Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0085288	08/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
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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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of analytes that were given passing scores but were not evaluated by the proficiency testing company for 5 of 5 proficiency testing events in 2018 and 2019. Findings include: 1) Review on 8/6/19 of proficiency testing results for the 2018 A event revealed the result for 1 allergen (box elder) was not evaluated by the proficiency testing company. 2) Review on 8/6/19 of proficiency testing results for the 2018 B event revealed the results for 6 allergens (aspergillus, box elder, ragweed, plantain, oak, and soybean) were not evaluated by the proficiency testing company. 3) Review on 8/6/19 of proficiency testing results for the 2018 C event revealed the results for 9 allergens (aspergillus, beech, chicken, cladosporum, ragweed, penicillium, perennial rye, russian thistle, and yeast) were not evaluated by the proficiency testing company. 4) Review on 8/6/19 of proficiency testing results for the 2019 A event revealed the results for 5 allergens (porks, russian thistle, ragweed, perennial rye, and coachroach mix) were not evaluated by the proficiency testing company. 5) Review on 8/6/19 of proficiency testing results for the 2019 B event revealed the results for 4 allergens (egg white, russian thistle, ragweed, and perennal rye) were not evaluated by the proficiency testing company. 6) Interview on 8/6/19 at 8:40 a.m. with Technical Consultant (TC) revealed that the laboratory did not have a mechanism for review of results that were not evaluated by the proficiency testing company. 7) The laboratory performed approximately 1700 allergens annually on the Hitachi CLA-1.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of 3 of 36 allergen analytes at least twice annually in 2018. Findings include: 1) Review on 8/6/19 of proficiency testing records for 2018 and 2019 revealed that the laboratory does not participate in proficiency testing for 3 of 36 allergens (codfish, mugwort, and cheddar cheese) in their allergen panel. 2) Interview on 8/6/19 at 8:40 a.m. with the Technical Consultant (TC) confirmed that the laboratory did not cover all the allergens in their testing panel with proficiency testing. The TC revealed that the laboratory did not do split sample testing or another method to demonstrate the laboratory's accuracy for the above allergens. 3) The laboratory performed approximately 35 patients annually on the Hitachi CLA-1.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to meet analytic system requirements for nonwaived chemistry and general immunology testing in 2018 and 2019. Findings include: 1) The laboratory failed to verify the manufacturer's performance specifications before implementing a modified allergen panel. Refer to tag D5421. 2) The laboratory's calibration verification procedures failed to verify reportable ranges for chemistry testing. Refer to tag D5439. 3) The laboratory failed to test general immunology procedures with a graded control material for 1 of 36 allergen antigens. Refer to tag D5451 4) The laboratory failed to verify the manufacturer's assayed ranges for control materials used for chemistry testing. Refer to tag D5469. 5) The laboratory failed to ensure results for general immunology control material met the manufacturer's acceptable criteria prior to reporting patient results. Refer to tag D5481.
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 record review and interview, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer when introducing a modified genreal immunology allergen panel in June of 2018. Findings include: 1) Review on 8/6/19 of patient test results for allergen testing revealed that the allergens on the panel the laboratory was using changed in June of 2018. 2) Interview on 8/6/19 at 9:45 a.m. with the Technical Consultant (TC) confirmed the above findings. The TC revealed that several allergens on the panel changed, the incubation time went from 24 hours to 4 hours, the amount of sample changed, and the color of the reagent changed. The TC also revealed the laboratory did not validate the performance specifications when they introduced the new panel but the manufacturer did run the internal control and a positive and negative control. 3) The laboratory performed approximately 1700 allergens annually on the Hitachi CLA-1.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibration verification procedures covering the span of the reportable ranges for routine chemistry testing in 2019. Findings include: 1) Upon requesting the procedure for the laboratory's reportable ranges, the Technical Consultant (TC) provided the package inserts for each of the analytes. Review on 8/6/2019 of the package inserts for 7 analytes below revealed the laboratory's reportable ranges were as follows: direct bilirubin (dBili), 0.1-14.0 mg/dL; total bilirubin (tBili), 0.2-40.0 mg/dL; carbon dioxide (CO2), 4.0-50.0 mEq/L; total cholesterol (Chol), 6-600 mg/dL; total iron (iron), 12-600 ug/dL total protein (tProt), 0.4-14.0 g/dL; triglycerides (Trig), 16-1000 mg/dL. 2) Review on 8/6/2019 of the laboratory's linearity studies performed in May

