Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521001	01/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Madison Memorial Hospital Lab	450 E Main St, Rexburg, ID	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Proficiency Institute (API), College of American Pathologists (CAP) and an interview with the Technical Supervisor (TS) on 1/27/2021, the laboratory failed to enroll in proficiency testing to verify the accuracy of testing of the platelet function assay in accordance with 493.1236(c)(1). The findings include: 1. A review of proficiency testing records from API and CAP identified that the laboratory failed to verify the accuracy of testing for the platelet function assay biannually for 2020. 2. An interview with the TS on 1/27/2021 at 10:20 am confirmed that the laboratory failed to verify the accuracy of testing for the platelet function assay biannually for 2020. 3. The laboratory reports performing two platelet function tests annually.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of immunohematology quality control (QC) records, training and competency records, laboratory policies and procedures and an interviews with the

	Technical Supervisor (TS) on 1/27/2021 and 1/28/2021, the laboratory failed to meet the the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299. The findings include: 1. The laboratory failed to have training and competency assessments documented for the testing personnel listed on the CMS 209 that were performing immunohematology testing. See D5209 2. The laboratory failed to establish a procedure for all immunohematology QC testing. See D5403 3. The laboratory failed to perform and document acceptable QC daily for immunohematology before reporting patient results. See D5401, D5447 [Repeat Deficiency], D5451 and D5481. 4. Interviews with the TS on 1/27/2021 and 1/28 /2021 confirmed the above findings. 5. The laboratory reports performing 9,489 immunohematology tests annually.
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 a review of training documentation and competency assessments, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview on 1/27/2021 with the Technical Supervisor (TS), the laboratory failed to establish and follow written policies and procedures to assess testing personnel in accordance with 42 C.F.R. 493.1451(b)(7)(8). The findings include: 1. A review of training and competency records identified that three (3) of ten (10) testing personnel listed on the CMS 209 had start days after the previous survey (9/18/2018) and the laboratory failed to have documentation of initial training. 2. A review of training and competency records identified that two(2) of ten (10) testing personnel listed on the CMS 209 failed to have documentation of six (6) month competency which included the six parameters as listed in 493.1451(b)(7)(8). 3. A review of training and competency records identified seven (7) of ten (10) testing personnel listed on the CMS 209 failed to have documentation of annual competency which included the six parameters as listed in 493.1451(b)(7)(8) for 2019 and eight (8) of ten (10) testing personnel listed on the CMS 209 failed to have documentation of annual competency which included the six parameters as listed in 493.1451(b)(7)(8) for 2020. 4. An interview with the TS on 1/27/2021 at 9:10 am confirmed the above findings.
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 a record review of proficiency testing (PT) from American Proficiency Institute (API) and an interview with the Technical Supervisor (TS) on 1/27/2021, the laboratory failed to review PT and evaluate results that were less than 100% but greater than or equal to 80% for 2020. The findings include: 1. A review of PT records from API for event one of 2020 identified that the laboratory failed to evaluate the results for the following analytes; Lactate (blood gas) 80%, Lipase 80%, NT pro-

	BNP 80%, Carbamazepine 80%, Gentamicin 80%, Salicylates 80% Carboxyhemoglobin 80%, and Molecular Virology Meningitis 97%. 2. A review of PT records from API for event two of 2020 identified that the laboratory failed to evaluate the results for the following analytes; Creatinine Kinase, Isoenzyme 80%, NT pro-BNP 80%, Molecular Virology Respiratory 99% and Compatibility Antigen Identification 80%. 3. A review of PT records from API for event three of 2020 identified that the laboratory failed to evaluate the results for the following analytes; Creatinine (blood gas) 80%, TIBC 80%, Hemoglobin (blood oximetry) 80%, Methemoglobin 80%, and Mycology Identification 80%. 4. An interview with the TS on 1/27/2021 at 8:30 am, confirmed that the laboratory failed to review and evaluate PT results from API that were less than 100% but greater than or equal to 80% for 2020. 