Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0367948	01/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Quasar Laboratory	20331 Farmington Road, Livonia, MI	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory director and/or testing personnel failed to attest to the routine integration of the non-chemistry (hematology) proficiency testing samples into the patient workload for three (event #2 and #3 of 2016, event #1 of 2017) of six events in 2016 and 2017. Findings include: 1. On January 18, 2018 at 12:20 p.m., record review of the American Association of Bioanalysts (AAB) final graded proficiency testing reports revealed the laboratory director and testing personnel did not sign the attestation statement sheets as follows: a. 2016 - 2nd event b. 2016 - 3rd event c. 2017 - 1st event 2. During the interview on January 18, 2018 at 12:20 p.m., testing personnel #1 as listed on the CMS-209 confirmed the laboratory did not attest to the routine integration of the testing samples into the patient workload.
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 record review and interview, the laboratory failed to ensure written

	competency policies were established and implemented for three (testing personnel #2, #5, and #6) of six testing personnel. Findings include: 1. On January 18, 2018 at 9: 38 a.m., record review of the annual competency revealed there was no documentation as follows: a. testing personnel #2 - no annual competency for 2016, and 2017 b. testing personnel #5 - no six month competency for 2017 c. testing personnel #6 - no six month competency for 2017 2. During the interview on January 18, 2018 at 9:38 a.m., testing personnel #1 confirmed the annual competency was not completed as required in 2016 and 2017. ***Repeat Deficiency from February 4, 2016 survey***
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to document and take corrective action when the Complete Blood Count (CBC) room temperature room was out of the acceptable range for 103 days during the year 2017. Findings include: 1. Chart review of "Room Temperature Chart 2017" performed on January 18, 2018 at 11:56 a.m., revealed the room temperature acceptable range listed on the chart was 20 - 25 C (68 -77 F). No corrective action was documented for when the room was out of range on the following days (a total of 103): a. January 2, 5, 9, 12, 16, 19, 20, 27 b. February 6, 14 c. March 3, 9, 20, 23, 31 d. April 21, 28 e. May 5, 8-9, 11-12, 23, 30 f. June 6, 9, 12, 19, 27, 29-30 g. July 3, 7, 10-11, 14, 16-17, 21, 27-28 h. August 1, 8, 10-11, 14-15, 17-18, 21-23, 28-29 i. September 8, 11-12, 14-15, 18-19, 21-22, 25-26, 28-29 j. October 3, 9-10, 12-13, 16-17, 19-20, 23-24, 26-27, 30-31 k. November 10, 13-14, 16-17, 20-21, 27- 28 l. December 8, 11, 12, 14-15, 18-22, 27-28 2. During the interview on January 18, 2018 at 2:46 p.m., testing personnel #1 confirmed that no corrective action was taken or documented when the room temperature was out of range.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: . Based on document review and interview, the laboratory failed to establish a system to ensure the chemistry tests [Vitamin D, B12, Folic Acid, Testosterone, Cholesterol, Triglycerides, High Density Lipoprotein] values that were reported using calculations were accurately sent from point of entry to the final report for accuracy during the twelve months (January to December) of twelve months of patient testing in 2017. Findings include: 1. On January 18, 2018 at 10:50 a.m., during a review of the procedure "Calculations Check" revealed "any calculations for patient results that are being performed by a machine or computer, are to be rechecked manually every 6 months. This must be done on a minimum of 10 patients". 2. On January 18, 2018, at 10:50 a.m., when queried, testing personnel #1 as listed on the CMS-209 was not able to provide the surveyor documentation that the calculations were checked for accuracy on all seven tests listed. 3. During the interview on January 18, 2018 at 10: 50 a.m., the testing personnel #1 confirmed the calculations were not checked for accuracy.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to provide the educational requirements for one (#6) of six testing personnel who perform moderately complex hematology testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to ensure that all testing personnel met the educational requirements at 493.1423 for one (#5) of five testing personnel as listed on the CMS-209. Findings include: 1. On January 18, 2018 at 9:15 a.m., record review revealed no documentation of the educational requirements for performing moderately complex laboratory testing for testing personnel #5. 2. During the interview on January 18, 2018 at 9:15 a.m., the technical consultant as listed on

	the CMS-209 confirmed there was no documentation of the educational requirements. 3. The laboratory was given five additional days to supply the necessary educational documents. The documents were not received.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: . Based on observation by the surveyor and interview with testing personnel #1 as listed on the CMS-209, the director failed to provide a safe environment in which employees are protected from biological hazards. Findings include: 1. On January 18, 2018 at 9:58 a.m., during a tour, the surveyor noted food stored in the refrigerator used to store the CBC reagents and refrigerated medications/vaccines: a sandwich and a cucumber. 2. On January 18, 2018 at 9:58 a.m., testing personnel #1 confirmed that the food was not being stored away from potential hazards.