Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2210993	05/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Honeycomb Medical Group,Plc	6401 Poplar Ave, Suite 296, Memphis, TN	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) records and interview with the technical consultant, the testing personnel and lab director/designee failed to sign attestation statements for seven of seven PT events in 2021 and 2022. The findings include: 1. Review of the laboratory's PT records revealed the following: No attestation statements signed by testing personnel for seven of seven events (urine chemistry events 2021 one and two, chemistry 2021 event three and 2022 event one, hematology 2021 events two and three, 2022 event one). No attestation statements signed by lab director/designee for six of seven events (urine chemistry events 2021 one and two, chemistry- 2022 event one, hematology 2021 events two and three, 2022 event one). 2. Interview with the technical consultant on 05/09/2022 at approximately 6 pm confirmed testing personnel and lab director/designee failed to sign attestation statements for seven of seven PT events in 2021 and 2022.
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the technical

	consultant, the laboratory failed have any policies and procedures to ensure the confidentiality of patient information. The findings include: 1. Review of the laboratory's quality assessment plan revealed the laboratory did not have any procedures in place to ensure the confidentiality of patient information. 2. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed the laboratory did not have policies and procedures in place to ensure confidentiality of patient information.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the technical consultant, the laboratory failed a process in place for investigation of complaints. The findings include: 1. Review of the laboratory procedure manual revealed the quality assessment plan did not include a procedure/process in place for documentation and investigation of complaints. 2. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed the laboratory did have a process in place for investigation of complaints against the laboratory.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, and interview with the technical consultant, the laboratory failed to establish written policies and procedures for testing personnel training and competency. The findings include: 1. Observation of the laboratory on 05/09/2022 at approximately 9 am revealed the following moderately complex test systems in use for patient testing: Beckman Coulter AU480 (serial #2020113901) in use for general chemistry and urine chemistry Beckman Coulter Access 2 (serial #572885) in use for general chemistry and endocrinology tests Beckman Coulter DxH 560 (serial # BD110127) in use for complete blood count Tosoh G8 (serial #15551706) in use for glycosylated hemoglobin (Hemoglobin A1c) 2. Review of the laboratory procedure manual revealed no testing personnel policies and procedures. 3. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed the laboratory failed to establish policies and procedures for testing personnel training and competency assessment in 2021 and 2022.
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 review of the laboratory's proficiency testing records and interview with the technical consultant, the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) scores in 2021 and 2022, two of two events with non-graded scores. The findings include: 1. Review of the laboratory's PT records revealed the following: 2021 Event Two for Hematology/Coagulation: Non-graded scores for Basophils % for sample numbers DXH-08 and DXH-10; Non-graded scores for Lymphocytes % for sample number DXH-07 and DXH-09. 2022 Event One for Hematology/Coagulation: Non-graded scores for Monocytes % for DXH-02 and DXH-04. The non-graded scores had not been evaluated to determine the accuracy of the laboratory's results. 2. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed the laboratory failed to verify the accuracy of non-graded PT scores for 2021 Event Two and 2022 Event One for Hematology (two of two PT events with non-graded scores).
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 observation of the laboratory, review of patient test reports, request for laboratory records, and interview with the technical consultant, the laboratory failed to verify the accuracy of Vitamin D assay twice a year in 2021 and 2022, with approximately 2137 patients reported since testing began on 08/31/2021. 1. Observation of the laboratory on 05/09/2022 at approximately 9 am revealed the Beckman Coulter Access 2 (serial #572885) in use for patient testing for Vitamin D. 2. Review of random patient test reports revealed Vitamin D was reported on the following patients/dates: Patient #35342 reported on 09/30/2021 Patient #60493 reported on 01/19/2022 3. Request made to the technical consultant on 05/09/2022 at 1 pm for records verifying the accuracy of the Vitamin D test revealed no records were available. 4. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed the laboratory failed to verify the accuracy of Vitamin D test twice a year in 2021 and 2022 with approximately 2137 patients reported since testing began on 08/31/2021.
