Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0659838	10/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Throckmorton County Memorial Hospital	802 North Minter Avenue Box 729, Throckmorton, TX	

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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory environmental records, and staff interview, the laboratory failed to monitor the storage temperature for 1 of 1 box of Quidel QuickVue RSV tests in October 2022. The findings include: 1. During a tour of the laboratory storage areas on 10/26/2022 at 08: 59 a.m., the surveyor observed 1 unopened box of Quidel QuickVue RSV tests (lot# 707709; expiration: 2023-10-26) on the shelf in testing person 1's (TP1) office. 2.

	Review of the manufacturer's instructions for Quidel QuickVue RSV tests revealed a storage temperature requirement of 15C-30C (59F-86F). 3. Review of laboratory environmental records from January through October 2022 revealed no documentation of temperature for the office. 4. During an interview with TP1 on 10/26 /2022 at 08:59 a.m., the surveyor asked if temperature was monitored in her office. TP1 confirmed that temperature was not monitored.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the facility's blood transfusion policies, staff interview, and patient transfusion records, the facility 's transfusion policy failed to provide specific criteria for a possible transfusion reaction and failed to identify, investigate and document possible transfusion reactions for 4 of 20 patients (randomly sampled) transfused in 2021 and 2022 (October 2021-October 2022). Findings included: 1. The facility policy titled "Laboratory Policy & Procedure" (note: this policy was the same policy as the laboratory's policy) stated the following: "In accordance with current AABB standards, the Service (TS) department in place for the recognition, investigation, and response to transfusion. This policy also dictates the evaluation and reporting of suspected transfusion reactions, including prompt evaluation, review of clerical information by the TS, and notification of the TS Medical Director. Signs and Symptoms of a Suspected Transfusion Reaction: 1. Adverse effects of transfusion therapy cannot always be accurately predicted or avoided. The transfusing physician should be aware of risks when discussing the need for transfusion with a patient. Medical staff administering blood components should be well aware of signs and symptoms of possible transfusion reactions. Many common signs and symptoms are associated with more than one type of adverse reaction. Early recognition, prompt cessation of the transfusion, and further evaluation are key to a successful outcome. 2. Common signs and symptoms that may be indicators of a transfusion reactions include the following: a. Fever, generally defined as a >/=2-degree F rise in temperature above 98.6-degree F b. Chills with or without rigors c. Respiratory distress (including wheezing, coughing, and dyspnea [sic] d. Hyper- or hypotension e. Abdominal, chest, flank, or back pain f. Pain in the infusion site g. Skin manifestations (including urticarial, rash, flushing, pruritus, and localized edema) h. Jaundice or hemoglobinuria i. Nausea/vomiting j. Abnormal bleeding k. Oliguria /anuria Clinical Evaluation and Management of a Transfusion Reaction: 1. The evaluation of a suspected transfusion reaction involves clinical evaluation of the patient along with laboratory verification testing. The nurse or transfusionist must treat the patient by administering supportive care at the direction of the physician, discontinue the transfusion immediately, and contact the TS for laboratory evaluation. 2. When a reaction is suspected, the following steps must be taken immediately: a. Stop the transfusion immediately but keep the line open with saline. b. Perform clerical recheck between the patient and the component. The labels on the component, patient records, and patient identification should be examined to detect any identification errors. c. Contact the treating physician immediately for instructions on patient care. d. Complete the transfusion reaction workup. e. Send the required

