Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0435278	09/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hshs Good Shepherd Hospital Laboratory	200 S Cedar St, Shelbyville, IL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with general supervisor (GS); the laboratory director failed to attest to the routine testing of proficiency testing (PT) samples in 2018 through 2019 for chemistry, immunohematology, and hematology. Findings Include: 1. Proficiency testing records from the American Proficiency Institute (API) were reviewed for 2017 through 2019. 2. Review of API PT records for hematology/coagulation, immunology/immunohematology, and core chemistry revealed the laboratory director failed to attest that PT samples were handled in the same manner as patient samples for the following events: Core Chemistry a. 2018 - Event 3 b. 2019 - Event 1 Hematology/Coagulation a. 2018 - Event 3 b. 2019 - Event 1 Immunology/Immunohematology a. 2018 - Event 3 b. 2019 - Event 1 3. On survey date 09-12-19, at 6:00 pm the findings were confirmed by the GS.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified

	in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the general supervisor (GS); the laboratory failed to successfully participate in proficiency testing (PT) for thyroid stimulating hormone and activated partial thromboplastin time (APTT) in the speciaties of chemistry and hematology. Findings include: 1. The laboratory failed to perform and document a corrective action for the unsatisfactory performance of thyroid stimulating hormone (TSH) in event 3 of 2018. See D2105. 2. The laboratory failed to perform and document a corrective action for the unsatisfactory performance of partial thromboplastin time (APTT) in event 2 of 2019. See D2128.
D2105	ENDOCRINOLOGY CFR(s): 493.843(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the general supervisor (GS); the laboratory failed to perform and document a corrective action for the unsatisfactory performance of thyroid stimulating hormone (TSH) in event 3 of 2018. Findings include: 1. Proficiency testing records from the American Proficiency Institute (API) were reviewed for 2017 through 2019. 2. Review of API proficiency testing (PT) records for event 3 of 2018, Core Chemistry, found no documented review and corrective action for the TSH unsatisfactory score of 40%. 3. During the survey on 09-12-2019, at 6:00 PM, the GS confirmed the laboratory failed to document a corrective action for the TSH unsatisfactory performance.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the

	proficiency testing event. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the general supervisor (GS); the laboratory failed to perform and document a corrective action for the unsatisfactory performance of partial thromboplastin time (APTT) in event 2 of 2019. Findings include: 1. Proficiency testing records from the American Proficiency Institute (API) were reviewed for 2017 through 2019. 2. Review of API proficiency testing (PT) records for event 2 of 2019, hematology/coagulation, found no documented review and corrective action for the APTT unsatisfactory score of 40%. 3. During the survey on 09-12-2019, at 6:00 PM, the GS confirmed the laboratory failed to perform a corrective action for the APTT unsatisfactory performance.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to properly monitor, evaluate, and maintain compliance. The laboratory failed to meet the requirements in 493.1231 through 493.1236 and monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239. Findings Include: 1. The laboratory failed to verify the accuracy of chemistry testing performance when given artificial scores due to non-graded proficiency testing samples for event 3 of 2018 and event 1 of 2019 core chemistry proficiency testing. See D5215.
