Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2111243	01/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Tweb Resources Llc	7826 E Evans Rd, Scottsdale, AZ	

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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of five out of five test requisitions and interview with the testing personnel (TP-1), the laboratory's test requisition failed to include the name of the authorized individual requesting the test. Findings include: 1. The laboratory utilizes the Tosoh AIA-360 instrument to perform patient testing under the subspecialty of Endocrinology with an annual test volume of 900. 2. The laboratory failed to indicate the authorized individual who requested the test(s) on the following test requisitions: Donor# 37168 collected on 02/20/23, Donor# 14203 collected on 10/3/22, Donor# 105508 collected on 5/16/23, Donor# 99737 collected on 7/18/23, and Donor# 37094 collected on 1/8/24. 3. At the time of the survey, it could not be determined how many test requisitions were missing the name of the authorized individual who ordered the

	test(s). 4. The TP-1 interviewed on 1/11/24 at 10:45 AM acknowledged the laboratory's test requisition failed to identify the authorized individual who ordered the tests for the patients indicated above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of established humidity criteria defined by the laboratory, review of the manufacturer's specifications for the Tosoh AIA-360 analyzer, and interview with the testing personnel (TP-1), the laboratory failed to define criteria for the humidity of the area where the Tosoh AIA-360 is utilized. Findings include: 1. The laboratory utilizes the Tosoh AIA-360 instrument to perform patient testing under the subspecialty of Endocrinology with an annual test volume of 900. 2. The laboratory began patient testing using the Tosoh AIA-360 analyzer in August 2021. 3. The manufacturer's specifications for the Tosoh AIA-360 reviewed during the survey listed an operating relative humidity range of 40% - 80%. 4. The laboratory failed to 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, including the humidity of the room where patient testing is performed. 5. The laboratory failed to monitor and document the humidity of the area where patient testing was performed each day of patient testing from August 2021 through the date of the survey, January 11, 2024. 6. The TP-1 interviewed on 1/11/24 at 10:39 AM confirmed the laboratory failed to define the humidity criteria for the area where the Tosoh AIA-360 is utilized.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The Condition of Laboratory Director was found to be not met based on: D6003- failure to have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart; and D6029 - failure to ensure testing personnel are properly trained prior to testing patients' specimens.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory

personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(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 (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, 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 (b)(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 (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) 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; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral

	pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on lack of a qualified laboratory director at the time of the survey conducted on 01/11/2024 and interview with the testing personnel (TP-1), the laboratory failed assign a qualified laboratory director to manage and direct the laboratory personnel and the performance of moderate complexity tests. Findings include: 1. During the onsite survey conducted on 01/11/2024, it was determined that the laboratory director listed in the CMS database for CLIA# 03D2111243 at the time of the survey was no longer affiliated with the laboratory since September 2023. 2. The laboratory failed to provide notification of a change in laboratory director within 30 days of the change, as required under C.F.R.493.51(a)(4). 3. The TP-1 interviewed on 01/11/2024 at 9:40 AM confirmed the laboratory failed to provide notification of a laboratory director change within 30 days of the change, and failed to have qualified laboratory director from October 2023 through the date of the onsite survey.
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 lack of initial training documentation for one out of one testing personnel (TP-2) and interview with the testing personnel (TP-1), the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered. Findings include: 1. No initial training documentation was presented for review for one out of one testing personnel (TP-2). 2. The TP-1 interviewed on 1/11/24 at 9:50 AM confirmed the laboratory failed to provide documentation of initial training for TP-2 as indicated above. 3. The laboratory performs 900 patient tests annually under the subspecialty of Endocrinology.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of competency records for three out of three testing personnel and interview with the testing personnel (TP-1), the procedures for evaluation of the competency of the staff failed to include the direct observations of routine patient test performance including patient preparation, if applicable, specimen handling, processing and testing. 1. Review of semiannual and annual competency records from 2022 and 2023 for three out of three testing personnel failed to include the direct observations of routine patient test performance including patient preparation, if applicable, specimen handling, processing and testing. 2. The TP-1 interviewed on 1 /11/24 at 9:55 AM confirmed the procedures for the evaluation of competency of testing personnel failed to include direct observations of routine patient test performance including patient preparation, if applicable, specimen handling, processing and testing.
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on review of personnel competency records for three out of three testing personnel and interview with the testing personnel (TP-1), the procedures for evaluation of the competency of the staff failed to include monitoring the recording and reporting of test results. Findings include: 1. Review of semiannual and annual competency records from 2022 and 2023 for three out of three testing personnel failed to include monitoring the recording and reporting of test results. 2. The TP-1

