Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0485200	**(X3) Date Survey Completed** 10/03/2023
Name of Provider or Supplier Glen Rose Medical Center	**Street Address, City, State** 1021 Holden Street, Glen Rose, 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	The laboratory was surveyed in response to complaint TX for compliance with CMS 42CFR regulations. Complaint TX00471994 was substantiated. CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.801 Enrollment and testing of [proficiency testing] samples 493.1441 Laboratory Director, high complexity 493.1447 Technical Supervisor
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory ' s proficiency testing (PT) policy, American Proficiency Testing (API) User Guide, PT records, laboratory records, Centers for Medicare and Medicaid Services (CMS) 209 form, and confirmed in interview, the laboratory failed to meet the requirements of participating in PT for the specialty of Hematology. The laboratory did not ensure proficiency testing samples were tested as required and engaged in any inter-laboratory communications pertaining to the results of proficiency testing samples. Refer to D2011 and D2013.
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:
Based on review of laboratory ' s proficiency testing (PT) policy, American Proficiency Testing (API) User Guide, PT records, laboratory records, Centers for Medicare and Medicaid Services (CMS) 209 form, and confirmed in interview, the laboratory engaged in inter-laboratory communications with another laboratory Glen Rose Medical Center Pecan Location(CLIA #45D1071102) prior to their submission for 3 of 5 testing events in 2022 and 2023 (2022 Event 3, 2023 Events 1 and 2). The laboratory manager had access to and knowledge of the PT results for both locations. Findings included: 1. The laboratory's PT policy "Proficiency Testing" revealed: "III. Proficiency Testing Requirements ... D. GRMC and PFC laboratories are not in any way permitted to send PT samples to another laboratory for analysis. This includes sending samples back and forth to each other. Each lab is enrolled separately in the PT program and must not test samples for or send samples to the other laboratory until after the result submission deadline for that testing event has passed. E. GRMC and PFC laboratories are not in any way permitted to communicate with another laboratory about the PT results. This includes communicating about PT results back and forth with each other. Each lab is enrolled separately in the PT program and must not share results with the other laboratory until after the result submission deadline has passed. F. It is the responsibility of GRMC Lab as well as PFC Lab to notify Centers for Medicare & Medicaid Services (CMS) and the Joint commission of proficiency testing samples received from another laboratory." 2. Review of API's User Guide revealed: "Treatment of Proficiency Testing Samples Proficiency testing samples should be treated in the same manner as patient samples. According to CMS, "this means testing the PT [proficiency testing] samples the same number of times you would patient specimens, by the same personnel that routinely test the patient specimens, and using the same test system, including analyzer and reagents, that is routinely used for the patient specimens. PT samples should be rotated among the testing personnel in your laboratory." Please note: For CMS/CLIA-regulated laboratories, do not refer any of your proficiency testing samples to another laboratory, even in cases where you would normally do so with a patient specimen." 3. According to PT records, the laboratory, Glen Rose Medical Center (GRMC) (CLIA #45D0485200), was enrolled in American Proficiency Testing (API) PT program in 2022 for Hematology/Coagulation event: 3 and in 2023 for Hematology /Coagulation events: 1 and 2. According to PT records, the laboratory, Glen Rose Medical Center Pecan Location (GRMCPL) (45D1071102), was enrolled in American Proficiency Testing (API) PT program in 2022 for Hematology/Coagulation event: 3 and in 2023 for Hematology/Coagulation events: 1 and 2. 4. Further review of PT records obtained from the laboratories revealed: GRMC 2022 Hematology /Coagulation Event 3(Kit 1; Seq # 14826), original evaluation electronically submitted: 11/30/2022 4:57 p.m. included the following analytes and samples: Analyte: Blood Cell ID (CMS Scored) (#224 +Photos) "224+Photos" were photo images included in the API PT testing package Samples: BCI-11 through BCI-15; ECI-11 through ECI-15 GRMCPL 2022 Hematology/Coagulation Event 3(Kit 1; Seq

