Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2177406	09/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Exacta Laboratory Systems	2400 E Kiehl Ave, Sherwood, AR	

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
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: Through observation, manufacturer's instrument instructions, review of lab environmental records for 2021 and 2022, and interview, it was determined that the room humidity, as required for the Cobas e-801 chemistry analyzer, the Sysmex XN-550 hematology analyzer, and the MiniSed erythrocyte sedimentation rate instrument had not been monitored in 21 of 21 months in 2021 and 2022. Survey findings include: A) During an initial tour of the laboratory at 9:13 a.m. on 9/14/2022 the Cobas e-801 chemistry analyzer, the Sysmex XN-550 hematology analyzer, and the MiniSed erythrocyte sedimentation rate instrument were observed in the main laboratory room. B) Review of manufacturer's instrument instructions revealed an operating humidity range of 30% to 85% for the Cobas e-801, 20% to 85% for the Sysmex XN-550 and 15% to 85% for the MiniSed. C) Review of lab environmental records for 2021 and 2022 revealed that the room humidity had not been documented in 21 of 21 months reviewed. D) In an interview during the initial tour of the laboratory (9:13 a.m. on 9/14/2022), employee #2, as listed on the CMS-209, stated that laboratory humidity is not monitored.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory and interviews with laboratory staff, it was determined the laboratory had Total PSA CalCheck and Vitamin B12 CalCheck available for use when it had exceeded it's expiration date. Survey findings include: A. During a tour of the laboratory at 2:33 p.m. on 9/14/2022, the surveyor observed one package of Total PSA CalCheck (lot # 45624101 expiration 6/30/2021) and one package of Vitamin B12 CalCheck (lot # 44019102 expiration 8/31/2022) in Refrigerator #2 in the main room of the laboratory. B. In an interview, at 2:33 p.m. on 9/14/2022, laboratory employee #2 (as listed on the form CMS-209), confirmed the expired CalCheck and stated that the expired CalChecks could be used for troubleshooting of the Cobas test system.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the Individualized Quality Control Plans (IQCP) for the microbiological media, and the IQCP for Meridian Revogene Clostridium difficile test system, and through interviews with laboratory staff, it was determined the laboratory failed to establish the number and type of control materials used for all test methods. Survey findings follow: A. A review of the IQCP binder revealed the laboratory had developed IQCP for the microbiological media and Meridian Revogene Clostridium difficile tests. During the review it was determined the Quality Control Plan failed to state the number and frequency of controls to be run or the specific type of control which would be used in two of two IQCP reviewed. B. In an interview at 2:20 on 9/14 /2022, laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of specific type of control, number of controls and frequency of control in two of two Quality Control Plans reviewed.
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: . Through a review of the CMS-116, ALCOR SEDITROL package insert, Quality Control (QC) records, as well as interviews with laboratory staff, it was determined the laboratory failed to establish the criteria for acceptability of Erythrocyte Sedimentation Rate (ESR) control. Survey Findings Follow: A. The laboratory utilizes ALCOR Scientific MiniSED automatic analyzer to perform ESR assay with an annual test volume of 609 assays. A review of package insert for ALCOR SEDITROL for automated Sedimentation Rate states: "It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as a guide." B. A review of ESR quality control data for January-May 2022 revealed the mean and acceptable range in five of five months reviewed matched the expected range as listed on the ALCOR SEDITROL package insert: January- May 2022 Lot # C139 (expiration date 07/25/2022) range (1-17 mm/hr) and Lot # C239 (expiration date 07/25/2022) range (37-89 mm/hr): C. The surveyor requested documentation of established ranges for ESR quality controls. None was provided. D. In an interview on 09/14/2022 at 1438 laboratory employee #2 (as listed on CMS-209) confirmed that the laboratory had not established their own mean and range for ESR quality controls. The laboratory uses the manufactures ranges for the ESR control.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through review of the laboratory policy and procedure "Reporting Quality Control Results", the Quality Control (QC) Log, notes of corrective action, patient result reports, and interviews with laboratory staff it was determined that the laboratory failed to evaluate patient results back to the last successful performance of QC, on eight of eight occasions in 3 months of operation when QC failed criteria for acceptability for glucose, aspartate aminotransferase (AST), digoxin (DIG), total triiodothyronine (T3 tot), and unsaturated iron binding capacity (UIBC) analyses and corrective action required changes to the analytic systems. Finding follow: A) Review of the laboratory policy and procedure (General Lab Procedures) revealed that action to be taken when QC fails criteria for acceptability included "If controls are out of

