Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472705	04/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Okeene Municipal Hospital	207 East F Street, Okeene, 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 04/02/19 to 04/04/19. The laboratory was found out of compliance with the following CLIA regulation: 493.1447: D6108: Condition: Technical Supervisor The findings were reviewed with the laboratory supervisor at the conclusion of the survey.
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 supervisor, the laboratory failed to follow the manufacturer's instructions for the testing performed in the laboratory. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the laboratory began using the Vitros ECiQ Immunoassay analyzer on 06/22/17 to perform patient Troponin I testing; (2) The surveyor reviewed the manufacturer's implementation instructions for the analyzer. The manufacturer required the method comparison be performed using a minimum of 20 samples; (3) The surveyor then reviewed the laboratory's implementation records for the new test system and identified the laboratory failed to use the manufacturer's minimum of 20 samples but used 17; (4) The surveyor reviewed the findings with the laboratory supervisor, who stated to the surveyor, the laboratory had not used 20 samples as required by the manufacturer to perform the method comparison for Troponin I testing on the new analyzer.
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, observation, and interview with the laboratory supervisor, the laboratory failed to ensure the manufacturers' environmental specifications were met. Findings include: SYSMEX XS-1000i (1) On the first of the survey, the laboratory supervisor stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (e.g. WBC (White Blood Count), RBC (Red Blood Count), Hematocrit, Hemoglobin, Platelet count, etc.) using the Sysmex XS-1000i hematology analyzer; (2) On the third day of the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required a humidity between 30 and 85%; (3) The surveyor then reviewed the laboratory humidity records from October 2017 through February 2019. The surveyor identified the humidity was either less than 30%, or had not been documented during 11 of the 17 months reviewed. The specific findings follow: (a) October 2017: 1 of 31 humidity readings was less than 30% (Day 27) (b) November 2017: (i) 6 of 30 humidity readings were less than 30% (Days 7,8,9,19,21,23) (ii) 4 of 30 humidity readings had not been documented (Days 22,24,25,26) (c) December 2017: (i) 11 of 31 humidity readings were less than 30% (Days 8,11,14,16,18,21,22,25,26,28,29) (ii) 14 of 31 humidity readings had not been documented (Days: 2,5,6,7,9,10,12,13,15,23,24, 27,30,31) (d) January 2018: (i) 14 of 31 humidity readings were less than 30% (Days 2,4,5,6,8,11,13,14,16,17,22,23,25,29) (ii) 11 of 31 humidity readings had not been documented (Days 1,3,12,15,18,19,24,27,28,30,31) (e) February 2018: (i) 20 of 28 humidity readings were less than 30% (Days 1,2,3,4,5,6,7,8,9,11,12,13,14,16,17, 20,22,23,24,25) (ii) 1 of 31 humidity readings had not been documented (Day 10) (f) March 2019: (i) 12 of 31 humidity readings were less than 30% (Days 2,8,9,10,12,13,16,19,20,21,22,30) (ii) 9 of 31 humidity readings had not been documented (Days 1,5,6,7,11,14,15,17,18) (g) April 2018: (i) 16 of 30 humidity readings were less than 30% (Days 1,2,4,8,9,10,11,14,15,16,17,18,19, 20,26,27) (h) November 2018: (i) 14 of 30 humidity readings were less than 30% (Days 9,10,11,13,14,17,18,19,20,21,25, 26,27,28) (i) September 2018: (i) 2 of 30 humidity readings had not been documented (Days 1,2) (j) December 2018: (i) 13 of 31 humidity readings were less than 30% (Days 3,4,5,6,7,9,10,14,15,16,20,22,28) (ii) 1 of 31 humidity readings had not been documented (Day 8) (k) January 