Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470045	12/03/2020
Name of Provider or Supplier	**Street Address, City, State**	
Arbuckle Memorial Hospital	2011 W Broadway Ave, Sulphur, 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 recertification survey was performed on 12/01,02,03/2020. The laboratory was found out of compliance with the following CLIA regulations: 493.1447; D6108: Technical Supervisor The findings were reviewed with the laboratory director, Chief Nursing Officer, laboratory manager, hospital administrator, and the laboratory consultants during an exit conference performed at the conclusion of the survey.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to retain patient records for at least 2 years. Findings include: (1) On 12/01/2020 at 10:45 am, the laboratory manager stated to surveyor #2 CBC (Complete Blood Count) testing was performed using the Horiba ABX Pentra XL80; (2) On 12 /01/2020, surveyor #2 reviewed patient testing records with the following identified: (a) Records between 07/01/2019 through 12/24/2019 were not available. (3) Surveyor #2 asked the laboratory manager if patient records between 07/01/2019 through 12/24 /2019 could be located; (4) The laboratory manager stated to surveyor #2 the patient testing records between 07/01/2019 through 12/24/2019 for CBC testing could not be located.
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 and interview with the laboratory manager, the laboratory failed to have a written technical consultant and general supervisor competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On 12/01/2020 surveyor #2 reviewed personnel records for competency assessments performed during 2019 and 2020. There was no evidence competencies had been performed for the technical consultant and general supervisor based on job responsibilities; (2) Surveyor #2 asked the laboratory manager if a written policy to evaluate the technical consultant and general supervisor, based on job responsibilities, was available and if competencies had been performed during the review period. The laboratory manager stated to surveyor #2 on 12/01/2020 at 12:35 pm, a policy to evaluate the technical consultant and general supervisor based on job responsibilities had not been written; and competencies had not been performed.
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 review of records and interview with the laboratory manager, the laboratory failed to thoroughly review and evaluate proficiency testing results for 2 of 22 events. Findings include: BIAS (1) On 12/01/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records. The following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) were identified: (a) 2019 Chemistry Core First Event (i) Total Iron - 5 of 5 results exhibited a negative bias (aa) CH-01 - SDI -2.8 (bb) CH-02 - SDI -2.6 (cc) CH-03 - SDI -2.9 (dd) CH-04 - SDI -2.2 (ee) CH-05 - SDI -2.4 (b) 2019 Hematology First Event (i) White Blood Cell - 4 of 5 exhibited a negative bias (aa) PNT-01 - SDI -3.1 (bb) PNT-02 - SDI -2.8 (cc) PNT-03 - SDI -2.0 (dd) PNT-05 - SDI -3.7 (2) Surveyor #2 reviewed the above findings with laboratory manager who stated on 12/01/2020 at 12:40 pm, the biases had not been thoroughly addressed. FAILURES (1) On 12/01 /2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records. The following was identified: (a) 2019 Chemistry Core First Event (i) TIBC (Total Iron Binding Capacity) - The laboratory received a score of 80% (failed 1 of 5 results for sample CH-10). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure; (ii) Red Blood Cell Identification - The laboratory received a score of 80% (failed 1 of 5 results for sample BCI-05). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure; (b) 2020 Chemistry Core First Event (i) Myoglobin - The laboratory received a score of 80% (failed 1 of 5 results for sample CM-01). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure; (2) Surveyor #2 reviewed the above findings with laboratory manger who stated on 12/01/2020 at 12:40 pm, the proficiency testing had not been thoroughly addressed.
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 a review of records and interview with the laboratory manager, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for 3 of 22 events. Findings include: (1) On 12/01/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Coagulation (i) 2019 First Event - PTT (Partial Thromboplastin Time) sample HCA-01; (b) Hematology (i) 2019 First Event - Urine Sediment sample US-02; (c) Hematology (i) 2019 Second Event - Red Blood Cell Identification sample ECI-10. (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded result; (3) Surveyor #2 asked the laboratory manager if the result had been documented as evaluated. The laboratory manager reviewed the records and stated on 12/01/2020 at 01:00 pm the non-graded result had not been documented as reviewed.
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 the policy and procedure manual and interview with the laboratory manager, the laboratory failed to have a written procedure for all tests performed in the laboratory. Findings include: (1) On 12/02/2020, surveyor #2 reviewed the Blood Bank manual and could not locate the following: (a) A written procedure for Emergency Release of blood products. (2) Surveyor #2 reviewed the findings with the laboratory manager and asked if a written procedure was available. The laboratory manager stated on 12/02/2020 at 02:45 pm the procedure had been written but could not be located.
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, and interview with the