range, test results from the last acceptable test run must be re-evaluated to determine if there is any clinical difference in the results." B) Review of the QC log for November 2021 revealed that chemistry controls for glucose were flagged as unacceptable on 11/5/21 with a corrective action of "repeat QC" and were subsequently flagged as unacceptable on 11/5/21 10:10am with a corrective action of " recalibrated." The corrective action represented a change in the analytic system. The previous passing QC was on 11/4/21 at 9:22am. Review of the QC log for January 2022 revealed that chemistry controls for glucose were flagged as unacceptable on 11 /5/22 with a corrective action of "repeat QC" and were subsequently flagged as unacceptable on 1/17/22 11:53am with a corrective action of " recalibrated." The corrective action represented a change in the analytic system. The previous passing QC was on 1/14/22 at 10:10am. Review of the QC log for April 2022 revealed that chemistry controls for glucose were flagged as unacceptable on 4/4/22 with a corrective action of "repeat QC" and were subsequently flagged as unacceptable on 4/4 /22 12:52pm with a corrective action of " recalibrated." The corrective action represented a change in the analytic system. The previous passing QC was on 4/1/22 at 11:12am. Review of the QC log for January 2022 revealed that chemistry controls for AST were flagged as unacceptable on 1/27/22 with a corrective action of "repeat QC" and were subsequently flagged as unacceptable on 1/27/22 10:45pm with a corrective action of " recalibrated." The corrective action represented a change in the analytic system. The previous passing QC was on 1/26/22 at 10:00am. Review of the QC log for April 2022 revealed that chemistry controls for DIG were flagged as unacceptable on 4/5/22 with a corrective action of "repeat QC" and were subsequently flagged as unacceptable on 4/5/22 1:07pm with a corrective action of " recalibrated." The corrective action represented a change in the analytic system. The previous passing QC was on 4/4/22 at 11:09am. Review of the QC log for April 2022 revealed that chemistry controls for T3tot were flagged as unacceptable on 4/18/22 with a corrective action of "repeat QC" and were subsequently flagged as unacceptable on 4 /18/22 12:51pm with a corrective action of " recalibrated." The corrective action represented a change in the analytic system. The previous passing QC was on 4/14/22 at 9:56am. Review of the QC log for November 2021 revealed that chemistry controls for UIBC were flagged as unacceptable on 11/3/21 with a corrective action of "repeat QC" and were subsequently flagged as unacceptable on 11/3/21 8:28am with a corrective action of " recalibrated." The corrective action represented a change in the analytic system. The previous passing QC was on 11/2/21 at 8:24am. Review of the QC log for April 2022 revealed that chemistry controls for UIBC were flagged as unacceptable on 4/5/22 with a corrective action of "repeat QC" and were subsequently flagged as unacceptable on 4/5/22 1:04pm with a corrective action of " recalibrated." The corrective action represented a change in the analytic system. The previous passing QC was on 4/4/22 at 11:20am. C) Review of patient result reports revealed that glucose tests were performed and reported on 1 patient, identified as number 1 on a separate patient identification list, on 11/4/21. Review of patient result reports revealed that glucose tests were performed and reported on 1 patient, identified as number 3 on a separate patient identification list, on 1/14/22. Review of patient result reports revealed that glucose tests were performed and reported on 1 patient, identified as number 4 on a separate patient identification list, on 4/1/22. Review of patient result reports revealed that AST tests were performed and reported on 1 patient, identified as number 6 on a separate patient identification list, on 1/27/22. Review of patient result reports revealed that digoxin tests were performed and reported on 14 patients, identified as numbers 7a-7n on a separate patient identification list, on 4/4/22 and 4/5/22. Review of patient result reports revealed that T3tot tests were performed and reported on 1 patient, identified as number 8 on a separate patient identification list, on 4/14/22. Review of patient result reports

	revealed that UIBC tests were performed and reported on 1 patient, identified as number 9 on a separate patient identification list, on 11/3/22. Review of patient result reports revealed that UIBC tests were performed and reported on 6 patients, identified as number 10a-10f on a separate patient identification list, on 4/4/22 and 4/5/22 D) Upon request, the laboratory was unable to provide documentation that, in the event of an instrument recalibration, the patient results reported back to the last successful QC had been evaluated. E) In an interview on 9/14/22 at 1:55 PM the laboratory staff member, identified as number 4 on the CMS 209 form, confirmed that results were not reviewed to the previous passed QC in the event of instrument recalibration. In an interview on 9/14/22 at 2:50 PM the laboratory staff member, identified as number 2 on the CMS 209 form, confirmed that results were not reviewed to the previous passed QC in the event of instrument recalibration.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Through a review of personnel records for seven of seven laboratory testing personnel and interviews with laboratory staff, it was determined the laboratory director failed to give written authorization for seven of seven testing personnel to perform testing without direct supervision. Survey findings follow: A. A review of personnel records for seven randomly selected laboratory employees, who have completed training, revealed that seven of seven (#2, #3, #4, #6, #10, #12, and #14 as listed on the form CMS-209) failed to have the laboratory director's written authorization to perform any testing without supervision. B. In an interview, at 10:41 a.m. on 9/14/2022, laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of written authorizations for the seven employees reviewed.