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 of laboratory records and interview with the general supervisor (GS); the laboratory failed to verify the accuracy of chemistry testing performance when given artificial scores due to non-graded proficiency testing samples for event 3 of 2018 and event 1 of 2019 for core chemistry proficiency testing. Findings include: 1. Proficiency testing records from the American Proficiency Institute (API) were reviewed for 2017 through 2019. 2. Review of API proficiency testing (PT) records for event 3 of 2018 and event 1 of 2019, Core Chemistry, revealed the laboratory

failed to verify the accuracy for artificial scoring, due to non-graded samples for the following analytes in each event: Event 3 2018 Blood Oximetry Carboxyhemoglobin (%) Samples BLX12, 14, and 15 Not Graded Hematocrit, calculated (BLX) (%) Samples BLX12, 14, and 15 Not Graded Hemoglobin (Blood Oximetry) (g/dL) Samples BLX12, 14, and 15 Not Graded Methemoglobin (%) Samples BLX12, 14, and 15 Not Graded Oxyhemoglobin (%) Samples BLX12, 14, and 15 Not Graded Chemistry Albumin (g/dL) Sample CH-11 Not Graded Alkaline Phosphatase (U/L) Sample CH-11 Not Graded ALT/SGPT (U/L) Sample CH-11 Not Graded Amylase (U /L) Sample CH-11 Not Graded AST/SGOT (U/L) Sample CH-11 Not Graded Bilirubin, Direct (mg/dL) Samples CH-11, 13, 15 Not Graded Bilirubin, Total (mg /dL) Sample CH-11 Not Graded Calcium, Total (mg/dL) Sample CH-11 Not Graded Chloride (mmol/L) Sample CH-11 Not Graded Cholesterol, HDL (mg/dL) Sample CH-11 Not Graded Cholesterol, Total (mg/dL) Sample CH-11 Not Graded CO2 (mmol/L) Sample CH-11 Not Graded Creatinine Kinase/CK (U/L) Sample CH-11 Not Graded Creatinine (mg/dL) Sample CH-11 Not Graded GGT (U/L) Sample CH-11 Not Graded Glucose (mg/dL) Sample CH-11 Not Graded Iron, Total (ug/dL) Sample CH-11 Not Graded Lactic Acid (mmol/L) Sample CH-11 Not Graded LD/LDH (U/L) Samples CH-11, 13, 15 Not Graded Lipase (U/L) Sample CH-11 Not Graded Magnesium (mg/dL) Sample CH-11 Not Graded Phosphorus (mg/dL) Sample CH-11 Not Graded Potassium (mmol/L) Sample CH-11, 13, 15 Not Graded Sodium (mmol /L) Sample CH-11 Not Graded TIBC, measured (ug/dL) Sample CH-11 Not Graded Total Protein (g/dL) Sample CH-11 Not Graded Triglycerides (mg/dL) Sample CH-11 Not Graded Urea Nitrogen/BUN (mg/dL) Sample CH-11 Not Graded Uric Acid (mg /dL) Sample CH-11 Not Graded Free Thyroxine (ng/dL) Sample CH-11 Not Graded Thyroid Stimulating Hormone (uU/mL) Sample CH-11 Not Graded Acetaminophen (ug/mL) Sample CH-11 Not Graded Digoxin (ng/mL) Sample CH-11 Not Graded Phenytoin (ug/mL) Sample CH-11 Not Graded Salicylates (mg/dL) Sample CH-11 Not Graded Valproic Acid (ug/mL) Sample CH-11 Not Graded Vancomycin (ug/mL) Sample CH-11 Not Graded Event 1 2019 Blood Oximetry Carboxyhemoglobin (%) Samples BLX-01, 04, and 05 Not Graded Hematocrit, calculated (BLX) (%) Samples BLX-01, 04, and 05 Not Graded Hemoglobin (Blood Oximetry) (g/dL) Samples BLX-01 , 04, and 05 Not Graded Methemoglobin (%) Samples BLX-01, 04, and 05 Not Graded Oxyhemoglobin (%) Samples BLX-01, 04, and 05 Not Graded Chemistry Albumin (g/dL) Samples CH-01, 04, and 05 Not Graded Alkaline Phosphatase (U/L) Samples CH-04 and 05 Not Graded ALT/SGPT (U/L) Sample CH-05 Not Graded Amylase (U/L) Sample CH-04 Not Graded AST/SGOT (U/L) Samples CH-04 and 05 Not Graded Bilirubin, Direct (mg/dL) Samples CH-02, 04, and 05 Not Graded Bilirubin, Total (mg/dL) Sample CH-05 Not Graded Calcium, Total (mg/dL) Samples CH-01, 04, and 05 Not Graded Chloride (mmol/L) Samples CH-01, 04, and 05 Not Graded Cholesterol, HDL (mg/dL) Samples CH-01 and 04 Not Graded Cholesterol, Total (mg/dL) Sample CH-01 and 02 Not Graded CO2 (mmol/L) Sample CH-04 Not Graded Creatinine Kinase/CK (U/L) Sample CH-04 Not Graded Creatinine (mg/dL) Samples CH-02, 03, 04, and 05 Not Graded Glucose (mg/dL) Samples CH-01, 04, and 05 Not Graded Iron, Total (ug/dL) Sample CH-04 Not Graded Lactic Acid (mmol/L) Sample CH-04 Not Graded LD/LDH (U/L) Samples CH-02 and 05 Not Graded Magnesium (mg/dL) Samples CH-01 and 04 Not Graded Phosphorus (mg/dL) Sample CH-04 Not Graded Potassium (mmol/L) Samples CH-01, 02, 04 Not Graded Sodium (mmol/L) Samples CH-01, 04, and 05 Not Graded TIBC, measured (ug/dL) Samples CH-04 and 05 Not Graded Total Protein (g/dL) Samples CH-01, 02, 04, and 05 Not Graded Triglycerides (mg/dL) Sample CH-02 Not Graded Urea Nitrogen/BUN (mg /dL) Samples CH-01, 04, and 05 Not Graded Uric Acid (mg/dL) Samples CH-01, 02, and 04 Not Graded Free Thyroxine (ng/dL) Samples CH-04 and 05 Not Graded Acetaminophen (ug/mL) Sample CH-02 Not Graded Digoxin (ng/mL) Sample CH-04

