Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0482101	11/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Paris Family Physicians Pa	1128 Clarksville Street Suite 100, Paris, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of the attestation statement, the Operator's Guide for the Beckman Coulter AcT diff 2 hematology analyzer, a review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2019, 2020, and 2021, and staff interview, it was revealed the laboratory failed to have documentation of testing proficiency samples in the same manner it tested its patient samples for 7 of 9 events in 2019, 2020, and 2021 for Hematology testing. Findings include: 1. A review of the API's attestation statement, signed by the laboratory's testing personnel for each proficiency testing event, revealed the following: "Person Performing the Test: We certify that as closely as possible, these proficiency testing samples were tested in the same manner as patient samples." 2. A review of the Operator's Guide for the

	Beckman Coulter AcT diff 2 hematology analyzer (PN 42374958, August 2010) under the section titled "What Flags and Codes Mean" revealed the manufacturer provided actions to take when specific flags were identified on CBC results. For the flag of '*' the manufacturer stated: " '*'Possible sample handling problem. Possible dual RBC population. Possible interference with WBC count. Platelet distribution failure. Possible sample interference or instrument problem. See instructions for +++++, +, or -----." "---- Thoroughly mix and rerun the sample. If flag repeats then Zap the machine and do bleach bath. ++++ Zap and rerun samples. If flag is still present after the rerun Call tech support. XXXX Mix the sample with a wooden applicator and rerun. If repeats ZAP and do bleach bath. If continues call tech support. " 3. A review of the laboratory's API proficiency testing records for 2019, 2020, and 2021 revealed the following events/samples where the proficiency sample's results were flagged with a '*' by the analyzer and not repeated: a) 2019 Hematology /Coagulation 2nd Event Specimen 07: LY, MO, GR, LY#, MO#, GR# Specimen 08: LY, MO, GR, LY#, MO#, GR# Specimen 09: MO, MO# b) 2019 Hematology /Coagulation 3rd Event Specimen 11: LY, MO, GR, LY#, MO#, GR# Specimen 13: MO, MO# c) 2020 Hematology/Coagulation 1st Event Specimen 02: LY, MO, GR, LY#, MO#, GR# Specimen 03: LY, MO, GR, LY#, MO#, GR# Specimen 05: MO, MO# d) 2020 Hematology/Coagulation 2nd Event Specimen 06: LY, MO, GR, LY#, MO#, GR# Specimen 07: WBC, LY#, MO#, GR# Specimen 10: MO, MO# e) 2020 Hematology/Coagulation 3rd Event Specimen 12: MO, MO# Specimen 14: LY, MO, GR, LY#, MO#, GR# Specimen 15: LY, MO, GR, LY#, MO#, GR# f) 2021 Hematology/Coagulation 2nd Event Specimen 07: LY, MO, GR, LY#, MO#, GR# Specimen 08: MO, MO#, RDW Specimen 10: LY, MO, GR, LY#, MO#, GR# g) 2021 Hematology/Coagulation 3rd Event Specimen 12: MO, MO# Specimen 13: LY, MO, GR, LY#, MO#, GR# Specimen 15: LY, MO, GR, LY#, MO#, GR# 5. An interview with the technical consultant (as indicated on the CMS 209 form) on 11/4 /21 at 10:05 a.m. in the conference room, after review of the records, confirmed the above findings. Key: CBC = complete blood count WBC = white blood cell GR = granulocytes MO = monocytes, eosinophils, basophils Ly = lymphocytes
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing records and staff interview, it was revealed that the laboratory failed to attain a score of at least 80% for the analyte Thyroid Stimulating Hormone (TSH) in the second event in 2020. Findings include: 1. A review of the laboratory's API proficiency testing records revealed the laboratory received an unsatisfactory score of 60% for the analyte Thyroid Stimulating Hormone (TSH) for 2020 Chemistry - Core - second event. 2. An interview with the technical consultant (as indicated on the CMS 209 form) on 11/4/21 at 10:00 a.m. in the conference room, after review of the records, confirmed the above findings.