Hematology competency assessment was not completed in 2017.