	Not Graded Phenytoin (ug/mL) Sample CH-04 Not Graded Salicylates (mg/dL) Sample CH-02 Not Graded Valproic Acid (ug/mL) Sample CH-04 Not Graded Vancomycin (ug/mL) Sample CH-04 Not Graded 3. During the survey on 09-12-2019, at 6:00 PM, the GS confirmed the laboratory failed to verify the accuracy of artificial PT scoring due to non-graded PT samples.
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 review of laboratory records, direct observation, and interview with the laboratory director (LD); the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings Include: 1. The laboratory failed to demonstrate they can obtain performance specification comparable to those established by the manufacturer for ketone testing using the Biorex Labs K-CHECK test kit. See D5421. 2. The laboratory failed to perform and document pipette maintenance for 3 of 3 pipettes in 2018 and 2019 to ensure accurate and reliable test performance for immunohematology testing. See D5433. 3. The laboratory failed to conduct calibration verifications as required for electrolytes (Sodium, Potassium, Chloride) tested on both Dimension EXL 200 analyzers 2018 and 2019. See D5439. 4. The laboratory failed to ensure two levels of quality control (QC) materials were acceptable prior to reporting patient test results for thyroid stimulating hormone (TSH) testing on the Siemens Dimension EXL 200 analyzer for 48 patients identified during the time period of 8-28-2018 through 9-12-2018. See D5481. 5. The laboratory failed to have a system to evaluate the relationship between testing results for chemistry analytes tested on both Siemens Dimension EXL 200 analyzers two times each year. See D5775.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, and interview with general supervisor (GS); the laboratory failed to demonstrate they can obtain performance specification comparable to those established by the manufacturer for ketone testing using the Biorex Labs K-CHECK test kit. Findings Include: 1. Direct observation of

	laboratory testing supplies on 9-12-2019 at 10:30 am identified the Biorex Labs K-CHECK test kit used for ketone testing. 2. Review of the laboratory procedure manual revealed the laboratory documentation indicated the test kit in use for ketone testing was the Germaine Laboratories AimTab Ketone Tablet. 3. Interview with the GS on 9-12-2019 at 10:45 am confirmed the laboratory switched test kits in 2017 or 2018 and no verification of performance was documented. 4. Review of test volume records found from July of 2018 to July of 2019 found the laboratory performed 19 ketone tests when no verification for the new Biorex Labs K-CHECK test kit was used for patient testing. 5. During the survey on 09-12-2019, at 6:00 PM, the GS confirmed the surveyor's findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with the general supervisor (GS); the laboratory failed to perform and document pipette maintenance for 3 of 3 pipettes in 2018 and 2019 to ensure accurate and reliable test performance for immunohematology testing. Findings Include: 1. Direct observation on 09-12-2019 at 5:00 pm, identified three MLA Precision pipettes used for immunohematology testing: I-1266 (10uL), I-1264 (25uL), and I-1265 (50uL). 2. Review of the laboratory's policy and procedure manual identified the policy, "Pipette Volume Calibration", which indicated that pipettes will be cleaned and calibrated by Novamed annually. 3. Review of pipette calibration records revealed the most recent cleaning and calibration by Novamed was performed in July of 2017. 4. Review of test volume records found from July of 2018 to July of 2019 found the laboratory performed 335 immunohematology tests when no annual pipette cleaning and calibration had been documented in 2018 or 2019. 5. On survey date 09-12-2019 at 6: 00 pm, the GS confirmed that annual cleanings and calibrations were not performed or documented as described in the laboratory's policy in 2018 and 2019 for the three pipettes used for immunohematology testing.
