Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0216863	11/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cd Laboratories, Inc	810 Gleneagles Ct Ste 100, Baltimore, MD	

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
D2026	BACTERIOLOGY CFR(s): 493.823(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) results and interview with the quality assurance manager, the laboratory did not investigate and correct problems associated with a PT failure. Findings: 1. The laboratory PT records for Q1 Gram Stain shows a score of 80%. The records showed that there was no documented investigation of the failure of the gram stain. 5. During the survey on 11/29/18 at 5:30 PM the quality assurance manager confirmed that there was no investigation of the PT failures.
D2116	TOXICOLOGY CFR(s): 493.845(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) results and interview with the quality assurance manager, the laboratory did not investigate and correct problems associated with a PT failure. Findings: 1. Review of the PT results for Q1 Chemistry 2018 showed that the laboratory did not investigate and correct problems associated with an unsatisfactory PT result. 2. The laboratory's PT records show a score of 100% for Entailing. Review of the actual results show that sample number 3 was recorded as 6.6 with an acceptable reference range of 7.5-12.6. Sample number 4 was recorded as 11 with an acceptable reference range of 3.5-5.8. 3. The laboratory's PT records show a score of 100% for Lithium. Review of the actual results show that sample number 4 was recorded as 2.1 with an acceptable reference range of 0.5-1.1. 4. The results were coded with a # sign. The # code lists the following comment- "This method was not graded due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed range should provide a reasonable guide to your performance. However, exercise caution in evaluating your results." 5. During the survey on 11/29/18 at 5:30 PM the quality assurance manager confirmed that there was no investigation of the PT failures.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: I. Based on quality control (QC) record review and interview with the laboratory staff, the laboratory did not retain chemistry QC records for at least 2 years. Findings: 1. A review of chemistry QC from July to November, 2018 showed that QC was rarely out of range. During an interview at 11:45 AM, the testing person stated that "QC is reviewed weekly" and that they "don't keep bad QC because it skews the averages." The testing person stated that they delete the out of range QC and only save the "good" QC. 2. The testing person stated that the DXI 600 chemistry analyzer does not print out the QC when run and that the analyzer does not save QC data older than 90 days. 3. During an interview on 11/29/18 at 11:45 AM, the laboratory staff confirmed that the laboratory did not retain chemistry QC records for at least 2 years. II. Based on quality control (QC) record review and interview with the laboratory staff, the laboratory did not retain urinalysis QC records for at least 2 years. Finding: 1. A review of urinalysis QC from January to October, 2018 showed that there was no out of range QC or corrective actions documented. 2. During an interview at 3:45 PM, the testing person stated that they "only write down good QC" even if the QC is out of range and a repeat is performed. They stated that they had had out of range QC but had not documented it.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD), the laboratory did not have a procedure manual for performing testing on the Unicel DxI 600 Access Immunoassay System. Findings: 1. Document review showed that on the day of the survey, the laboratory did not have an approved procedure manual for the operation of the Unicel DxI 600 Access Immunoassay System. 2. Laboratory staff downloaded and installed an electronic copy of the DXI 600 Access' operator's manual onto a shared laboratory drive prior to the end of the survey. 3. During an interview on 11/29/18 at 5:30 PM, the LD confirmed that a procedure manual was not available for the Unicel DxI 600 Access Immunoassay System at the time of the survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's procedure manual and interview with the laboratory manager, the laboratory's procedure manual did not include the identity of the abbreviations of the quality control (QC) organisms when documenting the QC results. Findings: 1. Review of the "Media QC" worksheets showed that the laboratory staff were using abbreviations when documenting the identity of the organisms being used for QC. 2. The procedure manual did not include a written key linking the abbreviation to the name of the organism being used. 3. During the survey on 11/29 /2018 at 5:30 PM the laboratory manager confirmed that the procedure manual did not include the identity of the abbreviations used when documenting QC organisms. II. Based on review of the procedure manual and interview with the laboratory manager, the procedure manual did not include all the procedures performed by the microbiology staff. Findings: 1. Review of the microbiology worksheets showed that the worksheet labeled "Deionized Water Sterility Check" included instructions for performing a sterility check of the deionized water used in the chemistry and hematology labs. 2. Review of the laboratory's procedure manual showed that the procedure for checking the sterility of the deionized water was not included in the approved procedure manual. 3. During the survey on 11/29/2018 at 5:30 PM the