2019: (i) 4 of 31 humidity readings were less than 30% (Days 1,2,9,13) (l) February 2019: (i) 9 of 30 humidity readings were less than 30% (Days 7,8,9,13,15,18,19,24,28) (4) The surveyor reviewed the findings with the laboratory supervisor. The laboratory supervisor stated to the surveyor the laboratory failed to ensure the manufacturer's humidity requirement had been met as listed above. VITROS 350 AND VITROS ECIQ (1) On the first of the survey, the laboratory supervisor stated to the surveyor the laboratory performed the following: (a) Chemistry testing (i.e. Glucose, Potassium, Uric Acid, etc.) using the Vitros 350 analyzer; (b) Immunoassay testing (e.g., TSH (Thyroid Stimulating Hormone), PSA (Prostate Specific Antigen), FreeT4, and Troponin I) using the Vitros ECiQ analyzer (put into use on 06/22/17). (2) On the third day of the survey, the surveyor reviewed

the manufacturer's environmental specifications for the analyzers. The following was required: (a) Vitros 350: The manufacturer required humidity between 15 and 60%; (b) Vitros ECiQ: The manufacturer required humidity between 15 and 75%. (3) The surveyor then reviewed the laboratory humidity/temperature records from October 2017 through February 2019. The surveyor identified 9 of the 17 months reviewed, the humidity was either less than 15%, or had not been documented. The specific findings follow: (a) November 2017: (i) 3 of 30 humidity readings were less than 15% (Days 8,19,21) (ii) On 4 of 30 humidity readings had not been documented (Days: 22,24,25,26) (b) December 2017: (i) 8 of 31 humidity readings were less than 15% (Days 8,11,14,16,22,26,28,29) (ii) 14 of 31 humidity readings had not been documented (Days 2,5,6,7,9,10,12,13,15,23,25, 27,30,31) (c) January 2018: (i) 14 of 31 humidity readings were less than 15% (Days 2,4,5,6,8,11,13,14,16,17,22,23,25,29) (ii) 11 of 31 humidity readings had not been documented (Days 1,3,12,15,18,19,24,27,28,30, 31) (d) February 2018: (i) 12 of 28 humidity readings were less than 15% (Days 1,2,3,4,5,6,7,9,12,13,20,22) (ii) 1 of 28 humidity readings had not been documented (Day 10) (e) March 2018: (i) 5 of 31 humidity readings were less than 15% (Days 2,8,9,12,13) (ii) 9 of 31 humidity readings had not been documented (Days 1,5,6,7,11,14,15,17,18) (f) April 2018: (i) 6 of 30 humidity readings were less than 15% (Days 1,4,14,15,16,19) (g) September 2018: (i) 2 of 30 humidity readings had not been documented (Days 1,2) (h) November 2018: (i) 1 of 30 humidity readings was less than 15% (Day 13) (i) December 2018: (i) 1 of 31 humidity readings was less than 15% (Day 9) (ii) 1 of 31 humidity readings had not been documented (Day 8) (j) January 2019: (i) 1 of 31 humidity readings was less than 15% (Day 2) (4) The surveyor reviewed the findings with the laboratory supervisor. The laboratory supervisor stated to the surveyor the laboratory failed to ensure the manufacturer's humidity requirement for the Vitros 350 and the Vitros ECiQ analyzers had been met as listed above. REFRIGERATOR TEMPERATURE (1) The surveyor observed the laboratory refrigerators and their contents and the manufacturer's storage requirements. The following were examples of the contents: (a) Whirlpool SS (stainless steel) refrigerator: (i) 1 box of directCHECK Whole Blood PT/PTT (Prothrombin Time/Partial Thromboplastin Time) QC (Quality Control) material, Lot #K8DAC008 and Lot #K8DAT005. The manufacturer's acceptable storage range: 2-8 C (Centigrade); (ii) 2 boxes of Thyroid Stimulating Hormone Calibration materials, Lot #5805. The manufacturer's acceptable storage range: 2-8 C; (iii) 2 packs of Prostate Specific Antigen reagent, Lot #3680. The manufacturer's acceptable storage range: 2-8 C; (iv) 1 pack Free T4 reagent, Lot #4190. The manufacturer's acceptable storage range: 2-8 C; (v) 2 boxes of Hemochron