5. The laboratory reports performing 519,353 moderate and high complexity tests annually.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review proficiency testing (PT) records and an interview with the Technical Supervisor (TS) on 1/27/2021 the laboratory failed to evaluate the accuracy of any analyte, specialty or subspecialty that was assigned an artificial score of 100% because it was ungraded by the PT provider. The findings include: 1. A review of Immunology/Immunohematology 2020 event 3 records from American Proficiency Institute (API) identified three ungraded samples, Antibody Identification, Antibody Screen and Direct Antiglobin, due to lack of consensus, that were given an artificial score of 100% that the laboratory failed to evaluate for accuracy. 2. A review of Microbiology 2020 event 3 records from API identified the laboratory failed to evaluate for accuracy two (2) Shiga toxin molecular samples that were ungraded due to no appropriate peer group resulting in an artificial score of 100%, one ungraded parasitology and one ungraded anaerobic wound culture sample due lack of consensus, resulting in an artificial score of 100%. 3. A review of Microbiology 2020 event 1 records from API identified 24 samples for Pneumonia resistance genes that were ungraded due to no appropriate peer group resulting in an artificial score of 100% that the laboratory failed to evaluate for accuracy. 4. A review of Hematology /Coagulation 2020 event 1 records from API identified one body fluid crystal samples, 6 sperm classification samples and two sperm morphology samples that were ungraded due to lack of consensus resulting in an artificial score of 100% that the laboratory failed to evaluate for accuracy. 5. An interview with the TS on 1/27/2021 at 8:30 am confirmed that the laboratory did not evaluate the accuracy of ungraded PT results that were given an artificial score of 100%. 6. The laboratory reports performing 519,353 moderate and high complexity tests annually.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic

	systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of quality control (QC) records, laboratory policies and procedures, corrective action logs, manufacturer's instructions, corrective action logs, instrument logs and interviews with the Technical Supervisor (TS) on 1/27/2021 and 1/28/2021, the laboratory failed to monitor and evaluate the analytical systems in the laboratory for quality and correct identified quality issues. The findings include: 1. A record review of laboratory policies and procedures, corrective action logs and QC records identified that the laboratory failed to perform and evaluate QC as required by manufacturers, regulation and policies and procedures. See D5403, D5407 [Repeat Deficiency], D5451, D5481 and D5783. 2. The laboratory director failed to approve, sign or date 209 of the laboratory's 209 policies and procedures. See D5401 3. The laboratory failed to follow manufacturer's instructions for test reporting. See D5411. 4. Interviews with the TS on 1/27/2021 and 1/28/2021 confirmed the above findings. 5. The laboratory reports performing 519,353 moderate and high complexity tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures, laboratory quality control (QC) records, corrective action logs and interviews with the Technical Supervisor (TS) on 1/27/2021 and 1/28/2021, the laboratory failed to follow the laboratory policies and procedures. The findings include: 1. A review of the policy, "Quality Control and Patient Results, Review of," and QC records the Laboratory Director failed to review hematology , chemistry, blood banking, coagulation, urinalysis and microbiology QC monthly. 2. A review of the policy, "Corrective Action, Out of Control Quality Control Results," and QC records, the laboratory failed to document all corrective actions taken for unacceptable controls. The TS and Laboratory Director failed to document the review of corrective actions monthly. 3. A review of the policy, "Blood Bank- Quality Assurance,"and immunohematology QC records, the testing personnel failed to perform and document daily control checks for immunohematology. 4. As established by the laboratory policies and procedures the testing personnel failed to document all corrective actions taken for unacceptable controls. 5. An interview with the TS on 1/28/2021 at 11:15 am confirmed that the testing personnel, TS and Laboratory Director failed to follow laboratory policies and procedures. 6. The laboratory reports performing 519,353 moderate and high complexity tests annually.