specimens to the laboratory for evaluation f. Return the remaining component (whether or not it contains any blood/blood component), associated intravenous fluid bags, and tubing to the TS." The policy did NOT define the criteria for hypertension or hypotension or criteria for changes in blood pressure. 2. In interview with nursing personnel on 10/27/2022 at 9:30 am, the RN was asked what the signs of a transfusion reaction were. The RN responded fever, itching or a spike in fever. The RN was asked what the facility's policy was for signs and symptoms of a transfusion reaction. She stated that she did not know and the signs and symptoms she listed were what she typically sees at another hospital where she was employed. She was asked if the signs or symptoms were posted anywhere while transfusions were taking place and she stated "no". The RN was then asked if the facility ever provided any training for identifying transfusion reactions and she again stated "no". She also stated if the facility ever has new policies, they would do an in-service or a read and sign if they were not present for the in-service. The RN was asked how the facility defined hypotension and hypertension. She stated hypertension was dependent on each individual patient. The nurse was shown the following Blood Transfusion Records and asked if she considered the blood pressure increases significant: a. 12/28/2021; Patient MRN 049602; Unit Number W141421355804 (second unit transfused); Date /Time of transfusion 12/28/2021 1438 hours Pre-Transfusion blood pressure 119/59 End of Transfusion blood pressure 175/79 The patient had a systolic blood pressure increase of 56 mm Hg. Unit Number W223221787878 (third unit transfused) Pre-Transfusion blood pressure 175/79 First transfusion reading (from pre-transfusion) blood pressure 138/66 The patient had a systolic blood pressure decrease of 37 mm Hg. b. 04/19/2022; Patient MRN 0494602; Unit Number W044422101851 (second unit transfused); Date/Time of transfusion 04/19/2022 0850 hours Pre-Transfusion blood pressure 129/63 Sixth transfusion reading (from pre-transfusion) blood pressure 171/78 The patient had a systolic blood pressure increase of 42 mm Hg. c. 08/17 /2022; Patient MRN 049602; Unit Number W141422253197 (second unit transfused); Date/Time of transfusion 08/17/2022 1422 hours Pre-Transfusion blood pressure 147 /69 End of Transfusion blood pressure 187/81 The patient had a systolic blood pressure increase of 40 mm Hg. d. 06/28/2022; Patient MRN 049602; Unit Number W141422362506; Date/Time of transfusion 06/28/2022 0955 hours Pre-Transfusion blood pressure 119/57 Fifth transfusion reading (from pre-transfusion) blood pressure 176/68 Sixth transfusion reading (from pre-transfusion) blood pressure 133/70 The patient had a systolic blood pressure increase of 57 mm Hg and then a decrease in systolic blood pressure of 43 mm Hg. She stated, "yes". The LVN interviewed was asked what the signs of a transfusion reaction were. She stated that nausea, vomiting, fever and an increase or decrease in blood pressure were signs of a transfusion reaction. The nurse was asked how the facility defines hypotension and hypertension. She stated that an increase or decrease in 20 points in blood pressure. The LVN was also shown the Blood Transfusion Records listed above. She was asked if she considered the changes in blood pressure significant. She stated "yes". During an interview on 10/27/2022 at 1000 am, Testing Person-1 (TP-1) was asked if the laboratory or the facility conducted a review of patient transfusion records. She stated "no". 3. A review of "Blood Transfusion Record" forms (10/2021 - 10/2022) revealed the following 4 of 20 possible transfusion reactions that were NOT identified, reported, or investigated by the facility: a. 12/28/2021; Patient MRN 049602; Unit Number W141421355804 (second unit transfused); Date/Time of transfusion 12/28 /2021 1438 hours Pre-Transfusion blood pressure 119/59 End of Transfusion blood pressure 175/79 The patient had a systolic blood pressure increase of 56 mm Hg. Common sign of suspected transfusion reaction indicated in the facility's policy: Hypertension. Transfusion reaction was NOT identified or reported by transfusing nurse. Unit Number W223221787878 (third unit transfused) Pre-Transfusion blood