Citrate PTT test cuvettes, Lot #J8JCC016. The manufacturer's acceptable storage range: 2-8 C. (b) Whirlpool white refrigerator: (i) 1 box of Vitros PV (Performance Verifier) I, Lot #A6018. The manufacturer's acceptable storage range: 2-8 C; (ii) 1 box of PV II, Lot #W5903. The manufacturer's acceptable storage range: 2-8 C; (iii) 1 vial each of eCHECK XS Sysmex QC materials in use during the survey. The manufacturer's acceptable storage range: 2-8 C: (aa) Level 1, Lot #90430804 (bb) Level 2, Lot #90430805 (cc) Level 3, Lot #90430806 (2) The surveyor reviewed temperature records for the laboratory refrigerators from 07/01/17 through 12/31/18. The laboratory's acceptable temperature range for the refrigerators was 2 to 6 degrees C. The surveyor identified 13 of the 487 days reviewed, the refrigerator temperature was than 2 degrees C. The specific findings follow: (a) Whirlpool SS refrigerator: (i) September 2017: (aa) 2 of 30 temperatures (Days 18,28) (ii) October 2017: (aa) 1 of 31 temperatures (Day 6) (iii) March 2018: (aa) 1 of 31 temperatures (Day 29) (iv) April 2018: (aa) 2 of 30 temperatures (Days 20,25) (v) June 2018: (aa) 1 of 30 temperatures (Day 24) (vi) November 2018: (aa) 3 of 30 temperatures (Days 5,16,27) (b) Whirlpool White refrigerator: (i) March 2018: (aa) 1 of 31 temperatures (Day 26)

	(ii) April 2018: (aa) 1 of 30 temperatures (Day 18) (iii) May 2018: (aa) 1 of 31 temperatures (Day 3) (3) The surveyor reviewed the findings with the laboratory supervisor, who stated to the surveyor the laboratory failed to ensure the manufacturer's storage requirements for the testing materials had been met, as listed above. NOTE: D5413 was cited on the previous recertification survey performed 06 /05/17-06/07/17
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 the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: VITROS 350 (1) On the first of the survey, the laboratory supervisor stated to the surveyor the laboratory performed Chemistry testing (i.e. Glucose, Potassium, Uric Acid, etc.) using the Vitros 350 analyzer; (2) The surveyor reviewed the manufacturer's maintenance requirements, as stated on the manufacturer's maintenance log and identified the following procedures were required on a weekly basis: (a) Clean tray platform and transport arm (b) Clean cup retainer (c) Clean diluent bottles (d) Clean tip locator (e) Clean control unit screen (f) Clean keypad cover (g) Inspect, clean, and/or replace air filter (h) Back up QC/Config/Calibration Data (3) The surveyor reviewed the maintenance records from 07/01/17 through 2/28/19 and identified the weekly maintenance procedures had not documented as having been performed: (a) Between 01/23/18 and 02/07/18 (b) Between 07/25/18 and 08/08/18 (4) The surveyor reviewed the findings with the laboratory supervisor who stated to the surveyor there was no documentation the manufacturer's required weekly maintenance procedures had been performed as listed above. VITROS ECIQ (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the laboratory performed Immunoassay testing (e.g., TSH (Thyroid Stimulating Hormone), PSA (Prostate Specific Antigen), FreeT4, and Troponin I) using the Vitros ECiQ analyzer. In addition, the laboratory supervisor stated the analyzer was put into use on 06/22/17; (2) The surveyor reviewed the manufacturer's maintenance requirements, as stated on the manufacturer's maintenance log and identified the following procedures were required: (a) Daily maintenance: (i) Verify slide inventory/load cartridges (ii) Empty mixing cup array/tip disposal box (iii) Empty slide disposal box (iv) Empty cartridge disposal box (v) Inspect sample trays; tube, cup, and height adaptors (vi) Load mixing cup arrays (vii) Load sample tips (viii) Change Reference Fluid micro tip and clean reference Fluid Proboscis (every 