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 direct observation, review of laboratory records, and interview with the general supervisor (GS); the laboratory failed to conduct calibration verifications as required for electrolytes (Sodium, Potassium, Chloride) tested on both Dimension EXL 200 analyzers 2018 and 2019. Findings include: 1. Direct observation of testing equipment during a tour the laboratory at 10:00 am, on 9-11-2019, identified two Siemens Dimension EXL 200 analyzers (Identified as EXL1 and EXL2). 2. Review of the laboratory procedure, "QuikLYTE (Sodium, Potassium, Chloride)", failed to identify the calibration verification procedure for electrolyte testing on the Siemens Dimension EXL 200 analyzers. 3. Interview with the GS, on 9-11-2019, at 10:40 am, confirmed that sodium, potassium, and chloride calibrations are 2 point calibrations and no calibration verification has been performed for these analytes on either analyzer. 4. Review of calibration records for both Siemens Dimension EXL 200 analyzers confirmed the laboratory failed to perform calibration verifications for sodium, potassium, and chloride. 5. Review of test volume records revealed from July of 2018 to July of 2019 the laboratory performed 28,841 tests for electrolytes (Sodium, Potassium, and Chloride) on the Siemens Dimension EXL 200 analyzers. 6. Interview on 9-12-2019, at 6:00 pm, with the GS confirmed calibration verifications were not performed for electrolytes (Sodium, Potassium, and Chloride) on the Siemens Dimension EXL 200 analyzers.
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 direct observation, review of laboratory records, and interview with the general supervisor (GS); the laboratory failed to ensure two levels of quality control (QC) materials were acceptable prior to reporting patient test results for thyroid stimulating hormone (TSH) testing on the Siemens Dimension EXL 200 analyzer for 48 patients identified during the time period of 8-28-2018 through 9-12-2018. Findings Include: 1. Review of the laboratory policy and procedure manual identified the policy, "Quality Control ", which outlined how the laboratory handles quality control testing. 2. The "Quality Control" policy instructs the laboratory to not report any patient data when repeating quality runs fail to give acceptable results. 3. Review of quality control data for TSH on the Siemens Dimension EXL 200 analyzer for 08-28-2018 through 09-12-2018 revealed the following quality control failures: Date

	/Time Control Value Acceptability 8-28-2018, 9:47am QC1 0.904 Hi 8-28-2018, 10: 10am QC1 0.887 Hi 8-28-2018, 11:21am QC1 0.883 Hi 8-29-2018, 1:26am QC1 0.876 Hi 8-29-2018, 2:11am QC1 0.907 Hi 8-29-2018, 1:28am QC3 36.72 Hi 8-29-2018, 2:11am QC3 35.85 Hi 8-30-2018, 1:12am QC1 0.887 Hi 8-30-2018, 1:36am QC1 0.885 Hi 8-30-2018, 3:17am QC1 0.886 Hi 8-30-2018, 10:10am QC1 0.954 Hi 9-03-2018, 1:14am QC3 37.21 Hi 9-03-2018, 2:28am QC3 36.87 Hi 9-03-2018, 4:58pm QC3 38.26 Hi 9-03-2018, 5:18pm QC3 38.57 Hi 9-04-2018, 9:19am QC3 37.86 Hi 9-04-2018, 1:52pm QC3 38.30 Hi 9-04-2018, 2:12pm QC3 38.64 Hi 9-04-2018, 6:53pm QC3 38.69 Hi 9-11-2018, 1:51am QC1 0.87 Hi 9-11-2018, 2:48pm QC1 0.866 Hi 4. Review of patient test records for the above mentioned dates found 48 patients were tested for TSH when quality control values were outside the manufacturer's acceptable range and the laboratory's quality control acceptance procedure was not followed. 