	laboratory manager, the laboratory failed to follow the manufacturer's instructions for verifying flags obtained on the Hematology analyzer for 6 of 14 records. Findings include: (1) On 12/01/2020 at 10:20 am, the laboratory manager stated to surveyor #1 CBC (Complete Blood Count) testing was performed on the Horiba ABX Pentra XL 80 analyzer; (2) On 12/02/2020, surveyor #1 reviewed the manufacturer's instructions for verifying morphology "For LMNE Matrix Flags, the instructions stated, "A manual diff must be performed for any matrix flag triggered". Examples of LMNE (lymphocyte, monocytes, neutrophils, eosinophills) Matrix flags listed included "LL, LL1, LN, ALY, RM" flags. (3) Surveyor #1 randomly reviewed 14 patient records containing flags from CBC testing performed during March 2019, December 2019, and September 2020. For 6 of 14 records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags: (a) Record #1 - LL, LN, and LL1 flags reported on patient testing performed on 03/19/2019 at 05:10 pm; (b) Record #2 - NL flag reported on patient testing performed on 03/22/2019 at 08:28 am; (c) Record #3 - LL1 flag reported on patient testing performed on 12/24/2019 at 08:56 pm; (d) Record #4 - LL, LL1, and ALY flags reported on patient testing performed on 09/05/2020 at 02:30 am; (e) Record #4 - LL and LL1 flags reported on patient testing performed on 09/05/2020 at 06:07 am; (f) Record #5 - LL and LL1 flags reported on patient testing performed on 09/05/2020 at 01:07 pm. (4) Surveyor #1 reviewed the records with laboratory manager who stated on 12/03/2020 at 01:55 pm, manual differentials had not been performed for the flags obtained for the above patients.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure reagents had not exceeded their expiration date for 2 of 13 days of testing. Findings include: (1) On 12/01/2020 at 10:20 am, the laboratory manager stated to surveyor #2 Crossmatch testing was performed in the laboratory which included ABO Typing using the tube method; (2) On 12/02/2020, surveyor #2 reviewed quality control and patient testing records for testing performed from 06/08 /2019 through 06/20/2019 and identified expired A,B reagent had been used 2 of 13 days of testing reviewed. The quality control and patient testing had been performed on 06/12/2019 and 06/16/2019 using the expired following reagents: (a) Immucor QC lot #304020, expiration date 06/07/2019. (3) Surveyor #2 reviewed the records with the laboratory manager who stated on 12/02/2020 at 04:10 pm an expired reagent had been used as indicated above.
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 a review of records and and interview with the laboratory manager, the laboratory failed to ensure the verified reportable ranges were used by the laboratory for 1 of 1 new test method. Findings include: (1) On 12/01/2020 at 10:50 am, the laboratory manager stated to surveyor #2 the laboratory performed Vitamin D testing on the Siemens Dimension EXL analyzer; (2) On 12/02/2020, surveyor #2 reviewed performance specification records for the analyzer and identified the laboratory had demonstrated the following reportable range for the following: (a) Vitamin D - 6.5 - 150 ng/mL (3) Surveyor #2 reviewed the manufacturer's reportable range for the following: (a) Vitamin D - 5.0 - 150 ng/mL (4) Surveyor #2 reviewed the findings with the laboratory manager. The laboratory manager stated on 12/02/2020 at 03:35 pm the laboratory was not using the reportable range that had been demonstrated by the laboratory as indicated