D5403	PROCEDURE MANUAL

	CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality control (QC) records and interview with the laboratory Technical Supervisor (TS) on 1/28/2021, the laboratory failed to ensure policies and procedures were established for immunohematology quality control (QC). The findings include: 1. A review of the laboratory's policies and procedures, the laboratory's QC records for immunohematology identified that the laboratory failed to establish a procedure for documentation of all immunohematology QC testing. 2. An interview with the TS on 1 /28/2021 at 11:00 am confirmed that the laboratory failed to establish a procedure for all documentation of immunohematology QC testing. 3. The laboratory reports performing 9,489 immunohematology tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and an interview with the Technical Supervisor on 11/28/2021, the Laboratory Director failed to approve, sign and date any of the laboratory policies and procedures. The findings include: 1. A record review of laboratory policies and procedures identified that the laboratory has 209 policies and procedures electronically stored on the hospitals computer system in the program PolicyTech. The Laboratory Director has no access to the hospital computer system or PolicyTech therefore failed to approve, sign or date the 209 policies and procedures for the laboratory. 2. An interview with the TS and the Director of Diagnostic Services on 1/28/2021 at 12:00 pm, confirmed that the Laboratory Director has not approved, signed or dated the 209 policies and procedures

	for the laboratory. 3. This deficient practice was identified during previous inspections in 2017 and 2018. 4. The laboratory reports performing 519,353 moderate and high complexity tests annually.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a record review and an interview with the Technical Supervisor (TS) on 1/28 /2021, the laboratory failed to follow the manufacturer's instructions for the drugs of abuse testing performed using the MedtoxScan. The findings include: 1. A record review of the MedtoxScan manufacturer's instructions identified that the laboratory failed to properly report results, as the manufacturer's instructions states, "Positives are preliminary positives for the drug/drug metabolite and should be sent to a reference laboratory for confirmation." The laboratory failed to report positives as preliminary positives and are not sending the sample for confirmation. 2. An interview with the TS on 1/28/2021 at 10:57 am confirmed that the laboratory does not report positive drug/drug metabolite results as preliminary as stated in the manufacturer's instructions. 3. The laboratory reports performing 11,672 tests for drugs of abuse annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of calibration records, instrument documents and an interview with

	the Technical Supervisor (TS), the laboratory failed to verify the reportable range at least once every 6 months for their Two Dimension EXL analyzers for 2019 and 2020. The findings include: 1. A review of calibration records and documents for the Dimension EXL identified that the laboratory failed to perform verifications of the reportable ranges for the analyte testing performed on the two Dimension EXL chemistry/immunology analyzers for 2019 and 2020. 2. An interview with the TS on 1/28/2021 at 8:50 am confirmed that the laboratory had not performed verifications of reportable range at least once every 6 months for the two Dimension EXL chemistry/immunology analyzers for 2019 and 2020. 3. The laboratory reports performing 312,354 tests annually on the Dimension EXL analyzers.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random record review of Quality Control (QC) documentation and interviews with the laboratory Technical Supervisor (TS) on 1/28/2021 the laboratory failed to successfully perform two levels of QC daily for each quantitative procedure. The findings include: 1. A random record review of QC from the Sysmex CA-600 identified that the laboratory did not have an acceptable result for level 1 QC for prothrombin time (PT) and partial thromboplastin time (PTT) on 12/7/2019. 2. A random record review of QC from the Dimension EXL identified that the laboratory did not have an acceptable result for the following analytes: Free thyroxine on 4/9/19 for level 1, Free thyroxine on 4/10/19 for level 1, Lactate Dehydrogenase on 4/8/19 for level 1, gamma-glutamyl transpeptidase on 7/20/19 for levels 1&2, Lactate Dehydrogenase on 4/21/20 for level 1, Salicylate on 4/21/20 for level 1, total iron binding capacity on 4/21/20 and 4/22/20 for level 3. 3. A random record review of QC from the Centaur identified that the laboratory did not have an acceptable result for the following analytes: Hepatitis C on 4/8/19 and 4/25/19 the "nonreactive" was "reactive" and Human immunodeficiency virus on 12/7/19 the "nonreactive" was "reactive". 4. A review of Immunohematology QC identified that there was no documentation of QC being performed on 9/23/19, 9/24/19, 9/25/19 and 6/26/20. There were 21 days in 2019 and 2020 where QC had been performed but the date and initial of testing personnel was not documented on the QC record. 5. An interview with the TS on 1/28/2021 at 10:40 confirmed that the above analytes had not been repeated after an unacceptable QC result. 6. This deficient practice was identified during the previous inspection on 9/18/18 for Hepatitis B surface antigen (HbsAg) and D-dimer and confirmed by interview with the laboratory manager on 9/18/18 at 2:30 pm. [Eight HbsAg and six D-dimer tests were reported without two levels of quality control performed.] 7. The laboratory reports performing 519,353 tests annually.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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--

	At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random review of immunohematology quality control (QC) records and an interview with the Technical Supervisor on 1/28/2021, the laboratory failed to document control material results with graded or titered reactivity and include a negative control material . 1. A random record review of immunohematology QC for 2019 and 2020 identified that the laboratory failed to document QC with a graded or titered reactivity. On 9/15/2019, 2/8/2020 and 2/9/2020, the laboratory failed to documented a 1-4+ as required by regulation and the laboratory QC record form. 2. A random record review of immunohematology QC for 2019 and 2020 identified the laboratory failed to document a negative control result on 1/11/2019-1/14/2019, 7/2 /2020, 6/18/2020 and 6/25/2020. 3. An interview with the TS on 1/27/2021 at 11:00 am, confirmed that the laboratory failed to document immunohematology QC as performed with a graded or titered reactivity and negative control results. 4. The laboratory reports performing 9,489 immunohematology tests annually.