8 hours) (ix) Install new reference Fluid disposable reservoir (white label) (x) Clean Reference Fluid cover/seal (xi) Change Immuno-Wash Fluid micro tip and clean Immuno-Wash Fluid proboscis (every 8 hours) (xii) Clean Immuno-Wash Fluid cover/seal (xiii) Inspect diluent tray and bottles (xiv) Check diluent levels and replace if required (xv) Clean diluent caps (xvi) Load diluent tray on analyzer (xvii) Verify correct date/time on screen (xviii) Verify that QC has been run (b) Weekly maintenance - "Date/Initial Boxes" (i) Clean the metering proboscis (ii) Clean the tip disposal chute/cup retainer (iii) Clean the sample supply subsystem (iv) Clean the touchscreen monitor (v) Clean the keyboard and keyboard cover (vi) Perform subsystem cleaning (vii) Clean the processing center (3) The

	surveyor reviewed the maintenance records from 9 months (October and December 2017; January, February, March, May, and November 2018; and January and February 2019) and identified the maintenance procedures listed above, had not been performed as required: (a) Daily: There was no documentation the maintenance procedures had been performed on 2 of 272 days reviewed: (i) 02/27/18 (ii) 02/28/18 (b) Weekly: (i) There was no documentation the maintenance procedures had been performed between: (aa) 04/23/18 and 05/06/18 (ii) Although the boxes for the weekly maintenance had been checked, the dates on which the maintenance was performed had not been documented. Therefore, the surveyor could not determine if the maintenance had been performed on a weekly basis as required, during the following months: (aa) October 2017 (bb) December 2017 (cc) January 2018 (dd) February 2018 (ee) March 2018 (ff) January 2019 (4) The surveyor reviewed the findings with the laboratory supervisor who stated to the surveyor there was no documentation the required maintenance procedures had been performed, as listed above.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's specifications for quality control materials. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor: (a) The laboratory used the Hemochron Signature Elite Jr. analyzer to perform: (i) PT (Prothrombin Time) testing using the Citrate PT cuvettes (ii) PTT (Partial Thromboplastin Time) testing using the Citrate PTT cuvettes (b) An IQCP (Individualized Quality Control Plan) had been developed for the system, and the quality control plan required the laboratory test two levels (Normal and Abnormal) of directCHECK Whole Blood Control every 30 days, and with a new cassette lot number. (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions for the directCHECK Whole Blood Controls, which stated "ITC recommends that each institution establish its own expected range or response based on the mean +/- 2 standard deviation of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range. Studies show that intra-laboratory variation in test results should produce a CV (Coefficient of Variation) of approximately 14%, or less for coagulation control tests"; (3) The surveyor then reviewed QC records from November 2017 through March 2019. For 3 of the 8 lot numbers of QC materials used during the review period, the laboratory failed to follow the manufacturer's instruction to obtain a CV of approximately 14% or less: (a) PT: Citrate Norman Control, Lot #A7DNC001 (In use from 11/12/17 through 02/28/18), the laboratory obtained a CV of 14.4% (b) PT: Citrate Normal Control, Lot #K8DNC008 (In use from 03/01/19 through 04/03/19), the laboratory obtained a CV of 14.6% (c) PTT: Citrate Normal Control, Lot #G7DNC0011 (In use from 02/28/18 through 10/02/18), the laboratory obtained a CV of 16.7% (4) The surveyor reviewed the finding with the laboratory supervisor, who stated to the surveyor, the laboratory obtained a CV% greater than 14%, for the QC materials listed above.

