

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0506572	<b>(X3) Date Survey Completed</b>  07/16/2021
<b>Name of Provider or Supplier</b>  Plains Memorial Hospital	<b>Street Address, City, State</b>  310 W Halsell, Dimmitt, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, patient reports, and interview, the laboratory failed to perform the gram stain for blood cultures in conjunction with the BioFire FilmArray Blood Culture Identification (BCID) Panel on the Biomerieux BioFire FilmArray 2.0 from May 13, 2021 to survey date, July 2, 2021. Findings follow. A. Review of the BioFire FilmArray BCID Panel Instruction Booklet, rev Feb 2021, under Summary and Explanation of the Test stated, "Sepsis (defined as system inflammatory response syndrome in response to infection) is the 11th leading cause of death in the United States. Life-threatening bacterial and fungal sepsis currently strikes approximately 240 out of 100,000 people per year in the U.S. (750,000 total cases) with severe sepsis (associated with acute organ dysfunction) in 95 out of 100,000 people. Timely diagnosis and administration of effective treatment can significantly reduce mortality, duration of hospital stays, and costs due to sepsis. The FilmArray Blood Culture Identification (BCID) Panel simultaneously tests a single positive blood culture sample to provide results for 24 different organisms and organism groups that cause bloodstream infections and thee genetic markers that are known to confer antimicrobial resistance. The test can be performed on blood culture bottles that are flagged as positive by continuously monitoring blood culture instrument. Results are intended to be interpreted in conjunction with Gram stain results." B. Review of patient test reports from June 2021 showed patient with MRN 101157 had a BCID ordered on 06/05/2021. One of 2 blood culture bottles drawn was positive. The BCID panel was performed and was reported on 06/08/2021 as none for</p>

the organisms tested. Cultures were sent to the reference laboratory on 06/09/2021. On 06/11/2021 the gram stain was reported by the reference laboratory as gram positive cocci in pairs, chains observed. C. Interview with the Technical Consultant #1 on June 30, 2021 at 1040 hours acknowledged they were no longer performing gram stains because the laboratory dropped from high complexity to moderate complexity. Interview with the Technical Consultant #1 on July 2, 2021 at 1105 hours confirmed MRN 101157 had a BCID report of "none" testing negative for the 24 organisms in the panel but was found to have gram positive cocci on the test report from the reference laboratory. The facility's laboratory had stopped reporting the gram stain. Phone interview with Technical Consultant #1 on July 16, 2021 at 1415 hours confirmed 3 BCID panels were performed from May 13, 2021 - July 2, 2021 where the gram stain was not reported. KEY: MRN = Medical Record Number

**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:  
I. Based on review of quality control results and interview, the laboratory failed to monitor over time the accuracy and precision of the test system for D-Dimer performed on the Triage Meter using the Triage Control Total 5 for 2 of 2 years reviewed. Findings follow. A. Review of quality control results showed mean and standard deviation (SD) were not calculated for the D-Dimer quality control results. B. Interview with the Technical Consultant on June 30, 2021 at 1540 hours confirmed statistical analysis was not performed on the D-Dimer quality control results. II. Based on review of quality control results and interview, the laboratory failed to monitor over time the accuracy and precision of blood gases performed on the Instrumentation Laboratory GEM Premier 3500 using GEM Calibration Valuation Product (CVP 1&2) for 2 of 2 years reviewed. Findings follow. A. Review of quality control results showed mean and standard deviation (SD) were not calculated for the blood gas quality control results. B. Interview with the Technical Consultant on July 1, 2021 at 1550 hours confirmed statistical analysis was not performed on the blood gas quality control results.

**D5775**

**COMPARISON OF TEST RESULTS**  
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:  
 Based on review of Complete Blood Count (CBC) test records, correlation of test results and interview, the laboratory failed to correlate test results twice a year between the automated differential and manual differential for 2 of 2 years reviewed. Findings follow. A. Review of CBC test records showed the laboratory was performing automated differentials using the Beckman Coulter DXH600 and manual differentials. B. Correlation of test results was requested on June 29, 2021 at 1555 hours but not provided. C. Interview with the Technical Consultant on June 29, 2021 at 1555 hours confirmed they were not enrolled in proficiency testing for the manual differential, and a comparison between automated differentials and manual differentials were not performed.

**D5805**

**TEST REPORT**  
 CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
 Based on review of patient test reports and interview, the laboratory failed to include the test report date on the test reports for 10 of 10 test reports reviewed. Findings follow. A. Review of patient test reports MRN Collected Tested 42670 06/23/2021 HgbA1C, Cardiac panel, Lipid panel, UA, CMP, CBC, D-Dimer 104554 05/11/2021 Blood gases 36730 05/11/2021 Blood gases 106958 06/14/2021 CMP, Cardiac panel, TSH, CBC, PT, APTT, D-Dimer 317670 06/14/2021 UA 42670 06/23/2021 Urine drug screen 105695 06/17/2021 CMP, Lipid panel, TSH, PSA, CBC 101491 06/29 /2021 CMP, Lipid panel, TSH, PSA, CBC 12077 06/23/2021 CBC 103474 06/14 /2021 CMP, Mg, Cardiac panel, TSH, Procalcitonin, CBC showed no reported date for the various tests performed. B. Interview with the Technical Consultant on July 2, 2021 at 1345 hours confirmed the EMR test reports do not have the reported date and the test reports are used for outpatient services. KEY: MRN = Medical Record Number EMR = Electronic Medical Record

**D6085**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1445(e)(3)

The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.

This STANDARD is not met as evidenced by:  
 Based on review of manufacturer's instructions, patient reports, and interview, the Laboratory Director failed to ensure the gram stain was performed for blood cultures required for quality of patient care. See D5411.