5. Interview with the GS on 09-12-2019, at 6:00 pm, confirmed quality control results were outside the acceptable range for TSH quality control testing for the above mentioned dates when patient testing was still reported for TSH on the Siemens Dimension EXL 200 analyzer.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with the laboratory's general supervisor (GS); the laboratory failed to have a system to evaluate the relationship between testing results of chemistry analytes tested on both Siemens Dimension EXL 200 analyzers. Findings include: 1. Direct observation of testing equipment during a tour the laboratory at 10:00 am, on 9-11-2019, identified two Siemens Dimension EXL 200 analyzers (Identified as EXL1 and EXL2). 2. Review of the laboratory's policy and procedure manual revealed the laboratory failed to establish a system that evaluates the relationship between the two Siemens Dimension EXL 200 analyzers twice a year. 3. Interview with the GS, on 9-12-2019, at 9:37 am, confirmed no comparisons have been performed for the analytes performed on both analyzers. 4. Review of the laboratory's "QC Chart Siemens EXL 200" identified the following analytes that are performed on both analyzers: albumin, alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, blood urea nitrogen, calcium, chloride, carbon dioxide, creatinine kinase, creatinine, direct bilirubin, glucose, potassium, magnesium, sodium, brain natriuretic peptide, total bilirubin, total protein, troponin. 5. Review of test volume records found from July of 2018 to July of 2019 the laboratory performed 129,287 tests for the analytes identified in finding #4 on the Siemens Dimension EXL 200 analyzers. 6. Interview on 9-12-2019, at 6:00 pm, with the GS confirmed the laboratory failed to evaluate testing results between the two Siemens Dimension EXL 200 analyzers.
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 review of the laboratory records and interview with the general supervisor (GS); the laboratory director failed to provide the overall management and direction to maintain proper laboratory operation. The laboratory director must meet the qualification requirements of 493.1443 and the overall management and direction in accordance with 493.1445. Findings include: 1. The laboratory director failed to identify immunohematology proficiency testing issues for event 2 of 2018. See D6091. 2. The laboragtory director failed to ensure a proficiency testing (PT) corrective action plan was followed for unsatisfactory performance of rheumatoid factor in PT event 1 of 2019. See D6092. 3. The laboratory director (LD) failed to ensure policies and procedures were established and followed to ensure 2 of 6 testing personnel were competent to perform testing in which they are authorized to perform. See D6103. 4. The laboratory director failed to ensure the responsibilities and duties for 6 of 6 testing personnel listed on the CMS-209, as well as each person engaged in the preanalytical, analytical, and postanalytical phases of testing duties were specified, in writing. See D6107.