	2019 revealed the laboratory failed to verify the reportable ranges for 7 of 24 analytes performed on the ACE AXCEL instrument. The linearity studies verified the following ranges (based on peer means or manufacturer limit): dBili, 0.4 - 10.4 mg /dL; tBili, 0.5-31.0 mg/dL; CO2, 5.9-37.5 mEq/L; Chol, 16-430 mg/dL; iron, 29-600 ug/dL; tProt, 1.5-9.5 g/dL; Trig, 28-814 mg/dL. 3) Interview on 8/6/2019 at 12:00 p. m. with the TC confirmed the reportable ranges in use by the laboratory are those listed in the package inserts. The TC confirmed linearity studies did not cover the full reportable ranges for all analytes and that the reportable ranges were not adjusted based on the ranges verified in the linearity studies.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to test general immunology procedures with a graded control material for 1 of 36 allergen antigens. Findings include: 1) Review on 8/6/19 of the manufacturer's instucetion for the Hitachi CLA- 1 quality controls revealed that the positive control did not contain maple box elder allergen analyte. 2) Interview on 8/6/19 at approximately 1:00 p.m. with the Technical Consultant confirmed the above finding. The TC revealed the laboratory did not have a control for the above analyte. 3) The laboratory performed approximately 35 patients annually on the Hitachi CLA-1.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to verify the manufacturer's assayed ranges for chemistry control material prior to putting the current lot into use. Findings include: 1) Observation on 8/6/2019 at 10:15 a.m. of control material for analytes tested on the Beckman Access 2 instrument revealed the

	current lot number of control material used for ferritin, folate, prostate specific antigen (PSA), thyroid stimulating hormone (TSH), total thyroxine (T4), testosterone, and vitamin B12 was 40343 with expiration date 11/30/19; and the control material used for vitamin D was 60260 with an expiration date of 8/31/21. 2) Review on 8/6/2019 of the package inserts for the control material listed above revealed the manufacturer provided assayed ranges. 3) The laboratory could not provide documentation that it had verified the manufacturer's ranges prior to implementing the current lot numbers of control material used for the analytes on the Beckman Access 2 instrument. 4) Interview on 8/6/2019 at 10:40 a.m. with the Technical Consultant (TC) revealed the laboratory has never verified the manufacturer's assayed ranges for the control materials used for the analytes tested on the Beckman Access 2 instrument since she began working for the laboratory in 2015. The TC could not provide documentation when the current lot numbers had been put into use.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure that the results of general immunology control material met the manufacturer's test system criteria for acceptability before reporting patient test results. Findings include: 1) Review on 8/6 /19 of the manufacturer's instructions for the control reagent kit for the Hitachi CLA-1 revealed the following instructions: "Individual laboratory means should fall within the expected range for each allergen, however each laboratory should establish its own mean values and acceptable ranges using the ranges provided as guides." 2) Review on 8/6/19 of quality control results and manufacturer's defined expected ranges for the Hitachi CLA-1 from 10/3/18 to present revealed the following positive controls run on days of patient testing had results that were outside of the manufacturer's acceptable range: 10/4/18 white birch 10/18/18 cheddar cheese, ragweed 12/11/18 white birch, ragweed 2/7/19 penicillium 2/28/19 penicillium 3/8/19 penicillium 4/24/19 penicillium 7/24/19 cheddar cheese, white birch, white elm, ragweed, and alternaria 3) Review on 8/6/19 of patient test results on the above days revealed that the laboratory ran and reported 1 to 2 patients results each day and run approximately 35 patients annually. 4) Interview on 8/6/19 at approximately 1:00 p.m. with the Technical Consultant (TC) confirmed the above findings. The TC revealed that the laboratory used the manufacturer's ranges expected ranges and accepted the positive control if 80% of the allergens fell within the expected range. 5) The laboratory performed approximately 1700 allergens annually on the Hitachi CLA-1.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to only report patient chemistry results within the laboratory's established reportable range for 2 of 3 patient's reviewed for triglycerides (Patient identification #19303 and #TW991954GP) Findings include: 1) Review on 8/6/19 of the laboratory's linearity performed on 5/14/19 for triglycerides revealed that the laboratory verified the reportable range for triglycerides as 28-814 mg/dL (milligrams per deciliter) 2) Review on 8/6/19 of patient reports revealed that a result of 917 mg/dL was reported for Patient #19303 and a result of 850 mg/dL was reported for Patient TW991954GP. Review of instrument reports for these patients revealed that the samples were not diluted. 3) Interview on 8/6/19 at approximately 11:30 a.m. with the Technical Consultant (TC) confirmed the above findings. The TC revealed the laboratory did not change their reportable ranges when they performed linearity studies and they used the manufacturer's upper range of 1000 mg/dL for triglycerides. 4) The laboratory did an annual test volume of 5,153 triglycerides.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish a procedure for ongoing monitoring of corrected reports to identify and correct problems in the postanalytic system. Findings include: 1) Review on 8/6/19 of the laboratory's changed results report for 7/1/19 to 8/1/19 revealed results for a complete blood count (CBC) were reported for accession #150656 on 7/8/19 at 10:16 a.m. and then repeated and reported on 7/11/19 at 4:48 p.m. The patient's medical record contained the results from 7/11/19. 2) Review of 8/6/19 of the laboratory's changed results report for 7/1/19 to 8/1/19 revealed results for a complete blood count (CBC) were reported for accession #150819 on 7/10/19 at 4:49 p.m. and then repeated and reported on 7/11/19 at 4:01 p.m. 3) Interview on 8/6/19 at approximately 1:00 p.m. with the Technical Consultant (TC) confirmed the above findings. The TC revealed that the TC did not monitor corrected or changed reports as part of their quality assurance and was not aware of any corrected or changed results. The TC revealed that CBC testing is performed within 24 hours of collection and could not explain why accession #150656 was repeated 3 days later and the results changed.