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: The laboratory failed to have a written procedure for the Tosoh G8 (Refer to D5401), failed to a have procedure for critical/alert values (Refer to D5403), failed to store control materials at temperatures consistent with manufacturer requirements (Refer to D5413), failed to label controls with open dates and corrected expiration dates (Refer to D5415), failed to perform calibration verification (Refer to D5439), failed to establish control ranges concurrently with current lot (Refer to D5469), failed to follow corrective action policies and procedures when controls were unacceptable (Refer to D5779), failed to evaluate patients tested since the last acceptable quality control run (Refer to D5783) and failed to follow quality assessment plan for monthly review of quality control (Refer to D5791).
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 observation of the laboratory, review of the laboratory procedure manual, and interview with the technical consultant, the laboratory failed to have a written procedure for use of the Tosoh G8 in 2022. 1. Observation of the laboratory on 05/09 /2022 at approximately 9 am revealed the following moderately complex test system in use for patient testing: Tosoh G8 (serial #15551706) in use for glycosylated hemoglobin (Hemoglobin A1c) 2. Review of the laboratory procedure manual revealed no written procedure for the Tosoh G8 Hemoglobin A1c instrument/test system. 3. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed the laboratory failed to have a procedure for performance of Hemoglobin A1c on the Tosoh G8 in 2022.
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: Based on observation of the laboratory, review of the laboratory procedure manual and interview with the technical consultant, the laboratory procedure manual failed to include panic or alert values and the protocol for reporting panic/alert values. The findings include: 1. Observation of the laboratory on 05/09/2022 at approximately 9 am revealed the following moderately complex test systems in use for patient testing: Beckman Coulter AU480 (serial #2020113901) in use for general chemistry and urine chemistry Beckman Coulter Access 2 (serial #572885) in use for general chemistry and endocrinology tests Beckman Coulter DxH 560 (serial # BD110127) in use for complete blood count Tosoh G8 (serial #15551706) in use for glycosylated hemoglobin (Hemoglobin A1c) 2. Review of the laboratory procedure manual revealed no defined panic/alert values or procedures for reporting panic values. 3. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed the laboratory procedure manual did not include panic/alert values or procedures for reporting panic values.
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 observation of the laboratory, review of the control manufacturer package insert, the laboratory procedure manual, the laboratory's temperature recording form, and interview with the technical consultant, the laboratory failed to define criteria for frozen storage of quality controls used for chemistry and endocrinology tests that was consistent with manufacturer requirements, resulting in storage of controls at temperatures that that were inconsistent with manufacturer requirements from 04/05 /2021 to the date of the survey (05/09/2022). The findings include: 1. Observation of the laboratory on 05/09/2022 at 9 am revealed storage of quality control material used for performing quality control for chemistry and endocrinology in the laboratory freezer. 2. Review of the manufacturer package insert for the controls revealed a frozen storage temperature requirement of -20 to -70 degrees Celsius. 3. Review of the laboratory policy titled "Quality Control Policy" revealed an acceptable temperature for freezers of "0 degrees Celsius or colder." 4. Review of the laboratory's form used for recording freezer temperatures revealed an acceptable temperature range of "(degrees Celsius) below 0-20." Temperatures recorded on the form beginning 04/05/2021 until the survey date exceeded the manufacturer required range. 5. Interview with the technical consultant on 05/09/22 at 9 am confirmed the laboratory failed to define temperature ranges for frozen storage of control material that was consistent with the manufacturer's requirements, resulting in improper storage of controls from 04/05/2021 to the date of the survey (05/09/2022).

