Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0698405	02/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Schoolcraft Memorial Hospital	7870 Us Highway 2, Manistique, 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
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to retain its Individualized Quality Control Plan (IQCP) Risk Assessment documentation for 9 (C. Diff Quick Check Complete, Leuko EZ Vue, I-Stat Handheld Analyzer, SureVue Qualitative Serm hCG, MedTox Urine Drug of Abuse, Microbiology Media, Abbott Piccolo Chemistry Analyzer, BioFire Film Array Panels, and Biomerieux Mini-Vidas assays) of 9 IQCP procedures in use by the laboratory. Findings include: 1. A review of the laboratory's IQCP documentation revealed the following testing employing an IQCP lacked the documentation supporting its risk assessment: a. C. Diff Quick Check Complete b. Leuko EZ Vue c. I-Stat Handheld Analyzer d. SureVue Qualitative Serm hCG e. MedTox Urine Drug of Abuse f. Microbiology Media g. Abbott Piccolo Chemistry Analyzer h. BioFire Film Array Panels i. Biomerieux Mini-Vidas assays 2. An interview on 2/7/23 at 3:52 pm with the General Supervisor confirmed the laboratory had not retained the supporting documentation used in the risk assessment in establishing its IQCP procedures listed above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to establish policies to assess the competency of its personnel serving as Clinical Consultant, Technical Consultant, Technical Supervisor, and General Supervisor roles for 2 (February 2021 to February 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's personnel competency assessment records revealed a lack of competency assessments for the following personnel listed on Form CMS-209: a. The General Supervisor serving the roles of Technical Consultant and Technical Supervisor. b. The Laboratory Director serving the roles of Clinical Consultant and Technical Supervisor for immunohematology. 2. An interview on 2/7/23 at 3:00 pm with the General Supervisor revealed the laboratory had not established a process for competency assessments for personnel holding the roles of Clinical Consultant, Technical Consultant, Technical Supervisor, and General Supervisor roles.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to verify the accuracy of its testing that had not been evaluated by its proficiency testing program for 3 (2021 Hematology/Coagulation 3rd Event, 2021 Microbiology 3rd Event, and 2022 Microbiology 2nd Event) of 4 testing events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the following events with not graded results: a. 2021 Hematology/Coagulation 3rd Event i. Basophil percent ii. Eosinophil percent iii. Lymphocyte percent iv. Lymphocyte, reactive percent v. Blood Cell Identification b. 2021 Microbiology 3rd Event i. Educational Susceptibility ii. Group C/G Strep iii. Urine Culture MIC/Zone Diameter Value c. 2022 Microbiology 2nd Event i. Educational Susceptibility ii. Urine Culture MIC/Zone Diameter Value 2. An interview on 2/7/23 at 3:52 pm with the General Supervisor revealed the laboratory had not assessed its performance for its testing that had not been given a score by the proficiency testing program.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor and Testing Personnel #4, the laboratory failed to test its control materials used in its serum and plasma Aimtab Ketone Analysis testing in the same manner as patients for 1

	(February 2022 to February 2023) of 1 year reviewed. Findings include: 1. A review of the laboratory's "LAB-072 Aimtab Ketone Analysis" procedure revealed a section stating, "Quality Control samples are analyzed on each day of use using the Urinalysis Negative and Positive controls." 2. An interview on 2/7/23 at 11:39 am with the General Supervisor and Testing Personnel #4 revealed the laboratory uses urine controls to perform control procedures for its Aimtab Ketone testing for urine, plasma, and serum testing and had not used control materials with a similar matrix to plasma or serum.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to document the positive and negative reactions of its control procedures performed using the Aimtab Ketone testing tablets for 1 (January 2021 to January 20230 of 1 year reviewed. Findings include: 1. A review of the laboratory's "LAB-072 Aimtab Ketone Analysis" procedure revealed a section stating, "Quality Control samples are analyzed on each day of use using the Urinalysis Negative and Positive controls." 2. A review of the laboratory's "Urinalysis/MedTox/Serology Maintenance and QC Performed Log" revealed a section for its ketone testing. On dates when controls were performed, there is a check mark and no reactions for its positive and negative controls were listed. 3. An interview on 2/8/23 at 2:55 pm with the General Supervisor confirmed the laboratory had not been documented the reactions of control testing for its ketone testing.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (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. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to review the effectiveness of its test procedures employing an Individualized Quality Control Program (IQCP) for 9 (C. Diff Quick Check Complete, Leuko EZ Vue, I-Stat Handheld Analyzer, SureVue Qualitative Serm hCG, MedTox Urine Drug of Abuse, Microbiology Media, Abbott Piccolo Chemistry Analyzer, BioFire Film Array Panels, and Biomerieux Mini-Vidas assays) of 9 IQCP procedures in use by the laboratory. Findings include: 1. A review of the laboratory's IQCP documentation revealed the following testing employing an IQCP lacked the documentation of its quality assessment reviews: a. C. Diff Quick Check Complete b. Leuko EZ Vue c. I-Stat Handheld Analyzer d. SureVue Qualitative Serm hCG e. MedTox Urine Drug of Abuse f. Microbiology Media g. Abbott Piccolo Chemistry Analyzer h. BioFire Film

	Array Panels i. Biomerieux Mini-Vidas assays 2. An interview on 2/7/23 at 11:52 am with the General Supervisor confirmed the laboratory had not performed and documented quality assessment reviews for its test procedures listed above employing an IQCP.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to include the test report date on its test reports for 12 (Patients 42513, 2664, 3263, 26880, 15136, 6708, 275, 28248, 17079, 39199, 8749, 12989, and 68569) of 12 patient test reports reviewed. Findings include: 1. A review of patient test reports revealed the following patients had specimens collected on the following dates and the test reports had not included the test report date: a. Patient 42513 specimen collected on 2/7/21 b. Patient 28248 specimen collected on 6/7/21 c. Patient 8749 specimen collected on 8/16/21 d. Patient 2664 specimen collected on 8/25/21 e. Patient 15136 specimen collected on 11/4/21 f. Patient 39199 specimen collected on 1/26/22 g. Patient 26880 specimen collected on 3/30/22 h. Patient 17079 specimen collected on 5 /13/22 i. Patient 275 specimen collected on 7/7/22 j. Patient 12989 specimen collected on 10/29/22 k. Patient 3263 specimen collected on 12/27/22 l. Patient 68569 specimen collected on 2/7/23 2. An interview on 2/7/23 at 1:09 pm with the General Supervisor confirmed the test reports above did not include the test report date.