Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0700830	07/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Integris Grove Hospital	1001 E 18th Street, Suite A, Grove, OK	

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
D0000	The validation survey was performed on 07/08,09,10,11/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, quality assurance manager, quality assurance specialist, technical supervisor #2, group lead, and chief operating officer for DLO during an exit conference performed at the conclusion of the survey.
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 records, written policy and interview with technical supervisor #2, the laboratory failed to follow their written technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On the second day of the survey, surveyor #3 reviewed personnel records for competency assessments performed during 2018 and 2019. There was no evidence competencies had been performed for the technical consultant, based on their job responsibilities; (2) Surveyor #3 asked technical supervisor #2 if a written policy to evaluate the technical consultant based on job responsibilities was available. Rechnical supervisor #2 provided the policy for surveyor #3 to review; (3) Surveyor #3 reviewed the policy which required competencies at least every two years be performed for the technical consultant based on job responsibilities; (4) Surveyor #3 asked technical supervisor #2 if competencies based on job responsibilities had been performed during the review period as required by policy. Technical supervisor #2 stated biennial competencies had not been performed.
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 review of records, manufacturer's instructions, observation, and interview with the technical supervisor #2, chief operating officer for DLO, and quality assurance specialist, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On the first day of the survey, the quality assurance specialist stated to the surveyors the Sysmex CA-600 analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean); (2) On the fourth day of the survey, surveyor #1 observed the refrigerator where the testing reagents were maintained and identified the following reagents which appeared to be currently in use: (a) PT - Siemens Dade Innovin reagent, lot #549715A (b) PTT - Siemens Actin FSL reagent, lot #556926 (3) Technical supervisor #2 stated to surveyor #1 the above reagent lot numbers were currently in use, and had initially been put into use on 07/12/18; (4) Surveyor #1 reviewed the manufacturer's instructions for implementing new reagents. For verifying the normal reference interval, the instructions stated: (a) "Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients); (b) "Donors should not take any medications, including aspirin; (c) "Donors should span the adult age range. (NOTE: A separate range should be established for pediatric populations). The FDA defines "pediatric" as up to 21 years of age"; (d) A Minimum of 20 donors with a reasonably even distribution of males and females should be included". (4) Surveyor #1 reviewed the implementation records for the PT and PTT reagent lot changes. The records showed that, although the laboratory utilized a minimum of 20 donors, 3 of the 20 donors did not meet the manufacturer's requirements as stated above: (a) Donor #10 - There was no documentation of the medication history for the donor; (b) Donor #11 - A pediatric donor, age 17, had been used to verify the normal reference interval; (c) Donor #14 - A pediatric donor, age 20, had been used to verify the normal reference interval. (5) The records were reviewed with technical supervisor #2, chief operating officer for DLO, and the quality assurance specialist, who stated the manufacturer's instructions had not been followed for the reagent lot changes as specified above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by:

	Based on a review of records, manufacturer's instructions, and interview with technical supervisor #2 and the quality assurance specialist, the laboratory failed to ensure the manufacturer's environmental requirements were met. Findings include: (1) On the first day of the survey, technical supervisor #2 and the quality assurance specialist stated to the surveyors the laboratory used the BD BacTec FX40 automated blood culture system to perform patient blood cultures. The BD BacTec FX40 was located in a room adjacent to the main laboratory; (2) Surveyor #2 reviewed the operator's manual for the instrument and identified the manufacturer required an operating relative humidity between 25-80%, non-condensing; (3) Surveyor #2 then reviewed the humidity logs for the microbiology room. The acceptable humidity range listed on the logs was 10-90%, which allowed humidity lower than the manufacturer's specification. The surveyor reviewed the logs from 03/05/19 through 06/30/19 (the laboratory put a new hygrometer into use on 03/05/19) and identified on 17 of the 122 days reviewed, the humidity was unacceptable (less than 25% as required by the manufacturer): (a) March 2019: 10 of 26 humidity readings were too low (i) Days: 6,7,8,9,16,17,18,19,23,24 (b) April 2019: 6 of 30 humidity readings were too low (i) Days: 1,2,3,4,13,14 (4) Surveyor #2 reviewed the findings with technical supervisor #2 and the quality assurance specialist. Technical supervisor #2 and the quality assurance specialist stated to the surveyors the laboratory failed to ensure the manufacturer's humidity requirement had been met for the BD BacTec FX40 blood culture instrument.
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 a review of records, manufacturer's instructions, and interview with technical supervisor #2 and the quality assurance specialist, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, the quality assurance specialist stated to the surveyors the Helmer Quick Thaw Plasma Thawing system was used to thaw units of Fresh Frozen Plasma (FFP). The units were to be used for patient transfusions; (2) On the third day of the survey, surveyor #1 reviewed the manufacturer's maintenance requirements, which were as follows: (a) Quarterly (i) Test the high temperature alarm - The manufacturer's instructions for this test required that the visual and audible alarms activated and stated, "Test the high alarm....Watch the chamber temperature reading on the temperature controller. The temperature should increase slowly. When the temperature reaches the high alarm setpoint, an alarm should sound and AL.hi should flash on the temperature controller. The baskets should also lift out of the chamber and E1 should flash on both cycle time indicators". (3) Surveyor #1 then reviewed blood bank records from January 2018 through the third day of the survey. The records showed the quarterly alarm checks had been performed on 01/05/18, 04/23/18, 07/18/18, 10/17/18, 01/18/19, and 04/10/19. The following was identified: (a) For 4 of 6 alarm checks (01/05/18, 04/23/18, 07/18/18, and 10/17/18), there was no documentation the audible alarm activated; (b) For 2 of 6 alarm check (01/18/19, and 04/10/19), the documentation for the audible alarm stated, "no audible". (4) Surveyor #1 asked technical supervisor #2 to explain the documentation. technical supervisor #2 explained the following to the surveyor: (a)