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer control package inserts, and interview with the technical consultant, the laboratory failed to label controls with open dates and corrected expiration dates in 2022. The findings include: 1. Observation of the laboratory on 05/09/2022 at 9 am revealed multiple controls for chemistry, urine chemistry, endocrinology and hematology that had been been opened and were in use with either no labeling to indicate the open date or not labeled with a corrected expiration date. 2. Review of the control manufacturer package insert for the controls revealed shortened expiration dates after opening for all controls that were in use. 3. Interview with the technical consultant on 05/09/2022 at 9 am confirmed the laboratory had multiple control materials in use with either no open date or no corrected expiration date. Manufacturer package inserts stated shortened stability /expiration dates after opening for all controls in use.
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 observation of the laboratory, review of laboratory procedures and calibration records, request for calibration verification records and interview with the technical consultant, the laboratory failed to perform calibration verification on the Beckman Coulter AU480 in 2021 and 2022. The findings include: 1. Observation of

	the laboratory on 05/09/2022 at 9 am revealed the Beckman Coulter AU480 chemistry instrument in use for patient testing for serum chemistry and urine chemistry (system ID #80395525). 2. Review of laboratory procedures and calibration records for the Beckman Coulter AU480 chemistry instrument revealed none of the methods used for performing serum chemistry testing included at least three calibration points that spanned the reportable range of the instrument. 3. Request for calibration verification records on 05/09/2022 at 1:30 pm revealed no calibration verification studies had been performed every six months in 2021 or 2022. 4. Interview with the technical consultant on 05/09/2022 at 1:30 pm confirmed the laboratory failed to perform calibration verification on the Beckman Coulter AU480 every six months in 2021 and 2022.
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 review of the laboratory's quality control records, patient test report and interview with the technical consultant, the laboratory failed to establish ranges for new lots of quality control (QC) by testing in parallel with the old lot of control material for lots 85311 and 85313 in use from 04/13/2022 to date of the survey (05/09/2022). The findings include: 1. Review of the laboratory's quality control records revealed the following: Control package insert for Biorad Liquichek Immunoassay Plus for lot numbers 85311 and 85313 revealed the controls were unassayed for the following analytes: Ferritin, Folate, Free Thyroxine, Total Thyroxine, Thyroid Stimulating Hormone, and Vitamin B12. The controls were put into use on 04/13/2022 and were in use on the survey date of 05/09/2022. Control records did not show any parallel testing with previous control lots. 2. Review of patient 85013 revealed total thyroxine reported on 5/03/2022 during the period when the current lot QC ranges had not established concurrently with previous lots. 3. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed control lots 85311 and 85313 were unassayed for the Ferritin, Folate, Free Thyroxine, Total Thyroxine, Thyroid Stimulating Hormone and Vitamin B12. She further confirmed the ranges in use for lots 85311 and 85313 were not established over time by testing concurrently with the previous lots and were in use from 04/13/2022 to the date of the survey on 05/09/2022.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a)

	Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, the laboratory's quality control (QC) records, patient test records and interview with the technical consultant, the laboratory failed to follow its' own policy for performing corrective action when quality control was unacceptable in 2021 and 2022. The findings include: 1. Review of the laboratory's procedure titled "Quality Control Policy" revealed the following statement "Anytime quality results are unacceptable, corrective action will be completed and controls retested. All these actions will be documented, and satisfactory control results will be obtained before patient specimens will be tested." 2. Review of the laboratory's quality control records for Total Thyroxine revealed both levels of QC were out of range on 10/14/2021; Level 3 QC was out on 01/04 /2022. There was no corrective actions performed for the out of range quality control. 3. Review of patient number 18332 reported on 10/14/2021, and patient number 34744 reported on 01/04/2022, revealed total thyroxine patient testing reported on two separate dates when quality control was unacceptable. 4. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed the laboratory tested patients for total thyroxine on dates when quality control was unacceptable with no corrective action performed. The laboratory failed to follow its' own corrective action policies and procedures in 2021 and 2022.
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: Based on review of the laboratory procedure manual, quality control (QC) records, patient test reports, document request and interview with the techncial consultant, the laboratory failed to evaluate patients performed since the last acceptable quality control run for the total thyroxine analyte when controls were unacceptable. Approximately 376 patients were tested during the period of quality control failures from 10/13/2021 until 04/12/2022. The findings include: 1. Review of the laboratory's procedure titled "Quality Control Policy" revealed the following statement "Anytime quality results are unacceptable, corrective action will be completed and controls retested. All these actions will be documented, and satisfactory control results will be obtained before patient specimens will be tested." 2. Review of the laboratory's quality control records for Total Thyroxine (T4) revealed both levels of QC were out of range on 10/14/2021. There was no corrective actions performed for the out of range quality control. Further review revealed lot numbers 85271 and 85273 were in use from 10/13/2021 until 04/12/2022. Lot 85271 (Level 1) was flagged as out of range 'H" from 10/13/2021 to 11/03/2021, 11/08/2021-11/11/2021, 11/17/2021-11/18