	pressure 175/79 First transfusion reading (from pre-transfusion) blood pressure 138 /66 The patient had a systolic blood pressure decrease of 37 mm Hg. The facility failed to define specific transfusion reaction criteria for blood pressure changes. b. 04 /19/2022; Patient MRN 0494602; Unit Number W044422101851 (second unit transfused); Date/Time of transfusion 04/19/2022 0850 hours Pre-Transfusion blood pressure 129/63 Sixth transfusion reading (from pre-transfusion) blood pressure 171 /78 The patient had a systolic blood pressure increase of 42 mm Hg. Common sign of suspected transfusion reaction indicated in the facility's policy: Hypertension. Transfusion reaction was NOT identified or reported by transfusing nurse. c. 08/17 /2022; Patient MRN 049602; Unit Number W141422253197 (second unit transfused); Date/Time of transfusion 08/17/2022 1422 hours Pre-Transfusion blood pressure 147 /69 End of Transfusion blood pressure 187/81 The patient had a systolic blood pressure increase of 40 mm Hg. Common sign of suspected transfusion reaction indicated in the facility's policy: Hypertension. Transfusion reaction was NOT identified or reported by transfusing nurse. d. 06/28/2022; Patient MRN 049602; Unit Number W141422362506; Date/Time of transfusion 06/28/2022 0955 hours Pre-Transfusion blood pressure 119/57 Fifth transfusion reading (from pre-transfusion) blood pressure 176/68 Sixth transfusion reading (from pre-transfusion) blood pressure 133/70 The patient had a systolic blood pressure increase of 57 mm Hg and then a decrease in systolic blood pressure of 43 mm Hg. Common sign of suspected transfusion reaction indicated in the facility's policy: Hypertension. Transfusion reaction was NOT identified or reported by transfusing nurse. The facility failed to define specific transfusion reaction criteria for blood pressure changes. 4. In 2022, the facility had transfused 47 blood components and had never identified and reported a transfusion reaction. The facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products. Word Key: RN=Registered Nurse mL=Milliliter Hg=Mercury LVN=Licensed Vocational Nurse
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 review of Centers for Medicare and Medicaid Services (CMS)-116 form, QIAstat-Dx Individualized Quality Control Plan (IQCP), quality control (QC) reports, patient test records, laboratory proficiency testing records, and confirmed in interview, the laboratory failed to verify the accuracy of non-regulated viral and bacterial pathogens at least twice annually for 1 testing event in 2022. The findings include: 1. Review of the CMS-116 form revealed the laboratory performed QIAstat-Dx Respiratory SARS-CoV-2 Panels. 2. Review of the QIAstat-Dx IQCP revealed the panel was implemented in February 2022. 3. Review of quality control reports and patient test records revealed the QIAstat-Dx Respiratory SARS-CoV-2 Panel tested for the following pathogens: Viruses: Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Human Metapneumovirus A+B Influenza A Influenza A H1 Influenza A H1N1 pdm09 Influenza A H3 Influenza B Parainfluenza virus 1 Parainfluenza virus 2 Parainfluenza virus 3 Parainfluenza virus 4 Respiratory Syncytial Virus A+B Rhinovirus/Enterovirus SARS-CoV-2 Bacteria: Bordetella pertussis Chlamydophila pneumoniae Mycoplasma pneumoniae 4. Review of the laboratory's proficiency testing records for 2022 revealed no documentation of

	twice annual accuracy assessments for the above non-regulated viral and bacterial pathogens for 1 testing event in 2022. 5. During an interview with testing person 1 on 10/26/2022 at 10:11 a.m., the surveyor requested documentation of twice annual accuracy assessments for the non-regulated viral and bacterial pathogens. None was provided. This confirmed the above findings.
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 the laboratory policy and confirmed in interview, the laboratory failed to have a written procedure available to testing personnel for performing the QIAstat-Dx Respiratory SARS-CoV-2 Panel on the QIAstat-Dx Analyzer. 1. Review of the laboratory policy and procedure manual revealed no standard operating procedure (SOP) for the QIAstat-Dx Analyzer. The laboratory was asked to provide a SOP for the QIAstat-Dx Analyzer. None was provided. 2. During an interview on 10 /26/2022 at 11:33 a.m., testing person 1 confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the Sysmex XN-550 hematology analyzer, review of laboratory policies, random review of patients' records (October 2022), and confirmed in staff interview, it was revealed the laboratory failed to follow manufacturer's instructions for specimens with instrument flags for 2 of 2 patients. Findings included: 1. Review of the manufacturer's instructions for the Sysmex XN-550 stated the following: "Chapter 5 IP Messages 5.1 Overview of IP Messages ... Results without an analysis error are classified as Positive or Negative based on preset criteria. The system judges flags for analysis based on comprehensive surveys of numerical data, distributions and scattergrams, and provides easy-to-understand messages indicating the results. These messages are referred to as "IP (Interpretive Program) messages" ... Caution! A Positive or Error judgement indicates the possibility of an abnormality. It is not a diagnosis of the patient. If a Positive or Error judgement occurs, check the data and repeat the analysis, or examine carefully in accordance with the protocol of your laboratory. IP messages are only intended for use in the clinical laboratory and are not for patient diagnosis. IP messages provide notification of the possibility of a specific sample abnormality based on examination of the analysis data ... Message types There are 2 types of IP messages that may be displaced for WBC, RBC/RET, and PLT: abnormal messages and suspect messages. Abnormal messages Indicates that the sample is clearly abnormal. With some