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 laboratory records and interview with the laboratory general supervisor (GS); the laboratory director failed to ensure proficiency testing (PT) issues were identified for immunohematology antibody screening in event 2 of 2018. Findings Include: 1. Proficiency testing records from the American Proficiency Institute (API) were reviewed for 2017 through 2019. 2. Review of API PT records for event 2 of 2018 revealed the laboratory had an unacceptable response for antibody screening sample SER-07. 3. Review of API PT documentation revealed the laboratory failed to identify the unacceptable response for antibody screening. 4. On survey date 09-12-2019, at 6:00 pm, the GS confirmed the laboratory failed to identify the unacceptable response for antibody screening.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory general supervisor (GS); the laboratory director failed to ensure a proficiency testing (PT) corrective action plan was followed for unsatisfactory performance of rheumatoid factor in PT event 1 of 2019. Findings Include: 1. Proficiency testing records from the

	American Proficiency Institute (API) were reviewed for 2017 through 2019. 2. Review of API PT records for event 1 of 2019 revealed the laboratory's performance for rheumatoid factor testing was unsatisfactory resulting in a score of 60% for the event. 3. Review of API PT documentation revealed the laboratory identified the failure for rheumatoid factor testing but the LD failed to ensure the corrective action plan was followed. 4. Review of rheumatoid factor testing identified 26 patients who had been tested by the laboratory from July of 2018 through April of 2019. 5. Review of patient testing found 2 of 26 patient's test results for rheumatoid factor had been performed by the individual who was identified as improperly performing the test and had performed the 2019 event 1 PT event. 6. On survey date 09-12-2019, at 6:00 pm, the GS confirmed the LD failed to ensure a corrective action plan was followed for the unsatisfactory rheumatoid factor PT failure.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the general supervisor (GS); the laboratory director (LD) failed to ensure policies and procedures were established and followed to ensure 2 of 6 testing personnel were competent to perform testing in which they are authorized to perform. Findings Include: 1. Review of the laboratory personnel authorization documentation, "Lab Assistants", found that testing personnel (TP) #5 and TP#6 were authorized to perform the following tests: urine pregnancy, serum pregnancy, influenza on the Sofia, occult blood, respiratory syncytial virus, streptococcus, urine drug screen, c. difficile, human immunodeficiency virus, mononucleosis, and urinalysis. 2. Review of competency assessment records found no documented competency assessments or training for the above mentioned tests for TP#5 and TP#6. 3. Interview on 9-12-2019, at 6:00pm, with the GS confirmed no competency assessments were completed for the above mentioned tests for TP#5 and TP#6.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the general supervisor (GS);

	the laboratory director (LD) failed to specify, in writing, the responsibilities and duties for 6 of 6 testing personnel listed on the CMS-209, as well as each person engaged in the preanalytical, analytical, and postanalytical phases of testing. Findings Include: 1. Review of the laboratory policy and procedure manual failed to identify documentation that specified, in writing, the responsibilities and duties for testing personnel #1, #2, #3, and #4. 2. Review of the laboratory authorization document "lab assistants" failed to identify which testing personnel were considered laboratory assistants and any additional duties that these individuals were responsible for in the laboratory. 3. On survey date 09-11-2019, at 11:30 am, the GS confirmed testing personnel #5 and #6 are considered laboratory assistants and perform the testing identified in the "lab assistants" authorization document as well as additional testing, maintenance, and quality control activities for additional test systems. 4. On survey date 9-12-2019, at 6:00pm, the GS confirmed the laboratory director failed to specify, in writing, the responsibilities and duties for 6 of 6 testing personnel listed on the CMS-209 and any other personnel engaged in laboratory testing.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory records and interview with the general supervisor (GS); the laboratory failed to have a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed. Findings Include: 1. The laboratory failed to ensure 2 of 6 testing personnel were qualified for high complexity respiratory syncytial virus testing. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60

	semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the general supervisor (GS); the laboratory failed to ensure 2 of 6 testing personnel were qualified for high complexity respiratory syncytial virus testing. Findings Include: 1. Review of educational documentation for 2 of 6 testing personnel identified on the CMS-209 failed to meet the educational and training requirements for high complexity testing. a. TP#5 - Bachelor's degree in Human Services, no training documented. b. TP#6 - High School Diploma, no training documented. 2. On survey date 09-12-2019, at 6:00 pm, the above findings were confirmed by the GS.