	interviewed on 1/11/24 at 9:55 AM confirmed the procedures for the evaluation of competency of testing personnel failed to include monitoring the recording and reporting of test results.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of personnel competency records for three out of three testing personnel and interview with the testing personnel (TP-1), the procedures for evaluation of the competency of the staff failed to include the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. Findings include: 1. Review of semiannual and annual competency records from 2022 and 2023 for three out of three testing personnel failed to include the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. 2. The TP-1 interviewed on 1/11/24 at 9:55 AM confirmed the procedures for the evaluation of competency of testing personnel failed to include the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of competency records for three out of three testing personnel and interview with the testing personnel (TP-1), the procedures for evaluation of the competency of the staff failed to include direct observation of performance of instrument maintenance and function checks. Findings include: 1. Review of semiannual and annual competency records from 2022 and 2023 for three out of three testing personnel failed to include an assessment of test performance through direct observation of performance of instrument maintenance and function checks. 2. The TP-1 interviewed on 1/11/24 at 9:35 AM confirmed the procedures for the evaluation of competency of testing personnel failed to include an assessment of test performance through direct observation of performance of instrument maintenance and function checks.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

	This STANDARD is not met as evidenced by: Based on review of competency records for three out of three testing personnel and interview with the testing personnel (TP-1), the procedures for evaluation of the competency of the staff failed to include the assessment of test performance through testing external proficiency testing samples. Findings include: 1. Review of semiannual and annual competency records from 2022 and 2023 for three out of three testing personnel failed to include an assessment of test performance through testing external proficiency testing samples. 2. The TP-1 interviewed on 1/11/24 at 9:55 AM confirmed the procedures for the evaluation of competency of testing personnel failed to include an assessment of test performance through testing external proficiency testing samples.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of competency records for three out of three testing personnel and interview with the testing personnel (TP-1), the procedures for evaluation of the competency of the staff failed to include the assessment of problem solving skills. Findings include: 1. Review of semiannual and annual competency records from 2022 and 2023 for three out of three testing personnel failed to include the assessment of problem solving skills. 2. The TP-1 interviewed on 1/11/24 at 9:55 AM confirmed the procedures for the evaluation of competency of testing personnel failed to include the assessment of problem solving skills.
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 lack of performance evaluation documentation and interview with the testing personnel (TP-1), the technical consultant failed to evaluate and document the performance of two out of two testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for two out of two testing personnel. 2. The TP-1 interviewed on 1/11/24 at 10:05 AM confirmed the technical consultant failed to perform and document a semiannual competency evaluation for the two testing personnel indicated above. 3. The laboratory performs 900 patient tests annually under the subspecialty of Endocrinology.
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 review of personnel records and interview with the testing personnel (TP-1), the laboratory failed to provide evidence of academic credentials required to qualify one out of four testing personnel for moderate complexity testing under the subspecialty of Endocrinology. See D6065 for findings.
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 review of personnel records and interview with testing personnel (TP-1), the laboratory failed to provide evidence of academic credentials to qualify one out of four testing personnel (TP-4) for moderate complexity testing. Findings include: 1. The laboratory failed to provide evidence of academic credentials to qualify TP-4 for moderate complexity testing under the subspecialty of Endocrinology. 2. Interview with the TP-1 on 1/11/24 at 9:50 AM confirmed the laboratory failed to provide evidence of academic credentials to qualify TP-4 for moderate complexity testing. 3. The laboratory performs 900 patient tests annually under the subspecialty of Endocrinology.