	exceptions, the criteria for abnormal message judgement can be preset. Suspect messages Indicates a possibility that the sample is abnormal. Positive/Negative judgement Positive Indicates that a blood cell analysis value or cell morphology exceeds the preset criteria for the IP message (abnormal sample)." 2. Review of the laboratory's policy titled "Laboratory Policy & Procedure" stated the following: "Hematology/Sysmex ... An asterisk indicates a possible count invalidation or support measured flag. These flags are generated after the instrument evaluates the measured data. The result maybe [sic] suspect due to inferring [sic] substances or the inability of the instrument to measure a particular measured [sic] due to sample abnormality. In the case of an asterisk the sample will be repeated. If the asterisk persists a peripheral smear will be sent to the reference lab for verification." 3. Review of patients' CBC records generated from the Sysmex XN-550 hematology analyzer in October 2022 revealed the following 2 of 2 patients with a positive IP flag: Date of test: 10/25/2022; Sample ID 70885; WBC IP flag: "#20: Lymphopenia: Send for Manual Diff; #23: Monocytosis: Send for Manual Diff"; the specimen sample was NOT repeated as required Date of test: 10/26/2022; Sample ID 70896; WBC IP flag: "#20: Lymphopenia: Send for Manual Diff" The laboratory reported patient specimens with possible abnormal patient results. The laboratory failed to follow manufacture's instructions. 4. During an interview on 10/26/2022 at 3:15 pm, the Testing Person-1, after review of the laboratory records, stated that she did not know if Specimen ID 70885 had been sent out for a manual differential and that Sample ID 70896 had not been picked up by the reference laboratory for a manual differential, confirming the above findings. Word Key: CBC=Complete Blood Count
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 review of the manufacturer's instructions, laboratory environmental records, and confirmed in interview, the laboratory failed to monitor storage temperature for 3 of 3 boxes of QIAstat-Dx Respiratory SARS-CoV-2 Panels in October 2022. The findings include: 1. During a tour of the laboratory storage areas on 10/27/2022 at 08: 59 a.m., the surveyor observed 3 unopened boxes QIAstat-Dx Respiratory SARS-CoV-2 Panels (lot# 172026017 /00380; expiration: 2022-11-27) on the shelf in testing person 1's (TP1) office. 2. Review of the manufacturer's instructions for the QIAstat-Dx Respiratory SARS-CoV-2 Panels revealed a storage temperature requirement of 15C-25C. 3. Review of the laboratory's environmental logs from January to October 2022 revealed no documentation of temperature for the office. 4. During an interview with TP1 on 10/26/2022 at 08:59 a.m., the surveyor asked if temperature was monitored in her office. TP1 confirmed that temperature was not monitored.
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 review of manufacturer's instructions, laboratory policy, review of laboratory records, and confirmed in interview the laboratory failed to perform calibration verification for the OPTI CCA-TS blood gas analyzer every 6 months as required in 2021 and 2022. Findings included: 1. Review of the OPTI CCA-TS operator's manual revealed: "4.4 Calibration Verification Calibration verification allows for the validation of the blood gas analyzer's ability to recover know values at various points within the reportable range of all parameters and may be required by various regulatory agencies." 2. Review of the laboratory's policy revealed the laboratory did NOT have a policy for performing calibration verifications. 3. Review of the OPTI CCA-TS laboratory records revealed no six-month calibration verification records for 2021 and 2022. 4. During an interview on 10/27/2022 at 12:10 pm, Testing Person-1 confirmed the laboratory failed to perform six-month calibrations in 2021 and 2022.
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 QIAstat-Dx Individualized Quality Control Plan (IQCP), QIAstat-Dx Respiratory SARS-CoV-2 Panel Instructions for Use, quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to