12977), original evaluation electronically submitted: 11/30/2022 4:54 p.m. included the following analytes and samples: Analyte: Blood Cell ID (CMS Scored) (Virtual Only) "Virtual Only" were digital images accessed through the API portal Samples: BCI-11 through BCI-15; ECI-11 through ECI-15 The following were the results submitted for both locations: Analyte/Method: Blood Cell Identification BCI-11: Nucleated red blood cell BCI-12: Monocyte BCI-13: Basophil, all stages BCI-14: Neutrophil, segmented BCI-15: Neutrophil, band (stab) Analyte/Method: Blood Cell ID (Educational) ECI-11: Neutrophil, hypersegmented ECI-12: Polychromatophilic RBC ECI-13: Red blood cell, normal ECI-14: Lymphocyte, normal ECI-15: Monocyte GRMC 2023 Hematology/Coagulation Event 1 (Kit 1; Seq # 14782), original evaluation electronically submitted: 03/29/2023 3:42 p.m. included the following analytes and samples: Analyte: Microscopy Package (#233 + Photos) Samples: US-01; US-02 Analyte: Blood Cell ID (CMS Scored) (#244 + Photos) "223+Photos" and "224+Photos" were photo images included in the API PT testing package Samples: BCI-01 through BCI-05; DIF-01 (virtual only); ECI-01 through ECI-05 "Virtual Only" were digital images accessed through the API portal GRMCPL 2023 Hematology/Coagulation Event 1 (Kit 1; Seq # 12910), original evaluation electronically submitted: 03/29/2023 2:27 p.m. included the following analytes and samples: Analyte: Microscopy Samples: US-01; US-02 Analyte: Blood Cell ID (CMS Scored) (Virtual Only) "Virtual Only" were digital images accessed through the API portal Samples: BCI-01 through BCI-05; DIF-01 (virtual only); ECI-01 through ECI-05 The following were identical results submitted for both locations: Analyte/Method: Urine Sediment US-01: Uric acid crystal(s) US-02: Yeast Analyte/Method: Blood Cell Identification BCI-01: Target cell (codocyte) BCI-02: Neutrophil, segmented BCI-03: Monocyte BCI-04: Lymphocyte, normal BCI-05: Polychromatophilic RBC Analyte/Method: Immature Cell (DIF) (%) DIF-01: 57 Analyte/Method: Lymphocyte (DIF) (%) DIF-01: 30 Analyte/Method: Monocyte (DIF) (%) DIF-01: 4 Analyte /Method: Neutrophil, band (DIF) (%) DIF-01: 6 Analyte/Method: Neutrophil, segmented (DIF) (%) DIF-01: 3 Analyte/Method: Blood Cell ID (Educational) ECI-01: Blast ECI-02: Neutrophil, band (stab) ECI-03: Blast ECI-04: Dacrocyte (tear-drop cell) ECI-05: Neutrophil with toxic gran GRMC 2023 Hematology/Coagulation Event 2 (Kit 1; Seq # 14789), original evaluation electronically submitted: 08/01/2023 4:16 p.m. included the following analytes and samples: Analyte: Microscopy Package (#233 + Photos) Samples: US-03; US-04 Analyte: Blood Cell ID (CMS Scored) (#244 + Photos) "223+Photos" and "224+Photos" were photo images included in the API PT testing package Samples: BCI-06 through BCI-10; DIF-02 (virtual only); ECI-06 through ECI-10 "Virtual Only" were digital images accessed through the API portal GRMCPL 2023 Hematology/Coagulation Event 2 (Kit 1; Seq # 13151), original evaluation electronically submitted: 08/01/2023 4:44 p.m. included the following analytes and samples: Analyte: Microscopy Samples: US-03; US-04 Analyte: Blood Cell ID (CMS Scored) (Virtual Only) "Virtual Only" were digital images accessed through the API portal Samples: BCI-06 through BCI-10; DIF-02 (virtual only); ECI-06 through ECI-10 The following were identical results submitted: Analyte/Method: Urine Sediment US-03: Calcium oxalate crystal(s) US-04: WBCs (Leukocytes) Analyte/Method: Blood Cell Identification BCI-06: Neutrophil, band (stab) BCI-07: Monocyte BCI-08: Metamyelocyte (juvenile) BCI-09: Eosinophil, all stages BCI-10: Neutrophil, segmented Analyte/Method: Eosinophil (DIF) (%) DIF-02: 4 Analyte /Method: Lymphocyte (DIF) (%) DIF-02: 11 Analyte/Method: Lymphocyte reactive (DIF) (%) DIF-02: 10 Analyte/Method: Monocyte (DIF) (%) DIF-02: 6 Analyte /Method: Neutrophil, band (DIF) (%) DIF-02: 2 Analyte/Method: Neutrophil, segmented (DIF) (%) DIF-02: 67 Analyte/Method: Platelet estimate (DIF) DIF-02: Adequate, normal Analyte/Method: Blood Cell ID (Educational) ECI-06: Lymph, reactive (atyp, variant) ECI-07: Neutrophil, segmented ECI-08: Red blood cell,