	/2021, 11/22/2021-12/17/2021, 12/23/2021, 12/28/2021, 01/21/2022, 01/24/2022, 01/26/2022, 02/01/2022, 02/04/2022, 02/07/2022, 02/10/2022, 02/14/2022, 02/15/2022, 02/17/2022, 02/21/2022 - 03/22/2022, 03/24/2022, 03/28/2022-03/30/2022, 04/01/2022-04/05/2022 and flagged as 'L' out of range on 01/27/2022. Lot 85273 (Level 3) was flagged as out of range 'H' from 10/13/2021 until 04/11/2022. The last acceptable QC run prior to 10/13/2021 was on 10/12/2021. 3. Review of patient number 18332 reported on 10/14/2021, and patient number 34744 reported on 01/04/2022, revealed total thyroxine reported on two separate dates when quality control was unacceptable. 4. Request for documentation on 05/09/2022 at 3:30 pm for corrective action including evaluation of all patients since the last acceptable run revealed no documentation was available. No corrective action was documented, no evaluation of patients tested since last acceptable QC was available. 5. Review of an email communication received from the technical consultant on 05/10/2022 revealed approximately 376 patients were tested for total thyroxine for the period from 10/13/2021 to 04/12/2022 when QC was unacceptable. 6. Interview with the technical consultant on 05/09/2022 at 5 pm confirmed the laboratory tested patients for total thyroxine on dates when quality control was unacceptable with no corrective action performed, and no evaluation of patients since the last acceptable quality control run.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory quality assessment plan, patient test reports, request for documentation, and interview with the technical consultant, the laboratory failed to follow the written policy for monthly review of quality control from 04/05/2021 to 05/09/2022. The findings include: 1. Observation of the laboratory on 05/09/2022 at approximately 9 am revealed the following moderately complex test systems in use for patient testing: Beckman Coulter AU480 (serial #2020113901) in use for general chemistry and urine chemistry Beckman Coulter Access 2 (serial #572885) in use for general chemistry and endocrinology tests Beckman Coulter DxH 560 (serial # BD110127) in use for complete blood count Tosoh G8 (serial #15551706) in use for glycosylated hemoglobin (Hemoglobin A1c) 2. Review of the laboratory quality assessment plan revealed the following statement under the section for "REVIEW OF QC DATA:" All QC records are to be reviewed on a monthly basis by the Laboratory Director and/or his(her) designee. The purpose of this review is an in-depth evaluation of long-term precision and accuracy trends. In particular, control charts have to examined for adequacy of control limits and adjusted if they are either too wide or too narrow." 3. Review of patient 4618 (the first patient tested) revealed patient testing began on 04/05/2021. 4. Request on 05/09/2022 at 4 pm for monthly review of the quality control for the test systems in use revealed no documentation that retrospective monthly review had been performed since the laboratory began testing. 5. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed there was no documentation that the laboratory had followed written policies for monthly review of quality control from the time patient testing began (04/05/2021) until the date of the survey on 05/09/2022.

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: The technical consultant failed to ensure the quality control program was maintained (Refer to D6042), failed to ensure patient's were not reported until corrective actions had been taken (Refer to D6044) and failed to ensure testing personnel had appropriate training for performing testing (Refer to D6045).
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 review of the laboratory's quality control records and interview with the technical consultant, the technical consultant failed to ensure the quality control program was maintained in 2021 and 2022. (Refer to D5469, D5779, D5783 and D5791) The findings include: 1. Review of the laboratory's quality control plan revealead that quality control would be reviewed monthly and corrective actions applied. 2. Review of the laboratory's quality control records revealed out of range quality control for total thyroxine from 10/13/2021 to 04/12/2022 with no corrective actions applied, patients tested when controls were out of range, no evaluation of patient results to determine effect, no documentation of corrective actions, and no documentation of monthly reviews (Refer to D5779, D5783 and D5791). 3. Interview with the technical consultant on 05/09/2022 at 6 pm confirmed the technical consultant failed to ensure the quality control program was maintained with patient testing performed from 04/05/2021 to 05/09/2022.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of quality control records, patient test reports and interview with the technical consultant, the technical consultant failed to ensure patient test results were not released until corrective actions had been taken and the test system was functioning properly in from 10/13/2021 to 04/12/2022 (Refer to D5779). 1. Review of laboratory quality control records for the total thyroxine assay revealed quality

	control was out of range for either one of two or two of two levels from 10/13/2021 to 04/12/2022. There was no evidence of corrective action for the out of range quality control. (Refer to D5779) 2. Review of patient test reports revealed patients were reported during the period when total thyroxine controls were not in range (patient 18332 on 10/14/2021 and patient 34744 on 01/04/2022). 3. Interview on 05/09/2022 at 6 pm with the technical consultant confirmed there was no documentation of corrective action for the total thyroxine assay quality control and quality control was out of range on dates when patients were tested. The technical consultant failed to ensure patients were not reported until corrective actions had been taken for the total thyroxine test from 10/13/2021 to 04/12/2022.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, testing personnel records and interview with the technical consultant, the technical consultant failed to ensure testing personnel number had documented training for the use of the Beckman Coulter DXH 560 complete blood count (CBC) instrument in 2022. The findings include: 1. Observation of the laboratory on 05/09/2021 at 9 am revealed the Beckman Coulter DxH 560 (serial # BD110127) in use for complete blood count. 2. Review of patient number 85013 revealed complete blood count testing performed by testing personnel number two on 05/03/2022. 3. Review of testing personnel records revealed no documented training for use of the DXH CBC instrument for testing personnel number two. 4. Interview with the techncial consultant on 05/09/2022 at 6 pm confirmed testing person number two was performing patient testing for complete blood without any documented training for the use of the instrument.