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 a random review of immunohematology quality control (QC) records and an interview with the Technical Supervisor (TS) on 1/28/2021 the laboratory failed to have acceptable QC or determine the acceptability of QC based on manufacturer's test system and laboratory requirements before reporting patient test results. The findings include: 1. A random record review of immunohematology QC identified that on 3/17 /19 and 1/11/19 the laboratory failed to have acceptable QC for Rh. Rh negative control was recorded as 4+ and the Anti D was marked as = and the QC was marked as acceptable. 2. A random record review of immunohematology QC identified that on 4/1/19 through 4/4/19 the laboratory failed to have acceptable QC for Rh. Anti D was recorded to be positive on the incorrect QC cells (Cell 1 AB rr) and QC was determined to be satisfactory. 3. A random record review of immunohematology QC identified that on 10/25/20 the laboratory failed to have acceptable QC for Rh. Anti D was marked negative (=) for Cell 2 (O Rr) and the QC was marked as satisfactory. 4. A random record review of immunohematology QC identified that on 6/18/20, 6/25 /20, 6/27/20 and 7/2/20 the laboratory failed to determine if the QC was satisfactory. 5. An interview with the TS on 1/28/21 at 11:00 am confirmed that the laboratory failed to have acceptable QC or determine the acceptability of QC on the above dates before reporting patient results. 6. The laboratory reports performing 9,489 immunohematology tests annually.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory quality control (QC) records and interviews on 1 /27/2021 and 1/28/2021 with the Technical Supervisor (TS), the laboratory failed to document all corrective actions taken when QC failed to meet the laboratories established acceptability and failed to document the evaluation of patient tests performed since the last acceptable QC result. The findings include: 1. A review of QC records for the Sysmex XN-1000, which is used for performing complete blood counts (CBC), identified that the laboratory failed to document corrective actions for unacceptable QC since the analyzer was put into service in February 2020. 2. A review of QC records for immunohematology identified that the laboratory failed to document corrective actions for unacceptable QC since the last inspection (9/18/18). 3. Interviews with the TS on 1/27/2021 and 1/28/2021 confirmed that the laboratory failed to document corrective actions for unacceptable QC on the Sysmex XN-1000 and for immunohematology. 4. The laboratory reports performing 122,631 tests on the Sysmex XN-1000 annually and 9,489 immunohematology tests annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the systematic nature of the deficient practices identified in proficiency testing (PT), quality control (QC), training and competency, the lack of review of laboratory testing and laboratory documentation review, the Laboratory Director (LD) failed to provide overall management and direction over the laboratory and failed to ensure quality patient results. See D6086, D6091, D6093, D6096 and D6102.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review of instrument verifications and an interview with the Technical Supervisor (TS) on 11/27/2021, the Laboratory Director (LD) failed to ensure that verification procedures that were used for verification of the Sysmex and Biofire were adequate to determine the accuracy, precision, and other pertinent

	performance characteristics of the method before their use in patient testing. The findings include: 1. A record review of the Sysmex XN-1000 verification performed in January 2020, identified that the Laboratory Director failed to approve verification of performance of Complete Blood Count Testing before implementation of patient testing in February of 2020. 2. A record review of the Biofire Pneumonia Panel verification performed in March of 2019, identified that the Laboratory Director failed to approve verification of performance for molecular testing of 33 organisms before implementation of patient testing. 3. An interview with the TS confirmed that the Laboratory Director did not sign the performance verifications for the Sysmex XN-1000 and the Biofire Pneumonia Panel before implementation of patient testing. 4. The laboratory reports performing 122,631 Complete Blood Count and 120 Biofire Pneumonia Panels annually.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and an interview with the Technical Supervisor (TS) on 1/27/2021, the Laboratory Director (LD) failed to ensure that the PT performance was evaluated to identify any problems that required corrective action. The findings include: 1. A review of PT records for 2020 identified that the laboratory failed to review and evaluate PT results that were less than 100% but greater than or equal to 80%. See D5211 2. A review of PT records for 2020 identified that the laboratory failed to evaluate ungraded PT results that were artificially given a score of 100%. See D5215