	The laboratory did not document the activation of the audible alarm for the checks performed in 2018; (b) The audible alarm did not activate for the checks performed to date in 2019 (refer to D5781).
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the point of care technologist and quality assurance specialist, the laboratory failed to define the number, type, and criteria to determine acceptability of quality control testing when implementing an IQCP. Findings include: BIOSITE TRIAGE METER PRO (1) On the second day of the survey, the quality assurance specialist and point of care technologist stated the following to surveyor #1: (a) D-dimer testing was performed in the laboratory using the Biosite Triage Meter Pro analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP. The QCP (Quality Control Plan) portion of the IQCP did not include the number and type of QC (Quality Control) materials and the criteria for acceptability. It stated, "External control material is analyzed at least every 31 days and with new lots and shipments"; (3) Surveyor #1 reviewed the QCP with the quality assurance specialist and point of care technologist. Both stated the QCP did not include the number, type, and criteria to determine acceptability of QC testing. ISTAT 1 (1) On the second day of the survey, the quality assurance specialist and point of care technologist stated to surveyor #1 IQCP's had been developed for the following testing that were performed by nursing staff in the hospital at the point of care using iSTAT 1 analyzers: (a) The Cath Lab Department had two analyzers (serial numbers 366299 and 366881) and performed ACT (Activated Clotting Time) testing using the ACT cartridge; (b) The ICU (Intensive Care Unit) had one analyzer (serial number 384939) and performed Blood Gas (pH, pO2, and pCO2) testing using the G3+ cartridge and Troponin I testing using the cTnI test cartridge; (c) The Respiratory Department had one analyzer (serial number 337401) and performed Blood Gas testing using the G3+ cartridge; (d) The Emergency Department had one analyzer (serial number 407238) and performed Blood Gas testing using the G3+ cartridge; (e) The Nursery Department had one analyzer (serial number 407323) and performed Blood Gas testing using the G3+ cartridge. (2) Surveyor #1 reviewed the IQCP's. The QCP portion of the IQCP did not include the number and type of QC materials and the criteria for acceptability. It stated, "External QC-performed monthly or upon receipt of new lot"; (3) Surveyor #1 reviewed the QCP with the quality assurance specialist and point of care technologist. Both stated the QCP did not include the number, type, and criteria to determine acceptability of QC testing. AVOXIMETER (1) On the second day of the survey, the quality assurance specialist and point of care technologist stated the following to