normal ECI-09: Platelets, normal ECI-10: Neutrophil with toxic gran 5. Review of laboratory records from the laboratory's LIS system revealed an " API Samples Report" that was used to enter raw data for test results of PT samples for Hematology /Coagulation 2022 Event 3, Hematology/Coagulation 2023 Events 1 and 2. The API Samples Report revealed a "Draw Location". The draw location was GRMC. 6. Review of the GRMCPL API attestation forms for Hematology/Coagulation 2022 Event 3 revealed seven testing personnel who attested to performing PT testing. Five of the seven individuals were NOT testing personnel listed on the CMS 209 form as testing personnel for this facility, GRMCPL. Review of the GRMCPL API attestation forms for Hematology/Coagulation 2023 Event 1 revealed eight testing personnel who attested to performing PT testing. Five of the eight individuals were NOT testing personnel listed on the CMS 209 form as testing personnel for this facility, GRMCPL. Review of the GRMCPL API attestation forms for Hematology/Coagulation 2023 Event 2 revealed no attestation form. The laboratory was asked to provide a copy, and none was provided. 7. A review of the CMS 209 form for GRMC revealed the following testing personnel who attested to performing PT for both facilities: 2022 Hematology/Coagulation Event 3 TP-1; samples: ECI-12 TP-11; samples: BCI-11, ECI-14 TP-5; samples: BCI-12, ECI-15 TP-4; samples: BCI-13 TP-3; samples: BCI-14 TP-2; samples: BCI-15 TP-7; samples: ECI-11, ECI-13 2023 Hematology /Coagulation Event 1 TP-2; samples: ECI-01, US-02 TP-8; samples: US-01 TP-5; samples: ECI-03 TP-4; samples: BCI-05 TP-1; samples: BCI-04, ECI-05 TP-9; samples: BCI-03 TP-6; samples: BCI-02 Samples: ECI-02, DIF-01, BCI-02 were performed by a terminated testing person who was not listed on the CMS 209 2023 Hematology/Coagulation Event 2 (GRMC only) TP-10; samples: BCI-06, ECI-06 TP-1; samples: DIF-02 TP-6; samples: ECI-07, US-04 TP-7; samples: BCI-07, ECI-10 TP-2; samples: BCI-10 TP-5; samples: BCI-09, ECI-09 TP-3; samples: BCI-08, ECI-08 7. During an interview in the break room of Glen Rose Medical Center Pecan Location (45D1071102) on 09/06/2023 at 11:00 am, the Technical Consultant-2 (TC-2) (as delegated on the CMS 209 form) was asked who the personnel were that signed the attestation forms and she stated that they were testing personnel from the laboratory's main facility Glen Rose Medical Center (CLIA #45D0485200). The TC-2 further stated that the testing for Hematology/Coagulation 2022 Event 1 and 2023 Events 1 and 2 were performed at facility Glen Rose Medical Center (CLIA #45D0485200). The TC-2 further stated that the laboratory had discontinued urine microscopic testing and blood smear differentials at the facility and those patient specimens requiring microscopic testing were sent to the hospital for testing. The TC-2 stated that she reached out to the accrediting agency for proficiency testing guidance for tests that were discontinued at the laboratory and sent to another facility for testing. According to the TC-2 she was told by the accrediting agency to treat her PT like she treated her patients. Therefore, she took the PT package to GRMC for testing. Laboratory testing personnel at GRMC logged into the API portal to complete the virtual image PT for 2022 Event 3 and 2023 Events 1 and 2. All PT results for GRMCPL were submitted at GRMC. During an interview in the board room of GRMC on 10/03/2023 at 11:00 am, Testing Person-4 (TP-4) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, "No." TP-4 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, "Yes ma'am." During a telephone interview in the board room of GRMC on 10/03/2023 at 11:25 am, Testing Person-6 (TP-6) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, "No, I work at the hospital." TP-6 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, "Yes." During a telephone interview in the board room of GRMC on 10/03/2023 at 11:29 am, Testing Person-3 (TP-3) (as designated

