Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2003235	05/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Taddy Healthcare Services Llc	615 W Mermod St, Carlsbad, NM	

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 New Mexico Department of Health completed a onsite survey on 4/06/2018. Based on survey findings the facility was not in compliance for 42 CFR 493, Laboratory Requirements. The laboratory was out of compliance with the following conditions: 42 CFR Part 493.1403 Laboratory Director, moderate complexity 42 CFR Part 493.1409 Technical Consultant 42 CFR Part 493.1771 Inspection Requirements
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of validation studies, manufacturer instructions, emails, laboratory policy and interview with laboratory staff, the laboratory failed to complete the validation studies for all analyzers used in the laboratory. Findings are: 1. Review of the TOSOH AIA 360 validation studies revealed no documentation of inter-assay (total) precision studies. The only study performed was a simple precision study dated 05/25/2016. The laboratory reported performing 498 TSH, 498 Free T3 and 498 Free T4 assays 06/01/2017-04/02/2018. 2. Review of the validation studies for the Pentra 400 revealed that the laboratory failed to perform the inter-assay precision studies. a. The analyzer was installed in the laboratory on 08/02/2016 and intra-assay (within run) studies were performed by "tech." The laboratory director signed the 08/02/2016 worklist on 5/31/2017. b. The laboratory performed a calibration verification study on 08/03/2016 which was not submitted to the calibration verification company for

	analysis until May 2017. c. The testing person stated on 04/03/2018 at 3:00 pm that she had performed the testing on 08/02/2016 and continued to run the daily quality control until the analyzer was replaced by the AU 400. No documentation was found indicating the laboratory had used the quality control data 08/02/2016 - 03/2018 for the inter-assay precision studies. d. The technical consultant confirmed this finding on 04/04/2018 at 7:35 am. 3. Review of the validation studies for the Horiba Micros 60 hematology analyzer revealed no documentation of evaluation of the data. The only documents were printouts from the quality control files that indicated the statistics for the lot. This document was signed by the laboratory director on 05/21/2017. The laboratory reported performing 628 CBC or Complete Blood Cell counts 06/01/2017-04/01/2018. 4. Review of the validation studies for the Horiba Micros 60 hematology analyzer revealed no verification of reference ranges for male or female, only the general adult population. The testing person confirmed on 04/05/2018 that the laboratory served only the adult population, not pediatric patients. The laboratory used a reference range from Mosby's Manual of Diagnostic and Laboratory Tests, 2nd edition. 5. The technical consultant stated on 04/03/2018 at 10:00 am that there was no written validation plan for the new AU 400 chemistry analyzer that will be used for general chemistry and toxicology. She also stated that the studies for toxicology were going to be repeated. Review of the toxicology validation studies revealed the following: a. The laboratory completed the first validation studies of the AU 400 in March 2018. b. The laboratory failed to include positive samples for 6 of 9 analytes in the correlation study with the Pentra 400 chemistry analyzer used to establish accuracy.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview with the testing person and the review of 2017-2018 quality control and patient records, the laboratory failed to have an effective quality control policy. Findings are: 1. Review of 2017 quality control records revealed the laboratory failed to perform at least 2 acceptable levels of quality controls each day prior to patient testing. a. On 06/05/2017 at 9:09 am, the laboratory ran 1 level of quality control for T3 on the TOSOH AIA 360. The second level of control material was not tested until 3:53 pm but one patient, P1 had been tested and reported at 2:17 pm. b. On 06/15/2017, only 1 level of quality control was tested on the Pentra 400 chemistry analyzer. 6 patients, P2-P7 were tested. Review of the P2's medical record confirmed that the test results were reported on 06/15/2017. 2. Review of 2017-2018 Micros 60 hematology quality control monthly summaries had no documentation of repeat testing of quality control materials. a. Interview with the testing person on 04/04/2018 at 2:30 pm revealed that the LIS (Laboratory Information System) used by the laboratory did not allow her to save multiple quality control results for the same date. She also stated that she did retain all of the quality control printouts for each day.

	However, the quality control reviews were conducted using the LIS, not the daily printouts.
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: Based on the review of validation studies, quality control and patient records, manufacturer instructions, emails, laboratory policy and interview with laboratory staff, the laboratory director failed to provide overall direction and management of the laboratory. Findings are 1. The laboratory director failed to ensure the technical consultant met the education requirement for technical consultant. See D6004 A 2. The laboratory director failed to ensure that the responsibilities delegated to the technical consultant were performed and met regulatory requirements. See D6004 B
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of validation studies, quality control and patient records, manufacturer instructions, emails, laboratory policy and interview with laboratory staff, the laboratory director failed to A) employ a qualified technical consultant and B) ensure that the responsibilities delegated to the technical consultant were performed and met regulatory requirements. Findings are: A. The laboratory director failed to ensure the technical consultant met the education requirement for technical consultant. 1. No documentation was provided by the technical consultant or the laboratory that indicated the technical consultant had earned a Bachelor degree in chemical, physical, biological, or clinical laboratory science. See D6035 B. The laboratory director failed to ensure the technical consultant responsibilities were performed and met regulatory requirements. 1. The laboratory failed to complete the validation studies for all analyzers used in the laboratory. See D5421 2. The laboratory failed to have an effective quality control policy. See D5445
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification

	requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the review of validation studies, manufacturer instructions, emails, laboratory policy, personnel records and interview with laboratory staff, the technical consultant failed to: (A) meet the educational requirements for technical consultant and (B) provide technical oversight of the laboratory. Findings are: A. The technical consultant did not have a Bachelor degree in Science that met the education requirement for technical consultant. See D6035 B. The laboratory failed to perform all required studies for test systems introduced into the laboratory. See D6040 1. The laboratory failed to perform inter-assay (between run or total) precision studies for the TOSOH AIA 360 immunoassay analyzer and the Pentra 400 chemistry analyzer. 2. The laboratory failed to evaluate the validation data for acceptability on the Horiba Micros 60. 3. The laboratory failed to verify reference ranges for male and female hematology reference ranges. 4. The laboratory failed to have a written validation plan for the AU 400 chemistry analyzer resulting in an invalid study that had to be repeated. 5. Review of an email from the technical consultant revealed a total of 3 technical consultants working with the laboratory since August 2016.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant 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 at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant 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, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be

	qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on the review of personnel records, the laboratory failed to employ a qualified technical consultant. Findings are: 1. Review of the academic transcripts and diplomas provided by the technical consultant revealed the following: a. Transcript #1, issued on 09/29/2017, indicated the technical consultant earned an Associate of Applied Science (Medical Lab Technology) in May 2003. b. Transcript #2, issued on 02/18 /2011, indicated the technical consultant earned a Bachelor of Applied Arts and Sciences in May of 2010. The "Plan" was listed as Applied Arts and Sciences and the "Sub-Plan" was Psychology. Only 1 science course, Comparative Anatomy for 3.0 hours, was on this transcript. 2. No documentation was provided by the technical consultant or the laboratory that indicated the technical consultant had earned a Bachelor degree in chemical, physical, biological, or clinical laboratory science.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on the review of validation studies, manufacturer instructions, emails, laboratory policy and interview with laboratory staff, the technical consultant failed to provide technical oversight of the laboratory. Findings are: The laboratory failed to perform all required studies for test systems introduced into the laboratory. 1. The laboratory failed to perform inter-assay (between run or total) precision studies for the TOSOH AIA 360 immunoassay analyzer and the Pentra 400 chemistry analyzer. See D5421 - 1 and 2 2. The laboratory failed to evaluate the validation data for acceptability on the Horiba Micros 60. See D5421 - 3 3. The laboratory failed to verify reference ranges for male and female hematology reference ranges. See D5421 - 4 4. The laboratory failed to have a written validation plan for the AU 400 chemistry analyzer resulting in an invalid study that had to be repeated. See D5421 - 4 Review of the toxicology validation studies revealed the following: a. The laboratory completed the first validation studies of the AU 400 in March 2018. b. The laboratory failed to include positive samples for 6 of 9 analytes in the correlation study with the Pentra 400 chemistry analyzer used to establish accuracy.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by:

	Based on interview with the testing person, the review of 2017-2018 quality control and patient records, the technical consultant failed to establish an effective quality control program. Findings are: The laboratory failed to have an effective quality control policy. See D5445
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on the review of emails from laboratory staff, 2016 application packet, invoices, patient reports, and interviews with laboratory staff, the laboratory the laboratory and the contracted laboratory operator failed to provide a complete copy of a current contract between the owner and the operator of the laboratory. See D8103
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on the review of emails from laboratory staff, 2016 application packet, invoices, patient reports, and interviews with laboratory staff, the laboratory and the contracted laboratory operator failed to provide a complete copy of a current contract between the owner and the operator of the laboratory. Findings are: 1. On 04/03/2018, the technical consultant was asked for the contract between the owner of the practice and the contracted laboratory operator. The technical consultant stated on 04/05/2018 at 3:00 pm that she did not have access to that document and gave the name and contact information of the laboratory director of the out-of-state contract laboratory. Later the same day, the technical consultant provided a copy of a 7 page Equipment Lease and Management Agreement dated 12/28/2015 that she had found in the office manager's records. This document was not signed by the laboratory operator. a.

	Review of this document revealed that it had not been revised since the initial CLIA application in June 2016 to reflect the changes in the laboratory test menu in 2017. The original test menu included high complexity toxicology testing but the laboratory had removed toxicology from the final approved CLIA application. b. Review of this document also indicated the contracted laboratory operator provided the equipment, electronic health records system, laboratory information system, reagents and testing supplies. The contracted laboratory operator also provided the personnel for operating the laboratory. 2. On 04/21/2018, the laboratory director of the out-of-state contract laboratory (laboratory operator) provided an unsigned copy of a document titled "Consulting Agreement". A signed contract was finally submitted on 04/21/2018 but there were no exhibits, schedules and/or attachments. On 04/30/2018, a fourth (4th) request for a current, signed, agreement/contract was sent via email to the laboratory director of the out-of-state contract laboratory. As of 05/30/2018, no additional documentation has been submitted to the state agency. a. Review of the Consulting Agreement dated 1/31/2017 revealed that the contract laboratory operator provided the following services: "Laboratory design, set up and installation Licensing, technical consulting and management consulting services Staff location and recruiting services, including finding laboratory directors, technicians and technologists for possible employment by Customer if needed." b. The contract term was 1 year after the laboratory became "licensed." 3. Interview with the technical statement on 4/05/2018 at 3:55 pm revealed that the technical consultant was authorized to hire staff for the laboratory. 4. Interview with the testing person on 04/05/2018 revealed that she had direct access to the out-of-state laboratory's LIS (laboratory information system) and could report out patient results on that laboratory's letterhead. 2 of 6 test reports used for the LIS validation study in August 2017 had the letterhead of the out-of-state laboratory. The testing person confirmed that she had performed the testing but used the wrong code and the reports were printed using the wrong letterhead. 5. Review of 2016-2018 shipping invoices identified either the laboratory operator as the client or both the owner and the operator for 7 of 8 invoices.