above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 laboratory manager, the laboratory failed to perform quality control as stated in the IQCP for PTT testing. Findings include: (1) On 12/01/2020 at 10:00 am, the laboratory manager stated the following to surveyor #1: (a) PTT (Partial Thromboplastin Time) testing was performed using the Hemochron Signature Elite analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system and external QC (quality control) materials were performed monthly and with new lot numbers of cuvettes. (2) Surveyor #1 reviewed QC records from January 2019 through November 2020 and identified that QC had not been tested monthly, as stated in the IQCP. QC had not been tested between 01/27/2019 and 04/12/2019 (3) Surveyor #1 reviewed the records with the laboratory manager, who stated on 12/01 /2020 at 10:30 am QC had not been performed as indicated above.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for 11 of 67 days. Findings include: (1) On 12/01 /2020 at 10:15 am, the laboratory manager stated the following to surveyor #1: (a) Blood Gas (pH, pCO2, pO2) testing was performed using the OPTI-CCA-TS analyzer; (b) Two levels of quality control (QC) testing (rotating between levels 1, 2, and 3) were performed each 8 hours of patient testing. (2) On 12/02/2020, surveyor #1 reviewed QC and patient testing records for January, July, and September 2020. The review showed that one level of QC testing had not been performed each eight hours of patient testing using a combination of control materials that include both low and high values on each day of patient testing for 11 of 67 days of patient testing reviewed as follows: (a) 01/03/2020 - A patient had been tested at 02:35 am and level 1 and level 3 QC had not been performed after 01/02/2020 at 01:10 pm; (b) 01/07/2020 - A patient had been tested at 03:30 am and level 1 and level 3 QC had not been performed after 01/06/2020 at 12:38 pm; (c) 01/10/2020 - A patient had been tested at 10:47 pm and level 1 and level 2 QC had not been performed after 01/09/2020 at 07: 00 am; (d) 07/03/2020 - A patient had been tested at 07:47 pm and level 1 and level 2 QC had not been performed after 07/01/2020 at 05:18 am; (e) 07/04/2020 - A patient had been tested at 07:22 pm and level 1 and level 3 QC had not been performed after 07/03/2020 at 07:50 pm; (f) 07/10/2020 - A patient had been tested at 10:05 am and level 1 and level 3 QC had not been performed after 07/09/2020 at 02:45 pm; (g) 07/19 /2020 - A patient had been tested at 07:55 pm and level 1 and level 3 QC had not been performed after 07/09/2020 at 07:00 am; (h) 07/28/2020 - A patient had been tested at 01:31 pm and level 1 and level 2 QC had not been performed after 07/28/2020 at 12: 59 am; (i) 09/03/2020 - A patient had been tested at 07:04 pm and level 1 and level 2 QC had not been performed after 09/02/2020 at 09:40 am; (j) 09/11/2020 - A patient had been tested at 04:35 am and level 1 and level 2 QC had not been performed after 09/09/2020 at 02:55 pm; (k) 09/18/2020 - A patient had been tested at 03:48 am and QC had not been peformed after 09/17/2020 at 03:30 am. (3) Surveyor #1 reviewed the records with the laboratory manager, who stated on 12/03/2020 at 09:50 am two levels of QC materials had not been performed each 8 hours of patient testing.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected for 1 of 4 blood bank alarm checks. Findings include: (1) On 12/01/2020 at 11:10 am, the laboratory manager stated to surveyor #2 that units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient

	transfusions; (2) Surveyor #2 reviewed the refrigerator alarm check records for 2019. Although the alarm check had been performed on 03/18/2019, the high and low temperatures were not documented; (3) Surveyor #2 reviewed the records with the laboratory manager who stated on 12/01/2020 at 03:55 pm the alarm checks did not include the high and low temperatures.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: HEMOCHRON SIGNATURE ELITE (1) On 12/01/2020 at 10:00 am, the laboratory manager stated the following to surveyor #1: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Hemochron Signature Elite analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 01/01/2016). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) Surveyor #1 reviewed the records with the laboratory manager and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the reviews. The laboratory manager stated on 12/02/2020 at 10:30 am, the QA plan did not include an evaluation of the QCP, and the frequency of the reviews. QUIDEL TRIAGE METER PLUS (1) On 12/01/2020 at 10:00 am, the laboratory manager stated the following to surveyor #1: (a) D-dimer testing was performed using the Quidel Triage Meter Plus analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 01/01/2016). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) Surveyor #1 reviewed the records with the laboratory manager and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the reviews. The laboratory manager stated on 12/02/2020 at 10:30 am, the QA plan did not include an evaluation of the QCP, and the frequency of the reviews.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of a patient report and interview with the laboratory manager, the

	laboratory failed to provide normal reference intervals for 1 of 1 Wet Prep examination test report. Findings include: (1) On 12/01/2020 at 10:20 am, the laboratory manager stated to surveyor #2 Wet Prep examinations were performed; (2) On 12/02/2020, surveyor #2 reviewed one Wet Prep examination report for a patient tested on 11/20/2020 at 11:14 am. The report did not include a normal reference range for the Wet Prep examination; (3) Surveyor #2 reviewed the report with the laboratory manager, who stated on 12/02/2020 at 03:15 pm the Wet Prep examination report did not include a normal reference range as indicated above.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 records and interview with the laboratory manager, the laboratory director failed to ensure that a person performing moderate complexity testing had the appropriate training for 1 of 3 testing person. Findings include: (1) On 12/01/2020, surveyor #2 reviewed personnel records. The following was identified: (a) Testing Person #2 - This person was hired to perform patient testing on 11/2018 (exact date could not be determined by the laboratory). There was no documentation this person had been initially trained. (2) Surveyor #2 reviewed the findings with the laboratory manager, who stated on 12/01/2020 at 03:50 pm, there was no additional documentation to prove the above person had been initially trained to perform moderate complexity testing.
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 the laboratory manager, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing for 2 of 3 testing persons. Findings include: (1) On 12/01/2020, surveyor #2 reviewed 2018, 2019 and 2020 personnel records. The following was identified: (a) Testing Person #1 - The initial training for this person was completed on 09/12/2019. There was no evidence that a semiannual evaluation had been performed (due 02/2020); (b) Testing Person #9 - The initial training for this person was completed on 09/12/2019. There was no evidence

	that a semiannual evaluation had been performed (due 02/2020). (2) Surveyor #2 reviewed the records with the laboratory manager who stated on 12/01/2020 at 12:45 pm there were no records to prove the above person had been evaluated semiannually.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 7 of 9 testing persons. Findings include: (1) On 12/01/2020 at 09:50 am, the laboratory manager stated to surveyor #2 carboxyhemoglobin testing was performed in the laboratory using the Avoximeter 4000 analyzer; (2) Surveyor #2 then reviewed personnel records for 9 persons performing carboxyhemoglobin testing in the laboratory. The records showed that evaluations had been performed as follows: (a) Testing Person #1 - Performed on 11/03/2020; (b) Testing Person #3 - Performed on 07/25/2019 and 08/14/2020; (c) Testing Person #4 - Performed on 07/31/2019 and 08/14/2020; (d) Testing Person #5 - Performed on 07/26/2019 and 08/14/2020; (e) Testing Person #6 - Performed on 10/05/2020; (f) Testing Person #8 - Performed on 08 /14/2019 and 09/25/2020; (g) Testing Person #9 - Performed on 09/25/2020; (3) There was no evidence the evaluations, performed for the above persons, included an assessment of carboxyhemoglobin testing using the Avoximeter 4000 analyzer; (4) The surveyor reviewed the findings with laboratory manager, who stated on 12/01 /2020 at 12:40 pm the above evaluations did not include carboxyhemoglobin testing using the Avoximeter 40000 analyzer;
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical supervisor failed to provide technical supervision in accordance with 493.1447 of this subpart. Findings include: (1) The technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor met the educational qualifications. Refer to D6111.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics

services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) 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; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum

of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) 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; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) 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; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology

with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) 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; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) 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; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or

experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) 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; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) 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; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or

possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology

specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) 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; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) 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; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) 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; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) 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; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical supervisor failed to ensure that individuals who performed the duties and responsibilities of the technical supervisor met the qualifications for 4 of 22 proficiency testing attestation forms. Findings include: (1) On 12/01/2020, surveyor #2 reviewed the Laboratory Personnel Report (Form CMS-209), that had been completed by the laboratory. The form listed the same individual as the laboratory director and the technical supervisor; (2) On 12/01/2020, surveyor #2 then reviewed proficiency testing records for the following events: (a) Immunohematology - First 2019, Second 2019, Third 2019, First 2020, and Second 2020. (3) The documentation showed that the attestation statements for 4 of 5 events (Second 2019, Third 2019, First 2020, and Second 2020.) had been signed by the laboratory manager instead of the laboratory director/technical supervisor (the laboratory manager had a bachelor's degree in applied science); (4) The findings were reviewed with the laboratory manager who stated to surveyor #2 on 12/01/2020 at 04:45 pm, the attestation statements for the above events had been signed by a person who did not qualify as a technical supervisor. NOTE: The regulations only allow for an individual qualifying as a general supervisor to perform initial training and annual competency evaluations as stated at 493.1463 "Standard; General supervisor responsibilities: (b)(3) Providing orientation to all testing personnel; and (b)(4) Annually evaluating and documenting the performance of all testing personnel"