Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0478401	03/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ellis County Medical Associates, Pa	802 West Lampasas, Ennis, 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 Dallas Regional Office (RO) 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.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Academy of Family Physicians (AAFP) testing records, laboratory's CMS (Centers for Medicare & Medicaid Services) 209 form, and staff interview, the laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory for 3 of 3 events in 2021 (Event A, B, C). Findings: 1. Review of the laboratory's policy titled "PROFICIENCY SURVEYS" signed by the laboratory director on 08/01/2016 stated: "PROCEDURE Receipt of

	Survey Kits ... 6. Survey completion should be rotated among the employees of the lab so that no one person is completing the same challenges with each kit." 2. Review of the AAFP testing records revealed Testing Person-1 (TP-1) tested the following events: Hematology 2021 Event A, B and C 3. Review of the laboratory's CMS 209 form revealed two Testing Persons (TP-1, TP-2) were listed as performing moderate complexity testing (hematology). Testing Person-1 (TP-1) Hire date: 06/11/2012 Testing Person-2 (TP-2) Hire date: 07/09/2020 TP-2 performed testing of patient specimens and did NOT participate in PT events. 4. During an interview on 03/01 /2022 at 10:12 am, TP-1 confirmed TP-2 had not participated in PT. The laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Academy of Family Physicians (AAFP) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to review and evaluate the results obtained on proficiency testing (PT) for hematology results for 2 of 3 events in 2020 (Event A, C) and 3 of 3 events in 2021 (Event A, B, C). Findings: 1. Review of the laboratory's policy titled "PROFICIENCY SURVEYS" signed by the laboratory director on 08/01/2016 stated: "PROCEDURE ... Results from the Survey ... 3. Results are reviewed and signed by the Laboratory Manager and the Laboratory Director. All results are reviewed and discussed with the Technical staff." 2. Review of AAFP PT records for 2020 and 2021 revealed the laboratory did not ensure the laboratory manager and the laboratory director documented their review/evaluation of hematology PT results, as follows: Hematology 2020 Event A & C 2021 Event A, B & C Note: The laboratory did not participate in the hematology Event B for 2020. 3. During an interview on 03/01/2022 at 10:12 am, TP-1 confirmed the above findings.
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 the CMS (Centers for Medicaid & Medicare Services) 116 form, laboratory policy, American Academy of Family Physicians ((AAFP) proficiency testing records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated urine microscopy procedures at least twice annually for 1 of 1 testing events in 2020 and 3 of 3 testing events in 2021. Findings: 1. Review of the CMS-116 form submitted on the day of the survey by the laboratory revealed the laboratory performed urine microscopy procedures. 2. Review of the laboratory's policy titled "PROFICIENCY SURVEYS" signed by the laboratory director on 08/01 /2016 stated: "PROCEDURE ... Results from the Survey ... 3. Results are reviewed and signed by the Laboratory Manager and the Laboratory Director. All results are

	reviewed and discussed with the Technical staff." 3. Review of the laboratory's AAFP PT records revealed the laboratory performed proficiency testing events for urine microscopy procedures as follows: Review of Event A in 2020 revealed the following scores: Urine Sediment ID, score 100% Review of Event A in 2021 revealed the following scores: Urine Sediment ID, score 100% Review of Event B in 2021 revealed the following scores: Urine Sediment ID, score 100% Review of Event C in 2021 revealed the following scores: Urine Sediment ID, score 100% There was NO documentation of the results being evaluated by the Technical Consultant (who was also the laboratory director) for accuracy for urine microscopy procedures for the events in 2020 and 2021. The laboratory failed to verify the accuracy of urine microscopy procedures at least twice annually in 2020 and 2021. 4. During an interview on 03/01/2022 at 10:12 am, TP-1 confirmed the above findings.