D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory supervisor, the laboratory failed to take corrective action when the manufacturer's environmental specifications had not been met. Findings include: SYSMEX XS-1000i (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (e.g. WBC (White Blood Count), RBC (Red Blood Count), Hematocrit, Hemoglobin, Platelet count, etc.) using the Sysmex XS-1000i hematology analyzer; (2) On the third day of the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required humidity be maintained between 30 and 85%; (3) The surveyor then reviewed the laboratory humidity records from October 2017 through February 2019. The surveyor identified the humidity was either less than 30%, or had not been documented during 11 of the 17 months reviewed. The specific findings follow: (a) October 2017: (i) 1 of 31 humidity readings was less than 30% (Day 27) (b) November 2017: (i) 6 of 30 humidity readings were less than 30% (Days 7,8,9,19,21,23). (ii) 4 of 30 humidity readings had not been documented (Days 22,24,25,26) (c) December 2017: (i) 11 of 31 humidity readings were less than 30% (Days 8,11,14,16,18,21,22,25,26,28,29) (ii) 14 of 31 humidity readings had not been documented (Days: 2,5,6,7,9,10,12,13,15,23,24, 27,30,31) (d) January 2018: (i) 14 of 31 humidity readings were less than 30% (Days 2,4,5,6,8,11,13,14,16,17,22,23,25,29) (ii) 11 of 31 humidity readings had not been documented (Days 1,3,12,15,18,19,24,27, 28,30,31) (e) February 2018: (i) 20 of 28 humidity readings were less than 30% (Days 1,2,3,4,5,6,7,8,9,11,12,13,14,16,17, 20,22,23,24,25) (ii) 1 of 31 humidity readings had not been documented (Day 10) (f) March 2018: (i) 12 of 31 humidity readings were less than 30% (Days 2,8,9,10,12,13,16,19,20,21,22,30) (ii) 9 of 31 humidity readings had not been documented (Days 1,5,6,7,11,14,15,17,18) (g) April 2018: (i) 16 of 30 humidity readings were less than 30% (Days 1,2,4,8,9,10,11,14,15,16,17,18,19, 20,26,27) (h) September 2018: (i) 2 of 30 humidity readings had not been documented (Days 1,2) (i) November 2018: 14 of 30 humidity readings were less than 30% (Days 9,10,11,13,14,17,18,19,20,21,25, 26,27,28) (ii) Although corrective action ("Humidifier as high as it will go. Notified maintenance.") had been documented on day 13, there was no documentation the humidity was checked to ensure the corrective action had been effective. (j) December 2018: (i) 13 of 31 humidity readings were less than 30% (Days 3,4,5,6,7,9,10,14,15,16,20,22,28) (ii) 1 of 31 humidity readings had not been documented (Day 8) (iii) Although on day 11, documentation stated corrective action had been taken (an additional humidifier had been installed), there was no evidence additional measures had been taken to ensure the humidity was acceptable on the days listed above. (k) January 2019: (i) 4 of 31 humidity readings were less than 30% (Days 1,2,9,13) (l) February 2019: (i) 9 of 30 humidity readings were less than 30% (Days 7,8,9,13,15,18,19,24,28) (4) The surveyor reviewed the records again but could not locate documentation the laboratory took corrective action (i.e. turned on humidifier, rechecked humidity, etc.) for the unacceptable humidity readings listed above, and could not find documentation the laboratory took corrective action (i.e. retraining of testing personnel, ensured

patient results had not been affected, etc.) for the days listed above when the humidity had not been documented; (5) The surveyor reviewed the findings with the laboratory supervisor. The laboratory supervisor stated to the surveyor the laboratory failed to take corrective action to ensure the manufacturer's humidity requirement had been met as listed above, and did not take corrective action for the dates the humidity had not been documented. VITROS 350 AND VITROS ECIQ (1) On the first of the survey, the laboratory supervisor stated to the surveyor the laboratory performed the following: (a) Chemistry testing (i.e. Glucose, Potassium, Uric Acid, etc.) using the Vitros 350 analyzer; (b) Immunoassay testing (e.g., TSH (Thyroid Stimulating Hormone), PSA (Prostate Specific Antigen), FreeT4, and Troponin I) using the Vitros ECiQ analyzer (put into use on 06/22/17). (2) On the third day of the survey, the surveyor reviewed the manufacturer's environmental specifications for the analyzers. The following was required: (a) Vitros 350: The manufacturer required humidity between 