

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2211596	(X3) Date Survey Completed 05/17/2022
Name of Provider or Supplier Pafford Health Systems, Medical Clinic	Street Address, City, State 100 East 20th Street, Suite D, Hope, AR	
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	This is the CLIA initial survey of the laboratory. The following condition level deficiency was cited: 493.1250 - Analytic Systems
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Through a review of validation documentation for tests performed on the Triage instrument, through a review of quality control documentation for D-dimer and Cardiac Panel performed on the Alere Triage instrument, through a review of patient test records, a review of Solana assay documents, a review of patient and quality control documentation on the Solana instrument, through lack of documentation, and through interviews with laboratory staff, it was determined the laboratory failed to meet analytic systems requirements, as evidenced by: D5423 - the laboratory failed to validate normal ranges for the Triage test system D5447 - the laboratory failed to perform two levels of quality control each day patient specimens were tested D5449 - the laboratory failed to run negative controls for tests performed on the Solana test system each day of patient testing</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces</p>

a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Through a review of validation documentation for tests performed on the Triage instrument, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to validate normal ranges for the Triage test system. Survey findings include: A. The surveyor reviewed documentation presented as validation records for the Triage test system. During the review, the surveyor noted that there was no documentation of validation of normal ranges for the moderate complexity D-dimer or Cardiac Panel tests performed. B. In an interview, at 11:37 on 5/17/2022, the technical consultant (listed as #2 on the form CMS-209) stated there was no documentation available to indicate the laboratory validated the normal ranges in use on the Triage.

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Through a review of quality control documentation for D-dimer and Cardiac Panel performed on the Alere Triage instrument, through a review of patient test records, through lack of documented quality control results, and through interviews with laboratory staff, it was determined the laboratory failed to perform two levels of quality control each day patient specimens were tested. Survey findings include: A. A review of quality control records for D-dimer and for the Cardiac Panel performed on the Alere Triage instrument revealed the quality control for these tests was performed monthly instead of each day of testing patient samples. A review of quality control results from May 2021 (when the laboratory first started testing) through April 2022 revealed quality control documented for D-dimer and the Cardiac Panel on 5/10/2021, 6/9/2021, 7/9/2021, 8/11/2021, 8/26/2021, 9/25/2021, 11/3/2021, 12/6/2021, 1/13/2022, 2/11/2021, 3/28/2021, and 4/28/2021. There was no other documentation of quality control for these tests. B. During an interview, at 12:23 on 5/17/2022, the technical consultant (listed as #2 on the form CMS-209) stated that the laboratory performs quality control monthly on the the Triage test system instead of each day of testing. C. A review of six randomly chosen patient test records from 2022 revealed that six of six were performed on days without documented quality control. Patients tested on days without quality control are as follows: Patients #1 and #2, from the patient identifier list, were reported on 5/9/2022; Patient #3, from the patient identifier

list, was reported on 3/7/2022; Patient #4, from the patient identifier list, was reported on 3/2/2022; Patient #5, from the patient identifier list, was reported on 4/20/2022; and Patient #6, from the patient identifier list, was reported on 4/18/2022. D. In an interview, at 12:40 on 5/17/2022, the technical consultant (listed as #2 on the form CMS-209) confirmed quality control was not documented on the days when the patients listed above were reported.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Through a review of Solana assay documents, a review of patient and quality control documentation on the Solana instrument, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to run negative controls for tests performed on the Solana test system each day of patient testing. Survey findings include: A. A review of the Quality Control section of the Solana assay documents for SARS-Cov-2 assay (listed as moderate or high complexity in the FDA/ EUA) revealed the following statement: "It is recommended that the reactivity of each new lot and each new shipment of the Solana SARS-Cov-2 Assay be verified on receipt and before use. External control tests should be performed thereafter in accordance with appropriate federal, state and local guidelines." B. A review of patient and control documentation from January through March 2022 revealed that negative control was not documented in 158 of 158 runs on 20 days of testing. C. In an interview at 12:48 on 5/17/2022, laboratory employee #4 (as listed on the form CMS-209) confirmed the lack of testing negative controls for testing performed on the Solana. He further stated that they didn't have to run negative controls because the manufacturer doesn't require it.