	perform the QIAstat-Dx Respiratory SARS-CoV-2 Panel quality control at the frequency specified by the laboratory (every 30 days) for 4 of 8 months in 2022 (February to September). The findings include: 1. Review of the laboratory's IQCP for the QIAstat-Dx revealed: "External Control Plan: -A minimum of one external positive and negative control will be performed per lot/shipment every 30 days (28th of each month)." 2. Review of the QIAstat-Dx Respiratory SARS-CoV-2 Panel Instructions for Use revealed: "Quality Control In accordance with QIAGEN's ISO-certified Quality Management System, each lot of QIAstat-Dx Respiratory SARS-CoV-2 Panel is tested against predetermined specifications to ensure consistent product quality. External controls are not provided with the QIAstat-Dx Respiratory SARS-CoV-2 Panel. Quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures..." 3. Review of QIAstat-Dx Respiratory SARS-CoV-2 Panel QC records from 02/20/2022 to 09/29/2022 revealed the laboratory performed positive and negative external QC on the following dates: QIAstat-Dx RP SARS-CoV-2 Control Panel Lot# 172011169; Expiration 2022-07-20 Lot# 220138; Expiration: 2022-11-17 Lot# 172026017; Expiration: 2022-11-27 Lot# 220054; Expiration: 2022-08-13 02/20/2022 03/28/2022 (36 days after previous QC run) 04/28/2022 05/28/2022 06/28/2022 (31 days after previous QC run) 07/28/2022 08/28/2022 (31 days after previous QC run) 09/29/2022 (32 days after previous QC run) Note: The QIAstat-Dx RP SARS-CoV-2 Control Panel is intended for use as an external positive and negative quality control. 4. Review of patient test records revealed the following 5 patients were analyzed when QC was not performed at the specified frequency (every 30 days) for the QIAstat-Dx Respiratory SARS-CoV-2 Panel to ensure accurate and reliable results: 03/25/2022 Procedure: Respiratory Panel PCR Order #s: 64331, 64330 QC was last performed on 02/20/2022 06/27/2022 Procedure: Respiratory Panel PCR Order #: 67073 QC was last performed on 05/28 /2022 09/27/2022 Procedure: Respiratory Panel PCR Order #s: 70151, 70152 QC was last performed on 08/28/2022 5. During an interview on 10/26/2022 at 12:48 p.m., testing person 1 confirmed the above findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel files and confirmed in interview the Laboratory Director failed to ensure that 3 of 5 Testing Persons (TP-2, TP-3, TP-4) received the appropriate training in moderate complexity testing prior to patient testing. Findings included: 1. Review of personnel files for TP-2 revealed a hire date of 01/01/2020. There were no documented training records for the Opti CCA TS blood gas analyzer, Alere Triage Meter analyzer and the MedTox urine drug screen test kit. Review of personnel files for TP-3 revealed a hire date of 11/01/2021. There were no documented training records for the Alere Triage Meter analyzer and the MedTox

	urine drug screen test kit. Review of personnel files for TP-4 revealed a hire date of 03 /14/2020. There were no documented training records for the Opti CCA TS blood gas analyzer, Alere Triage Meter analyzer and the MedTox urine drug screen test kit. The Laboratory Director failed to ensure TP-2, TP-3, TP-4 received the appropriate training in moderate complexity testing prior to patient testing. 2. During an interview on 10/26/2019 at 9:50 am, the Laboratory Director confirmed the above findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory policies, and confirmed in interview, the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 5 of 5 Testing Persons (TP-1, TP-2, TP-3, TP-4, TP-5) performing moderate complexity testing. Findings: 1. Review of the CMS 209 form revealed 5 Testing Persons (TP-1, TP-2, TP-3, TP-4, TP-5) performing moderate complexity testing. 2. The laboratory was asked to provide a policy for personnel performing moderate complexity testing. No policy was provided. 3. During an interview on 10/26/2022 at 11:15 am, TP-1 stated that there were no laboratory policies for training or competency assessments for testing personnel. Word key: CMS: Centers for Medicare and Medicaid Services
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of CMS 209 form, personnel records, and staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties for testing persons (TP-1 through TP-5) engaged in performance of moderate complexity