	on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, "I have never been to the clinic." TP-3 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, "PT was performed at Glen Rose Medical Center, absolutely." During a telephone interview in the board room of GRMC on 10/03/2023 at 11:34 am, Testing Person-7 (TP-7) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, "No." TP-7 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, "Yes." During a telephone interview in the board room of GRMC on 10/03 /2023 at 11:44 am, Testing Person-8 (TP-8) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, "Yes." TP-8 stated that she worked at GRMCPL on Friday's or as needed and she believed the urine microscopy PT at this location, GRMCPL. TP-8 was asked if the PT testing for GRMCPL was performed at GRMCPL and she stated, PT for blood cell identification was performed at GRMC. During a telephone interview in the board room of GRMC on 10/03/2023 at 11:51 am, Testing Person-10 (TP-10) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if he had ever been toGRMCPL to perform proficiency testing and he stated, "No." TP-10 was asked if the PT testing for GRMCPL was performed at GRMC and he stated, "Yes." During a telephone interview in the board room of GRMC on 10/03/2023 at 1:02 pm, Testing Person-11 (TP-11) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, that it had been more than two years since she worked at that location. TP-11 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, "Yes." During an interview in the board room of GRMC on 10/03/2023 at 12:01 pm, Testing Person-1/Technical Supervisor-2 (TP-1/TS-2) (as designated on the CMS 209 form for CLIA #45D0485200) stated "I 100% take ownership for the PT." "I was trying to finish up fast and was having issues logging into API to discontinue testing." She further stated that patient testing for urine microscopy and blood cell identification had been discontinued at GRMCPL in early 2023. TP-1/TS-2 stated that there was no attestation form for 2023 Hematology/Coagulation Event 2 because she used the answers from GRMC for GRMCPL. TP-1/TS-2 stated, "It was the exact same picture." TP-1/TS-2 revealed that the PT for GRMCPL was not entered into the laboratory's LIS system since testing was no longer being performed there. She stated that for the above-mentioned Hematology/Coagulation 2022 Event 3, 2023 Events 1 and 2 the responses for GRMCPL and GRMC were identical. TP-1/TS-2 logged into the API portal at GRMC and used the responses from testing personnel at GRMC to enter the PT responses for GRMCPL. Note: TP-1/TS-2 was also the TC-2/TP-1 for GRMCPL. 9. As confirmed above, the laboratory engaged in inter-laboratory communication with both sister laboratories (Glen Rose Medical Center CLIA #45D0485200 and Glen Rose Medical Center Pecan Location 45D1071102) prior to the November 30, 2022 submission cutoff date for Hematology/Coagulation testing events in 2022 (Event 3), March 29, 2023 submission cutoff date for Hematology /Coagulation testing events in 2023 (Event 1) and August 2, 2023 submission cutoff date Hematology/Coagulation testing events in 2023 (Event 2). Word Key: BCI- blood cell identification DIF- differential ECI- educational blood cell identification US: urine sediment LIS: laboratory information system TP- testing person
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency

testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on review of laboratory ' s proficiency testing (PT) policy, American Proficiency Testing (API) User Guide, PT records, laboratory records, Centers for Medicare and Medicaid Services (CMS) 209 form, and confirmed in interview, the laboratory received Hematology PT samples from another laboratory for analysis for 3 of 5 testing events in 2022 and 2023 (2022 Event 3, 2023 Events 1 and 2). Findings included: 1. The laboratory's PT policy "Proficiency Testing" revealed: "III. Proficiency Testing Requirements ... D. GRMC and PFC laboratories are not in any way permitted to send PT samples to another laboratory for analysis. This includes sending samples back and forth to each other. Each lab is enrolled separately in the PT program and must not test samples for or send samples to the other laboratory until after the result submission deadline for that testing event has passed. E. GRMC and PFC laboratories are not in any way permitted to communicate with another laboratory about the PT results. This includes communicating about PT results back and forth with each other. Each lab is enrolled separately in the PT program and must not share results with the other laboratory until after the result submission deadline has passed. F. It is the responsibility of GRMC Lab as well as PFC Lab to notify Centers for Medicare & Medicaid Services (CMS) and the Joint commission of proficiency testing samples received from another laboratory." 