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 direct observation, review of the manufacturer's instructions, and confirmed in interview, the laboratory failed to have documentation of the revised expiration date for the in-use COULTER AcT 5diff quality control reagents for 3 of 3 reagents. Findings: 1. Review of the COULTER AcT 5diff quality control package insert revealed: "Open Vial Stability 15 days" 2. During a tour of the laboratory on 03/01 /2022 at 12:38 pm, the following COULTER AcT 5diff controls were observed to be stored in the reagent refrigerator with an open date of 02/21/2022 and no revised expiration date: 1 COULTER AcT 5diff low control lot# 360122, manufacturer expiration date 03/05/2022 1 COULTER AcT 5diff normal control lot# 370122, manufacturer expiration date 03/05/2022 1 COULTER AcT 5diff high control lot# 380122, manufacturer expiration date 03/05/2022 3. During an interview on 03/01 /2022 at 12:38 pm, Testing Person-2 was asked when the opened vials of the COULTER AcT 5diff control material expired, and she stated: "14 days". During the exit interview on 03/01/2022 at 1:35 pm, the Testing Person-1 confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, manufacturer's package inserts, LIS (laboratory information system) quality control (QC) files, and staff interview, the laboratory failed to have a system in place to monitor errors over time for accuracy and precision for the Coulter AcT 5diff test performance with accurate statistical parameters. Findings: 1. Review of the laboratory's policy "ESTABLIHSING/MONITORING QUALITY CONTROL RANGES FOR ACT5DIFF CP COUTLER [sic] ACT5DIFF CONTROL PLUS" stated: "PROCEDURE It is recommended that each laboratory verify the mean supplied by the manufacturer for the assayed materials. 1. Set up the controls in the Laboratory LIS system and ACT5diff instrument using the ranges in the package insert to follow manufactures guidelines ... 2. QC is reviewed weekly by the lab manager reviewing the L-J charts. When reviewing the L-J charts look for shifts or trends. Shifts- an abrupt change is followed by six or more consecutive QC results that fall on one side of the mean. Trends- values gradually, but continually move in one direction over six or more analytical runs. Monthly, the QC results are submitted to the Beckman Coulter QC program. The QC program allows your controls to be put into a pool with your peers who use the same material and or instrument." 2. Review of the current package insert for Coulter AcT 5diff Controls put into laboratory use on 01/26/2022 revealed the following acceptable limits for each level of control: Control Level Low; Lot# 360122; Expiration date 03/05/2022 Limits: WBC 2.2-3.0 RBC 2.20-2.44 HGB 5.5-6.3 HCT 15.7-18.7 MCV 69-79 MCH 23.4-27.4 MCHC 31.4-37.4 RDW 12.0-20.0 PLT 45-85 MPV 7.5-11.5 NE% 50.0-70.0 LY% 22.5-38.5 MO% 0.0-3.0 EO% 0.0-16.0 BA% 58.5-76.5 Control Level Normal; Lot# 370122; Expiration Date 03/05/2022 Limits: WBC 7.0-9.0 RBC 4.34-4.64 HGB 12.7-13.7 HCT 35.3-39.3 MCV 78-88 MCH 27.4-31.4 MCHC 32.4-38.4 RDW 9.5-17.5 PLT 211-271 MPV 7.0-2.0 NE% 56.0-76.0 LY% 21.0-37.0 MO% 0.0-3.0 EO% 0.0-7.0 BA% 57.0-77.0 Control Level High; Lot# 380122; Expiration Date 03/05/2022 Limits: WBC 16.2-20.2 RBC 4.90-5.30 HGB 16.2-17.4 HCT 44.4-49.4 MCV 87-97 MCH 30.4-35.4 MCHC 33.8-38.8 RDW 7.8-15.8 PLT 450-550 MPV 7.0-11.0 NE% 69.0-89.0 LY% 6.5-22.5 MO% 0.0-3.0 EO% 0.0-10.0 BA% 78.5-94.5 3. During an interview on 03/01/2022 at 11:32 am, Testing Person-1 (TP-1) stated that day to day QC acceptability was