	testing. Findings included: 1. Review of CMS 209 form listed TP-1, TP-2, TP-3, TP-4, TP-5 as testing persons performing moderate complexity testing. 2. Review of the personnel records for TP-1, TP-2, TP-3, TP-4, TP-5 revealed the laboratory director did not specify in writing the responsibilities and duties for testing persons engaged in moderate complexity testing. 3. During an interview on 10/26/2022 at 10:26 am, TP-1 confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel files and confirmed in interview the technical consultant (who was also the laboratory director) failed to evaluate and document the performance 3 of 5 Testing Persons (TP-2, TP-3, TP-4) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens in 2020, 2021, and 2022. Findings included: 1. Review of the laboratory's policies revealed the laboratory did NOT have a policy for performing competency assessments for testing personnel. Refer to D6030. 2. Review of personnel records for 2020, 2021, 2022 revealed the following: TP-2 personnel records revealed an initial training assessment was performed on 05/2020 for the Vitros 350 chemistry analyzer, Emerald hematology analyzer and Ortho ECQI endocrinology/chemistry analyzer. Further review of personnel records revealed one semiannual performance for the Vitros 350, Emerald and Ortho ECQI analyzers were conducted on 4/6/2021. The semiannual assessment failed to include an assessment for the Opti CCA TS blood gas analyzer, Alere Triage Meter and the MedTox urine drug screen test kit. There was no documentation of a second semiannual performance for the Vitros 350, Emerald, Ortho ECQI, Opti CCA TS blood gas analyzer, Alere Triage Meter, and the MedTox urine drug screen test kit. Note T-P 2 failed to have documentation of an initial training for the Opti CCA TS blood gas analyzer, Alere Triage Meter and the MedTox urine drug screen test kit. Refer to D6029. TP-3 personnel records revealed an initial training assessment was performed on 01/2022 for the Vitros 350 chemistry analyzer, Emerald hematology analyzer, Ortho ECQI endocrinology/chemistry analyzer and the Opti CCA TS blood gas analyzer. Additional training records revealed training on the Sysmex hematology analyzer in 4 /2022. Further review of personnel records revealed a semiannual performance for the Vitros 350, Sysmex, Ortho ECQI analyzers and the MedTox urine drug screen test kits were conducted on 10/21/2022. The semiannual assessment failed to include an assessment for the Opti CCA TS blood gas analyzer and the Alere Triage Meter. Note T-P 3 failed to have documentation of an initial training for the Alere Triage Meter analyzer and the MedTox urine drug screen test kit. Refer to D6029. TP-4 personnel records revealed an initial training assessment was performed on 05/2020 for the Vitros 350 chemistry analyzer, Emerald hematology analyzer and Ortho ECQI endocrinology/chemistry analyzer. Further review of personnel records revealed one semiannual performance for the Vitros 350, Emerald and Ortho ECQI analyzers were conducted on 4/12/2021. The semiannual assessment failed to include an assessment for the Opti CCA TS blood gas analyzer, Alere Triage Meter and the MedTox urine drug screen test kit. There was no documentation of a second semiannual performance for the Vitros 350, Emerald, Ortho ECQI, Opti CCA TS blood gas analyzer, Alere

	Triage Meter, and the MedTox urine drug screen test kit. Note T-P 4 failed to have documentation of an initial training for the Opti CCA TS blood gas analyzer, Alere Triage Meter and the MedTox urine drug screen test kit. Refer to D6029. The technical consultant did not ensure semi-annual competency assessments were evaluated and documented for the above TP's. 3. During an interview on 10/26/2022 at 9:50 am, the Laboratory Director confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory policies, personnel records and confirmed in interview, the technical consultant (who was also the laboratory director) failed to evaluate and document the annual performances 4 of 5 Testing Persons (TP-1, TP-2, TP-4, TP-5) responsible for moderate complexity testing in 2021 and 2022. Findings included: 1. Review of the laboratory's policies revealed the laboratory did NOT have a policy for performing competency assessments for testing personnel. Refer to D6030. 2. Review of personnel records for TP-1 revealed there was no annual competency assessment performed in 2021 and 2022 for the Opti CCA TS blood gas analyzer, Alere Triage Meter and the MedTox urine drug screen test kit. Review of personnel records for TP-2 revealed there was no annual competency assessment performed in 2022 for the Opti CCA TS blood gas analyzer, Alere Triage Meter and the MedTox urine drug screen test kit. Review of personnel records for TP-4 revealed there was no annual competency assessment performed in 2022 for the Opti CCA TS blood gas analyzer, Alere Triage Meter and the MedTox urine drug screen test kit. Review of personnel records for TP-5 revealed there was no annual competency assessment performed in 2021 and 2022 for the Opti CCA TS blood gas analyzer, Alere Triage Meter and the MedTox urine drug screen test kit. 3. During an interview on 10/26/2022 at 9:50 am, the Laboratory Director confirmed the above findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the instrument verification studies, personnel files, and confirmed in interview, the Technical Consultant failed to evaluate and document the performance of 5 of 5 testing personnel following the implementation of a new test methodology in February 2022. The findings included: 1. Review of the verification studies revealed the addition of QIAstat DX analyzer in February 2022: 2. Review of testing personnel files indicated that testing performance had not been evaluated and documented prior to reporting patient test results for Testing Persons 1, 2, 3, 4 and 5.

	3. During an interview at 10:00 am on 10/26/2022, Testing Person 1 confirmed the Technical Consultant did not document testing personnel performance for the new test methodologies prior to reporting patient results in 2022.