2. Review of API's User Guide revealed: "Treatment of Proficiency Testing Samples ... Please note: For CMS/CLIA-regulated laboratories, do not refer any of your proficiency testing samples to another laboratory, even in cases where you would normally do so with a patient specimen." 3. According to PT records, the laboratory was enrolled in American Proficiency Testing (API) PT program in 2022 for Hematology /Coagulation event: 3 and in 2023 for Hematology/Coagulation events: 1 and 2. 4. Further review of PT records obtained from the laboratory revealed: 2022 Hematology /Coagulation Event 3(Kit 1; Seq # 14826), original evaluation electronically submitted: 11/30/2022 4:57 p.m. included the following analytes and samples: Analyte: Blood Cell ID (CMS Scored) (#224 + pictures) "224+Photos" were photo images included in the API PT testing package Samples: BCI-11 through BCI-15; ECI-11 through ECI-15 The following were the results submitted: Analyte/Method: Blood Cell Identification BCI-11: Nucleated red blood cell BCI-12: Monocyte BCI-13: Basophil, all stages BCI-14: Neutrophil, segmented BCI-15: Neutrophil, band (stab) Analyte/Method: Blood Cell ID (Educational) ECI-11: Neutrophil, hypersegmented ECI-12: Polychromatophilic RBC ECI-13: Red blood cell, normal ECI-14: Lymphocyte, normal ECI-15: Monocyte 2023 Hematology/Coagulation Event 1 (Kit 1; Seq # 14782), original evaluation electronically submitted: 03/29/2023

3:42 p.m. included the following analytes and samples: Analyte: Microscopy Package (#233 + Photos) Samples: US-01; US-02 Analyte: Blood Cell ID (CMS Scored) (#244 + Photos) "223+Photos" and "224+Photos" were photo images included in the API PT testing package Samples: BCI-01 through BCI-05; DIF-01 (virtual only); ECI-01 through ECI-05 "Virtual Only" were digital images accessed through the API portal The following were the results submitted: Analyte/Method: Urine Sediment US-01: Uric acid crystal(s) US-02: Yeast Analyte/Method: Blood Cell Identification BCI-01: Target cell (codocyte) BCI-02: Neutrophil, segmented BCI-03: Monocyte BCI-04: Lymphocyte, normal BCI-05: Polychromatophilic RBC Analyte/Method: Immature Cell (DIF) (%) DIF-01: 57 Analyte/Method: Lymphocyte (DIF) (%) DIF-01: 30 Analyte/Method: Monocyte (DIF) (%) DIF-01: 4 Analyte/Method: Neutrophil, band (DIF) (%) DIF-01: 6 Analyte/Method: Neutrophil, segmented (DIF) (%) DIF-01: 3 Analyte/Method: Platelet estimate (DIF) DIF-03: Decreased Analyte/Method: Blood Cell ID (Educational) ECI-01: Blast ECI-02: Neutrophil, band (stab) ECI-03: Blast ECI-04: Dacrocyte (tear-drop cell) ECI-05: Neutrophil with toxic gran 2023 Hematology/Coagulation Event 2 (Kit 1; Seq # 14789), original evaluation electronically submitted: 08/01/2023 4:16 p.m. included the following analytes and samples: Analyte: Microscopy Package (#233 + Photos) Samples: US-03; US-04 Analyte: Blood Cell ID (CMS Scored) (#244 + Photos) "223+Photos" and "224+Photos" were photo images included in the API PT testing package Samples: BCI-06 through BCI-10; DIF-02 (virtual only); ECI-06 through ECI-10 "Virtual Only" were digital images accessed through the API portal The following were the results submitted: Analyte/Method: Urine Sediment US-03: Calcium oxalate crystal(s) US-04: WBCs (Leukocytes) Analyte/Method: Blood Cell Identification BCI-06: Neutrophil, band (stab) BCI-07: Monocyte BCI-08: Metamyelocyte (juvenile) BCI-09: Eosinophil, all stages BCI-10: Neutrophil, segmented Analyte/Method: Eosinophil (DIF) (%) DIF-02:4 Analyte/Method: Lymphocyte (DIF) (%) DIF-02: 11 Analyte /Method: Lymphocyte reactive (DIF) (%) DIF-02: 10 Analyte/Method: Monocyte (DIF) (%) DIF-02: 6 Analyte/Method: Neutrophil, band (DIF) (%) DIF-02: 2 Analyte /Method: Neutrophil, segmented (DIF) (%) DIF-02: 67 Analyte/Method: Platelet estimate (DIF) DIF-02: Adequate, normal Analyte/Method: Blood Cell ID (Educational) ECI-06: Lymph, reactive (atyp, variant) ECI-07: Neutrophil, segmented ECI-08: Red blood cell, normal ECI-09: Platelets, normal ECI-10: Neutrophil with toxic gran 5. Review of laboratory records from the laboratory's LIS system revealed an " API Samples Report" that was used to enter raw data for test results of PT samples for Hematology/Coagulation 2022 Event 3, Hematology/Coagulation 2023 Events 1 and 2. The API Samples Report revealed a "Draw Location". The draw location was Glen Rose Medical Center (GRMC) (CLIA #45D0485200). 