	surveyor #1: (a) Total Hemoglobin and O2 Saturation testing were performed by staff in the Cath Lab Department at the point of care using the Avoximeter 1000E analyzer; (b) An IQCP had been developed for the test system. (2) Surveyor #1 reviewed the IQCP. The QCP portion of the IQCP did not include the number and type of QC materials. It stated, "Liquid QC performed weekly" and under "Acceptance Criteria" it stated, "Within established acceptance limits"; (3) Surveyor #1 reviewed the QCP with the quality assurance specialist and point of care technologist. Both stated the QCP did not include the number and type of QC materials.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical supervisor #2 and the quality assurance specialist, the laboratory failed to take corrective action or ensure corrective action was complete for unacceptable alarm checks on the plasma thawer. Findings include: (1) On the first day of the survey, the quality assurance specialist stated to the surveyors the Helmer Quick Thaw Plasma Thawing system was used to thaw units of Fresh Frozen Plasma (FFP). The units were to be used for patient transfusions; (2) On the third day of the survey, surveyor #1 reviewed the manufacturer's maintenance requirements, which were as follows: (a) Quarterly (i) Test the high temperature alarm - The manufacturer's instructions for this test required that the visual and audible alarms activated and stated, "Test the high alarm....Watch the chamber temperature reading on the temperature controller. The temperature should increase slowly. When the temperature reaches the high alarm setpoint, an alarm should sound and AL.hi should flash on the temperature controller. The baskets should also lift out of the chamber and E1 should flash on both cycle time indicators". (3) Surveyor #1 then reviewed blood bank records from January 2018 through the third day of the survey. The records showed the quarterly alarm checks had been performed on 01/05/18, 04/23/18, 07/18/18, 10/17/18, 01/18/19, and 04/10/19. The following was identified for 2 of 6 alarm checks reviewed: (a) 01/18/19 - The documentation stated, "Visual alarm activated/No audible". Corrective action had not been documented; (b) 04/10/19 - The documentation stated, "Visual alarm activities /No audiable". The corrective action documentation stated, "4/10/19-no audiable alarm, called Helmer to troubleshoot. No audible confirmed. Helmer suggested new thawer due to age". (4) Surveyor #1 reviewed the records with technical supervisor #2 and asked if corrective action had been taken for the alarm check performed 01/18/19 and if there was documentation the problem identified had been solved for the alarm check performed 04/10/19. Technical supervisor #2 stated the following to surveyor #1: (a) Corrective action had not been taken and documented for the failed audible

	alarm check on 01/18/19; (b) Although corrective action had been documented for the failed audible alarm check on 04/10/19, the problem had not been resolved (the laboratory had not purchased a new plasma thawer as suggested by Helmer).
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 a review of records, manufacturer's instructions, written policy and procedure, and interview with technical supervisor #2 and the quality assurance specialist, the laboratory failed to have a quality assessment program that monitored the effectiveness of corrective actions, revised policies and procedures to resolve, and prevent the recurrence of problems. Findings include: (1) On the first day of the survey, technical supervisor #2 and the quality assurance specialist stated to the surveyors the laboratory used the BD BacTec FX40 automated blood culture system located in a room adjacent to the main laboratory, to perform patient blood cultures; (2) Surveyor #2 reviewed the operator's manual for the instrument and identified the manufacturer required an operating relative humidity between 25-80%, non-condensing; (3) Surveyor #2 then reviewed the humidity logs for the microbiology room. The acceptable humidity range listed on the logs was 10-90%, relative humidity, which allowed humidity lower than the manufacturer's specification. The surveyor reviewed the logs from 03/05/19 through 06/30/19 (the laboratory put a new hygrometer into use on 03/05/19) and identified on 17 of the 122 days reviewed, the humidity was unacceptable (less than 25% as required by the manufacturer): (a) March 2019: 10 of 26 humidity readings were too low (i) Days: 6,7,8,9,16,17,18,19,23,24 (b) April 2019: 6 of 30 humidity readings were too low (i) Days: 1,2,3,4,13,14 (4) Although documentation on the logs stated corrective action had been taken ("Humidity issues across the hospital during colder months. Humidifier used in the lab to try to maintain humidity. Issue continues to be monitored. No testing affected. 1/14/19"), there was no documentation the humidity had been checked to ensure the corrective action was effective; (5) Surveyor #2 then reviewed the laboratory's "Policy for Temperature/Humidity Monitoring," which stated the following: (a) "Each humidity dependent piece of equipment, instrument, and/or space must have an acceptable performance range defined based on intended use. This information is available in the user's manual, instrument set-up guide or package insert for reagent and/or supplies." (b) "Corrective Action: Initiate and document appropriate corrective action when readings exceed the acceptable performance range. Documentation must include the date and description of the corrective action to include patient impact and the reading after corrective action was completed." (6) Surveyor #2 reviewed the findings with technical supervisor #2 and the quality assurance specialist who stated to the surveyors the laboratory failed to monitor the effectiveness of corrective actions taken for unacceptable humidity readings, and failed to ensure corrective actions taken, prevented further issues with unacceptable humidity levels.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical supervisor #2, the technical consultant failed to ensure that a person performing moderate complexity testing (FMH RapidScreen) had been evaluated semiannually during the first year of testing. Findings include: (1) On the second day of the survey, surveyor #3 reviewed personnel records. The following was identified: (a) Testing Person #17 - The initial training for this person was completed on 07/10/18. There was no evidence that a semiannual evaluation had been performed; (2) Surveyor #3 reviewed the records with technical supervisor #2 who stated there were no records to prove the above person had been evaluated semiannually.