verified on the Beckman Coulter hematology analyzer, but QC was monitored over time for accuracy and precision using the Levy-Jennings (L-J) charts from the laboratory's LIS reports. The following laboratory LIS "Quality Control Files" revealed the limits used to monitor the accuracy and precision of the Coulter AcT 5diff hematology analyzer were based on a 4 SD (standard deviation): Control Level Low; Lot# 360122; Expiration date 03/05/2022 Limits: WBC 1.80-3.40 RBC 2.08-2.56 HGB 5.10-6.70 HCT 14.20-20.20 MCV 64.00-84.00 MCH 21.40-29.40 MCHC 28.40-40.40 RDW 8.00-24.00 PLT 25.00-105.00 MPV 5.50-13.50 NE% 40.00-80.00 LY% 14.50-46.50 MO% -1.50-4.50 EO% -8.0-24.00 BA% 49.50-85.50 Control Level Normal; Lot# 370122; Expiration Date 03/05/2022 Limits: WBC 6.00-10.00 RBC 4.19-4.79 HGB 12.20-14.20 HCT 33.30-41.30 MCV 73.00-93.00 MCH 25.40-33.40 MCHC 29.40-41.40 RDW 5.50-21.50 PLT 181-301.00 MPV 5.00-13.00 NE% 46.00-86.00 LY% 13.00-45.00 MO% -1.50-4.50 EO% -3.50-10.50 BA% 50.00-86.00 Control Level High; Lot# 380122; Expiration Date 03/05/2022 Limits: WBC 14.20-23.00 RBC 4.70-5.50 HGB 15.60-18.00 HCT 41.90-51.90 MCV 82.00-102.00 MCH 27.90-37.90 MCHC 29.80-41.80 RDW 3.80-19.80 PLT 400.00-600.00 MPV 5.00-13.00 NE% 59.00-99.00 LY% -1.50-30.50 MO% -1.50-4.50 EO% -5.00-15.00 BA% 70.50-102.50 Because the facility failed to ensure that the statistical parameters (limits) for the 3 levels of hematology control material currently in use were programmed into the LIS correctly, the laboratory failed to have

	a system in place to monitor errors over time for accuracy and precision of Coulter AcT 5diff test performance. 4. The laboratory performs 18,600 hematology tests annually. 5. During an interview on 03/01/2022 at 11:32 am, TP-1 confirmed the above findings.
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 Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records and staff interview, the laboratory director failed to specify in writing the responsibilities and duties for2 of 2 Testing Persons (TP-1, TP-2) performing moderate complexity testing. Findings: 1. Review of the Centers for Medicare & Medicaid (CMS) 209 form revealed TP-1, TP-2 as testing persons performing moderately complex laboratory testing in the specialty of hematology. 2. The laboratory was asked to provide documentation of the delegation of responsibilities by the laboratory director for each testing person. No documentation was provided. 3. During an interview on 03/01/2022 at 10:59 am, TP-1 stated that there was no documentation of the delegation of responsibilities by the laboratory director for each testing person, confirming the findings.
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 review of Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records and staff interview, the technical consultant (who was also the laboratory director) failed to ensure that 1 of 2 Testing Persons (TP-2) received the appropriate training in moderate complexity testing (hematology) prior to patient testing. Findings: 1. Review of the Centers for Medicare & Medicaid (CMS) 209 form revealed TP-2 as a testing person performing moderately complex laboratory testing (hematology). 2. Review of personnel records revealed the following hire dates: TP-2: 07/09/2020 3. The laboratory was asked to provide documented training for TP-2 who

	performed complete blood count (CBC) testing on the Beckman Coulter AcT2 diff hematology analyzer. No documentation of training was provided. 4. During an interview on 03/01/2022 at 10:59 am, TP-1 confirmed the findings.