6. Review of the Glen Rose Medical Center Pecan Location (GRMCPL) (45D1071102) API attestation forms for Hematology/Coagulation 2022 Event 3 revealed seven testing personnel who attested to performing PT testing. Five of the seven individuals were NOT testing personnel listed on the CMS 209 form as testing personnel for this facility, GRMCPL Review of the GRMCPL API attestation forms for Hematology /Coagulation 2023 Event 1 revealed eight testing personnel who attested to performing PT testing. Five of the eight individuals were NOT testing personnel listed on the CMS 209 form as testing personnel for this facility, GRMCPL. Review of the GRMCPL API attestation forms for Hematology/Coagulation 2023 Event 2 revealed no attestation form. The laboratory was asked to provide a copy, and none was provided. 7. A review of the CMS 209 form for GRMC revealed the following testing personnel who attested to performing PT for both facilities: 2022 Hematology /Coagulation Event 3 TP-1; samples: ECI-12 TP-11; samples: BCI-11, ECI-14 TP-5; samples: BCI-12, ECI-15 TP-4; samples: BCI-13 TP-3; samples: BCI-14 TP-2; samples: BCI-15 TP-7; samples: ECI-11, ECI-13 2023 Hematology/Coagulation

Event 1 TP-2; samples: ECI-01, US-02 TP-8; samples: US-01 TP-5; samples: ECI-03 TP-4; samples: BCI-05 TP-1; samples: BCI-04, ECI-05 TP-9; samples: BCI-03 TP-6; samples: BCI-02 Samples: ECI-02, DIFF-01, BCI-02 were performed by a terminated testing person who was not listed on the CMS 209 2023 Hematology/Coagulation Event 2 (attestation for GRMC only) TP-10; samples: BCI-06, ECI-06 TP-1; samples: DIFF-02 TP-6; samples: ECI-07, US-04 TP-7; samples: BCI-07, ECI-10 TP-2; samples: BCI-10 TP-5; samples: BCI-09, ECI-09 TP-3; samples: BCI-08, ECI-08 8. During an interview in the break room of GRMCPL on 09/06/2023 at 11:00 am, the Technical Consultant-2 (TC-2) (as delegated on the CMS 209 form) was asked who the personnel were that signed the attestation forms and she stated that they were testing personnel from the laboratory's main facility GRMC. The TC-2 further stated that the testing for Hematology/Coagulation 2022 Event 1 and 2023 Events 1 and 2 were performed at facility GRMC. The TC-2 further stated that the laboratory had discontinued urine microscopic testing and blood smear differentials at the facility and those patient specimens requiring microscopic testing were sent to the hospital for testing. The TC-2 stated that she reached out to the accrediting agency for proficiency testing guidance for tests that were discontinued at the laboratory and sent to another facility for testing. According to the TC-2 she was told by the accrediting agency to treat her PT like she treated her patients. Therefore, she took the PT package to GRMC for testing. Laboratory testing personnel at GRMC logged into the API portal to complete the virtual image PT for 2022 Event 3 and 2023 Events 1 and 2. All PT results for GRMCPL were submitted at GRMC. During an interview in the board room of GRMC on 10/03/2023 at 11:00 am, Testing Person-4 (TP-4) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, "No." TP-4 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, "Yes ma'am." During a telephone interview in the board room of GRMC on 10/03/2023 at 11:25 am, Testing Person-6 (TP-6) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, "No, I work at the hospital." TP-6 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, "Yes." During a telephone interview in the board room of GRMC on 10/03/2023 at 11:29 am, Testing Person-3 (TP-3) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, "I have never been to the clinic." TP-3 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, "PT was performed at Glen Rose Medical Center, absolutely." During a telephone interview in the board room of GRMC on 10/03/2023 at 11:34 am, Testing Person-7 (TP-7) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, "No." TP-7 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, "Yes." During a telephone interview in the board room of GRMC on 10/03/2023 at 11:44 am, Testing Person-8 (TP-8) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, "Yes." TP-8 stated that she worked at GRMCPL on Friday's or as needed and she believed the urine microscopy PT at this location, GRMCPL. TP-8 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, PT for blood cell identification was performed at GRMC. During a telephone interview in the board room of GRMC on 10/03/2023 at 11:51 am, Testing Person-10 (TP-10) (as designated on the CMS 209 form for CLIA #45D0485200) was asked if he had ever been to GRMCPL to perform proficiency testing and he stated, "No." TP-10 was asked if the PT testing for GRMCPL was performed at GRMC and he stated, "Yes." During a telephone interview in the board room of GRMC on 10/03/2023 at 1:02 pm, Testing Person-11 (TP-11) (as designated

	on the CMS 209 form for CLIA #45D0485200) was asked if she had ever been to GRMCPL to perform proficiency testing and she stated, that it had been more than two years since she worked at that location. TP-11 was asked if the PT testing for GRMCPL was performed at GRMC and she stated, "Yes." During an interview in the board room of GRMC on 10/03/2023 at 12:01 pm, Testing Person-1/Technical Supervisor-2 (TP-1/TS-2) (as designated on the CMS 209 form for CLIA #45D0485200) stated "I 100% take ownership for the PT." "I was trying to finish up fast and was having issues logging into API to discontinue testing." She further stated that patient testing for urine microscopy and blood cell identification had been discontinued at GRMCPL in early 2023. TP-1/TS-2 stated that there was no attestation form for 2023 Hematology/Coagulation Event 2 because she used the answers from GRMC for GRMCPL. TP-1/TS-2 stated, "It was the exact same picture." TP-1/TS-2 revealed that the PT for GRMCPL was not entered into the laboratory's LIS system since testing was no longer being performed there. She stated that for the above-mentioned Hematology/Coagulation 2022 Event 3, 2023 Events 1 and 2 the responses for GRMCPL and GRMC were identical. TP-1/TS-2 logged into the API portal at GRMC and used the responses from testing personnel at GRMC to enter the PT responses for GRMCPL. This confirmed the above findings. Note: TP-1 /TS-2 was also the TC-2/TP-1 for GRMCPL. Word Key: BCI- blood cell identification DIF- differential ECI- educational blood cell identification US: urine sediment LIS: laboratory information system TP- testing person
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory ' s proficiency testing (PT) policy, American Proficiency Testing (API) User Guide, PT records, laboratory records, Centers for Medicare and Medicaid Services (CMS) 209 form, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory ' s proficiency testing (PT) policy, American Proficiency Testing (API) User Guide, PT records, laboratory records, Centers for Medicare and Medicaid Services (CMS) 209 form, and confirmed in interview, the Laboratory Director did not ensure proficiency testing samples were tested as required and did not engage in any inter-laboratory communications pertaining to the results of proficiency testing samples. Refer to D2011 and D2013.
D6108	LABORATORY TECHNICAL SUPERVISOR

	CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory ' s proficiency testing (PT) policy, American Proficiency Testing (API) User Guide, PT records, laboratory records, Centers for Medicare and Medicaid Services (CMS) 209 form, and confirmed in interview, it was revealed that the Technical Supervisor failed to provide technical and scientific oversight. Refer to D6112.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory ' s proficiency testing (PT) policy, American Proficiency Testing (API) User Guide, PT records, laboratory records, Centers for Medicare and Medicaid Services (CMS) 209 form, and confirmed in interview, the Technical Supervisor failed to provide technical oversight, did not ensure proficiency testing samples were tested as required, and ensure the laboratory did not engage in any inter-laboratory communications pertaining to the results of proficiency testing samples. Refer to D2011 and D2013.