15 and 60%; (b) Vitros ECiQ: The manufacturer required humidity between 15 and 75%. (3) The surveyor then reviewed the laboratory humidity/temperature records from October 2017 through February 2019. The surveyor identified 9 of the 17 months reviewed, the humidity was either less than 15%, or had not been documented. The specific findings follow: (a) November 2017: (i) 3 of 30 humidity readings were less than 15% (Days 8,19,21) (ii) 4 of 30 humidity readings had not been documented (Days: 22,24,25,26) (b) December 2017: (i) 8 of 31 humidity readings were less than 15% (Days 8,11,14,16,22,26,28,29) (ii) 14 of 31 humidity readings had not been documented (Days 2,5,6,7,9,10,12,13,15,23,25, 27,30,31) (c) January 2018: (i) 14 of 31 humidity readings were less than 15% (Days 2,4,5,6,8,11,13,14,16,17,22,23,25,29) (ii) 11 of 31 humidity readings had not been documented (Days 1,3,12,15,18,19,24,27,28,30, 31) (d) February 2018: (i) 12 of 28 humidity readings were less than 15% (Days 1,2,3,4,5,6,7,9,12,13,20,22) (ii) 1 of 28 humidity readings had not been documented (Day 10) (e) March 2018: (i) 5 of 31 humidity readings were less than 15% (Days 2,8,9,12,13) (ii) 9 of 31 humidity readings had not been documented (Days 1,5,6,7,11,14,15,17,18) (f) April 2018: (i) 6 of 30 humidity readings were less than 15% (Days 1,4,14,15,16,19) (g) September 2018: (i) 2 of 30 humidity readings had not been documented (Days 1,2) (h) November 2018: (i) 1 of 30 humidity readings was less than 15% (Day 13) (ii) Although corrective action ("Humidifier as high as it will go. Notified maintenance.") had been documented on day 13, there was no indication the humidity was checked to ensure the corrective was effective. (i) December 2018: (i) 1 of 31 humidity readings was less than 15% (Day 9) (j) January 2019: (i) 1 of 31 humidity readings was less than 15% (Day 2) (4) The surveyor reviewed the records again but could not locate documentation the laboratory took corrective action for the unacceptable humidity on the days listed above, and could not find documentation the laboratory took corrective action for the days the humidity had not been documented; (5) The surveyor reviewed the findings with the laboratory supervisor. The laboratory supervisor stated to the surveyor the laboratory failed to take corrective action to ensure the manufacturer's humidity requirement had been met as listed above, and failed to take corrective action for the dates the humidity had not been documented. REFRIGERATOR TEMPERATURE (1) The surveyor observed the contents of the laboratory refrigerators and the manufacturer's storage requirements and identified the following: (a) Whirlpool SS (stainless steel) refrigerator: (i) 1 box of directCHECK Whole Blood PT/PTT (Prothrombin Time/Partial Thromboplastin Time) QC (Quality Control) material, Lot #K8DAC008 and Lot #K8DAT005. The manufacturer's acceptable storage range: 2-8 C (Centigrade); (ii) 2 boxes of Thyroid Stimulating Hormone Calibration material, Lot #5805. The manufacturer's acceptable storage range: 2-8 C; (iii) 2 packs of Prostate Specific Antigen reagent, Lot #3680. The manufacturer's acceptable storage range: 2-8 C; (iv) 1 pack of Free T4 reagent, Lot #4190. The

	manufacturer's acceptable storage range: 2-8 C; (v) 2 boxes of Hemochron Citrate PTT test cuvettes, Lot #J8JCC016. The manufacturer's acceptable storage range: 2-8 C. (b) Whirlpool white refrigerator: (i) 1 box of Vitros PV (Performance Verifier) I, Lot #A6018. The manufacturer's acceptable storage range: 2-8 C; (ii) 1 box of PV II, Lot #W5903. The manufacturer's acceptable storage range: 2-8 C; (iii) 1 vial each level of eCHECK XS Sysmex QC materials in use during the survey. The manufacturer's acceptable storage range: 2-8 C: (aa) Level 1, Lot #90430804 (bb) Level 2, Lot #90430805 (cc) Level 3, Lot #90430806 (2) The surveyor reviewed temperature records for the laboratory refrigerators from 07/01/17 through 12/31/18. The laboratory's acceptable temperature range for the refrigerators was 2 to 6 degrees C. The surveyor identified 13 of the 487 days reviewed, the refrigerator temperature was less than 2 degrees C. The specific findings follow: (a) Whirlpool SS refrigerator: (i) September 2017: (aa) 2 of 30 temperatures (Days 18,28) (ii) October 2017: (aa) 1 of 31 temperatures (Day 6) (iii) March 2018: (aa) 1 of 31 temperatures (Day 29) (iv) April 2018: (aa) 2 of 30 temperatures (Days 