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, policies and procedures, corrective action logs and an interviews with the Technical Supervisor (TS) on 1/27/2021 and 1 /28/2021, the Laboratory Director (LD) failed to ensure that QC programs were established and maintained and to identify failures in quality as they occur. The findings include: 1. Based on a review of the policy, "Quality Control and Patient Results, Review of," and QC records the LD failed to review hematology, chemistry, blood banking, coagulation, urinalysis and microbiology QC monthly as required by the policy. See D5401 2. Based on a review of QC records and polices and procedures the LD failed to ensure that QC testing was performed as required by regulations and policies and procedures for chemistry, hematology, immunology and immunohematology. See D5401, D5447 [Repeat Deficiency], D5451, and D5481.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, corrective action logs, policies and procedures and interviews with the Technical Supervisor (TS) on 1/27/2021 and 1/28 /2021, the Laboratory Director (LD) failed to ensure that all necessary corrective actions were taken and documented whenever there were any deviations in the laboratory's established performance characteristics. The findings include: 1. A review of polices and procedures, QC records and corrective action logs identified that the LD failed to ensure that the laboratory document corrective actions when QC failed to meet the established acceptability for hematology and immunohematology and the LD failed to evaluate if all necessary corrective actions were taken and failed to review the corrective actions taken monthly. See D5026, D5401, D5447[Repeat Deficiency], D5451 and D5481.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the 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 a review of training and competency records, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, quality control (QC) records, corrective action logs, policies and procedures and interview with the Technical Supervisor on 1/27/2021, the Laboratory Director (LD) failed to ensure that prior to testing patient samples, the testing personnel have appropriate training and have demonstrated competency that they can perform all testing operations to provide and report accurate patient test results. The findings include: 1. A review of training records and the CMS 209 identified the LD failed to ensure that three (3) testing personnel with start dates since the last survey (9/18/18) had initial training documented. 2. A review of competency assessments identified that the LD failed to ensure that competency assessments were performed on their testing personnel for 2019 and 2020. See D5209
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 a review of training and competency assessment documentation, quality control (QC) records, corrective action logs and an interview with the Technical Supervisor (TS) on 1/27/2021, the TS failed to identify training needs and evaluate the competency of all testing personnel for 2019 and 2020 to ensure accurate patient test reporting. The findings include: 1. A review of training and competency records identified that three (3) of ten (10) testing personnel listed on the CMS 209 failed to have documentation of initial training. See D5209 2. A review of training and competency records identified that two(2) of ten (10) testing personnel listed on the CMS 209 failed to have documentation of six (6) month competency which included the six parameters as listed in 493.1451(b)(7)(8). 3. A review of training and competency records identified seven (7) of ten (10) testing personnel listed on the CMS 209 failed to have documentation of annual competency which included the six parameters as listed in 493.1451(b)(7)(8) for 2019 and eight (8) of ten (10) testing personnel listed on the CMS 209 failed to have documentation of annual competency which included the six parameters as listed in 493.1451(b)(7)(8) for 2020. 4. A review of QC records and corrective action logs identified the the TS failed to identify training needs. 5. An interview with the TS on 1/27/2021 at 9:10 am confirmed that there was no documentation of initial training and annual competency assessments for the testing personnel listed on the CMS 209.
D6181	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(6) Each individual performing high complexity testing must document all corrective actions taken when test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on a review of Sysmex XN-1000 quality control (QC) records, immunohematology QC records and laboratory policies and procedures and and interview with the Technical Supervisor (TS) on 1/27/2021, the testing personnel failed to document corrective actions taken when QC was unacceptable. The findings include: 1. A review of QC records from the Sysmex XN-1000, used for complete blood counts, and a review of the "Corrective Action , Out of Control Results,"policy identified that the testing personnel failed to document corrective actions taken when QC was unacceptable as required by the laboratory policy. See D5783 2. A review of immunohematology QC records identified that the testing personnel failed to document corrective actions taken when QC was unacceptable as required. See D5451 and D5481. 3. An interview with the TS on 1/27/2021 at 3:00 pm, confirmed that there was no documented corrective actions for failed QC on the Sysmex XN-1000. 4. The laboratory reports performing 122,631 tests on the Sysmex XN-1000 and 9,489 immunohematology tests annually.