	laboratory manager confirmed that the procedure manual did not include an approved procedure for checking the sterility of the deionized water. III. Based on observation in the laboratory, review of the procedure manual and interview with the laboratory manager, the procedure for "Blood Cultures" did not include written instructions for performing a gram stain. Findings: 1. During the tour of the laboratory the surveyor observed a microbiology testing person preparing slides for gram stains using a sterile disposable tip that was attached to the blood culture bottles. 2. The laboratory's procedure for "Blood Cultures" states "Perform Gram stain on all bottles flagged positive." The procedure does not provide instructions for performing the Gram stain. 3. During the survey on 11/29/2018 at 5:30 PM the laboratory manager confirmed that the procedure manual did not include instructions for performing the Gram stain. IV. Based on review of the procedure manual and interview with the laboratory manager, the "Competency Assessment" section in the "Quality Manual" procedure did not include written instructions identifying the location of the worksheets used to document the evaluation of the testing personnel. Findings: 1. Review of the "Competency Assessment" section in the "Quality Manual" procedure did not include written instructions identifying the location of the worksheets used to document the evaluation of the testing personnel. 2. During the survey on 11/29/2018 at 5:30 PM the laboratory manager confirmed that the procedure manual did not include written instructions identifying the location of the worksheets used to document the evaluation of the testing personnel.
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 review of the procedure for serum pregnancy and interview with the laboratory manager, the laboratory did not perform two levels of quality control (QC) each day of testing as required in paragraph (d)(3) of this section for serum pregnancy testing. Findings: 1. The laboratory performs urine and serum pregnancy testing. The pregnancy worksheet shows that two levels of QC are tested with each new lot number. The worksheet did not differentiate between urine and serum when the test was performed and recorded. 2. A patient was randomly selected to determine the specimen type. The requisition showed that the specimen that was received was serum which makes the test moderately complex. The worksheet showed that two levels of QC had not been tested on 10/12/18 when the serum pregnancy test was performed. 3. The laboratory is required to test two levels of QC materials each day of testing unless they have a written Individualized Quality Control Plan (IQCP). An IQCP plan requires the laboratory to perform a risk assessment that included an evaluation of the specimen used; environment for testing; integrity of the reagent; components of the test system; and competency of the testing personnel. The quality assessment portion of the IQCP should include a review of the QC, proficiency testing records, patient results and all other records pertaining to the serum pregnancy test. 4. During the

	survey on 11/29/18 at 5:00 PM the laboratory manager confirmed that the laboratory did not have an established IQCP for performing serum pregnancy testing to reduce the frequency of QC testing.
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 quality control (QC) and patient record review and interview with the laboratory staff, the laboratory did not ensure that the results of cholesterol QC met the laboratory's criteria for acceptability before performing patient testing. Findings: 1. A review of cholesterol QC from 11/1/18 to 11/29/18 showed that on 11/3/18, the "Chemtrak L1" cholesterol QC for the AU680 chemistry analyzer was 184 mg/dL and flagged as "Outside 2SD." The reference range was 186-204 mg/dL. The testing person documented, "will accept QC and monitor next run"; and 2. On 11/3/18, the "Chemtrak L3" cholesterol QC on the same analyzer was 78 mg/dL and flagged as "Outside 2SD." The reference range was 80-90 mg/dL. The testing person documented, "will accept QC and monitor next run." 3. A review of patient records showed that cholesterol results were reported for 12 patients after both levels of QC were found to be out of range on 11/3/18. 4. During an interview on 11/29/18 at 12:00 PM, the laboratory staff confirmed that patient testing was performed after QC was found to be unacceptable for cholesterol testing.
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: I. Based on laboratory procedure manual and hematology quality control (QC) record review and interview with the quality manager, the laboratory failed to document corrective action when hematology QC was out of range. Findings: 1. The laboratory utilizes two Sysmex analyzers to perform hematology testing. The analyzers (serial #17607 and #17609) are designated as "R" and "L" by the laboratory. The procedure manual states that, "All remedial action for out of range QC and the outcome of each step will be documented and become part of the Quality Assurance assessment and review." All "QC Discrepancies" are to be documented on the "XN-2000 Daily Log." The laboratory records "QC Discrepancies" for both analyzers on one log. 2. A review of "XN-2000 Daily Logs" for October and November, 2018 showed that 5 of 6 "QC

	Discrepancies" recorded did not identify which analyzer ("R" or "L") had a problem. 3. A review of "XN-2000 Daily Logs" for February and March, 2018 showed entries on 2/2/18 for "R-Level 1," and on 2/14/18 for "R-BF Level 2" and no entries in March 2018. 4. QC was reviewed for both analyzers for lot # 8008 for QC run between 1/10 /18 and 4/1/18. QC was repeated on Sysmex #17607 for "L1" on 2/6/18, 2/8/18, 2/17 /18, 3/14/18, and 3/22/18; for "L2" on 2/1/18, 2/6/18, 2/8/18, 3/1/18, and 3/15/18; and for "L3" on 2/1/18, 2/6/18, 2/8/18; and 5. QC was repeated on Sysmex #17609 for "L1" on 2/1/18, 2/6/18, 2/17/18, 3/7/18, 3/12/18, 3/15/18, and 3/22/18; for "L2" on 2/1 /18, 2/6/18, 2/14/18, and 3/15/18; and for "L3" on 2/1/18 and 3/15/18. 6. During an interview on 11/29/18 at 5:30 PM, the quality manager confirmed that corrective actions were not documented when hematology QC was out of range on the Sysmex hematology analyzers and that documented corrective actions did not identify the analyzer which had the QC or maintenance problem. II. Based on laboratory procedure manual and urinalysis quality control (QC) record review and interview with the laboratory staff, the laboratory failed to document corrective action when urinalysis QC was out of range. Cross refer to tag D3031 II for details.
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 review of a patient final report and interview with the laboratory manager, the laboratory did not ensure that the final test report listed the specimen source for qualitative pregnancy testing. Findings: 1. The laboratory performs serum and urine qualitative pregnancy testing. The worksheet did not differentiate between urine and serum when the test was performed and recorded. 2. A patient was randomly selected to determine the specimen type. The requisition showed that the specimen that was received was serum. The final report that was reviewed did not identify the specimen source. 3. During the survey on 11/29/18 at 5:00 PM the laboratory manager confirmed that the laboratory final report for qualitative pregnancy testing did not identify the specimen source.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by:

	Laboratory staff did not follow the laboratory's procedures for documenting corrective actions when hematology quality control was out of range. Refer to tag D5781 for details.