20,25) (v) June 2018: (aa) 1 of 30 temperatures (Day 24) (vi) November 2018: (aa) 3 of 30 temperatures (Days 5,16,27) (b) Whirlpool White refrigerator: (i) March 2018: (aa) 1 of 31 temperatures (Day 26) (ii) April 2018: (aa) 1 of 30 temperatures (Day 18) (iii) May 2018: (aa) 1 of 31 temperatures (Day 3) (4) The surveyor reviewed the records again but could not locate documentation the laboratory took corrective action (i.e. adjused thermostat, checked temperature reading, move test materials to another refrigerator, etc.) for the unacceptable refrigerator temperatures listed above; (5) The surveyor reviewed the findings with the laboratory supervisor. The laboratory supervisor stated to the surveyor the laboratory failed to take corrective action, as listed above.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to maintain accurate documentation on laboratory records. Finding include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the laboratory performed Compatibility testing (i.e. ABO/Rh typing, Antibody Screening, and Crossmatch) of units of PRBC's (Packed Red Blood Cells) for patient transfusion purposes; (2) On the second day of the survey, the surveyor reviewed blood bank quality control testing records from 08/01/17 through 03/28/19 and identified changes had been made on the records using correction tape. Examples follow: (a) 08/03/17: (i) Reagent Red Blood A1 Cells (Used for patient reverse ABO typing): Correction of the lot number and expiration date had been made with correction tape and lot # "A006", Expiration date "2017-8-15" had been written over it. (ii) Reagent Anti D Control (Used for patient Rh typing): Correction of the lot number and expiration date had been made with correction tape and lot # "RH 1860", Expiration date "2017-10-17" had been written over it. (b) 09/07/17: (i) Reagent Anti-Human Globulin (Used in patient antibody screening): Correction of the lot number and expiration date had been made with correction tape and lot # "RMG 467",

	Expiration date "03/23/19" had been written over it. (c) 10/13/17: (i) Reagent Red Blood A1 Cells: Correction of the lot number and expiration date had been made with correction tape and lot # "A025," Expiration date: "10-10-17" had been written over it. (d) 03/04/18: (i) Selectogen Cell I and Cell II Red Blood Cells (Used in Antibody Screen testing): Correction of the lot number and expiration date had been made with correction tape and lot # "S023", Expiration date: "03/06/18" had been written over it. (e) 09/05/18: (i) Reagent Anti-B serum (Used for ABO typing): Correction of the lot number and expiration date had been made with correction tape and lot # "BBB806A", Expiration date: "01/04/2020" had been written over it. (f) The quality control result for Reagent Anti-A serum had been corrected with correction tape and "4+" had been written over it. (3) The surveyor reviewed the findings with the laboratory supervisor and explained that in order to maintain accurate documentation, the use of correction tape was unacceptable.
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 laboratory supervisor, 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 techical 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 supervisor, the

	technical supervisor failed to ensure an individual who performed the duties and responsibilities of the technical supervisor, met the qualifications as required at 493.1449 of this subpart. Findings include: (1) On the first day of the survey, the surveyor reviewed the Laboratory Personnel Report (Form CMS-209), completed by the laboratory prior to the survey. The form listed the same individual as the laboratory director and the technical supervisor; (2) The surveyor then reviewed Immunohematology proficiency testing records for the Second and Third 2017 Events; and the First, Second, and Third 2018 Events. The documentation verified the attestation statements for 1 of the 5 events had been signed by the laboratory supervisor instead of the laboratory director/technical supervisor. (The technical consultant obtained a Bachelor of Science degree in Medical Technology); (3) The surveyor reviewed the findings with the laboratory supervisor, who stated to the surveyor the attestation statement for the Immunohematology event listed above, had been signed by the laboratory supervisor who did not meet the educational qualifications of a technical supervisor.