

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0506572	<b>(X3) Date Survey Completed</b> 09/21/2022
<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>D0000</b>	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations f 493. 1487 Condition: Laboratories Performing High Complexity Testing; Testing Personnel
<b>D5477</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for use, the laboratory's own written policy, quality control records, patient test records and interview of facility personnel, the laboratory failed to check each batch of media for, sterility, its ability to support and or inhibit growth and document the physical characteristics , for BD BACTEC Peds Plus/F Culture Vials, BD BACTEC Standard/10 Aerobic/F Culture Vials and the BD BACTEC Standard Anaerobic/F culture vials used for patient testing between January 1, 2021 and September 20, 2022. The findings included: 1. Review of the manufacturer's instructions found: a. BD BACTEC Peds Plus/F Culture Vials- On page 2 under the heading QUALITY CONTROL: "Quality control requirements must be performed in accordance with local, state and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures." b. BD BACTEC Standard/10 Aerobic/F Culture Vials - On page 2 under the heading QUALITY CONTROL: "Quality control requirements must be performed in accordance with local, state and/or federal regulations or accreditation</p>

requirements and your laboratory's standard quality control procedures." c. BD BACTEC Standard Anaerobic/F culture vials - On page 2 under the heading QUALITY CONTROL: "Quality control requirements must be performed in accordance with local, state and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures." 2. Review of the laboratory's own written procedure titled QUALITY CONTROL OF COMMERCIALY PREPARED MEDIA(Revised October 2012) found ON PAGE 2 "V. Blood culture media are received from BD BACTEC. The bottles are shipped with QC certification Forms that should be filed in the Blood Culture QC Log Book. The bottles are checked visually for breakage and gross contamination before being put into use." 3. Review of quality control records found the laboratory retained the certificates of analysis for the following lot numbers used: a. BD BACTEC Peds Plus /F Culture Vials- lot 1202910 expiration 2022/05/31 opened 12/1/2021 lot 1027297 expiration 2021/11/30 opened 6/3/2021 lot 0288773 expiration 2021/07/31 opened 1/18/2021 b. BD BACTEC Standard/10 Aerobic/F Culture Vials - lot 1231018 expiration 2022/05/31 opened 3/2/2022 lot 1195582 expiration 2022/04/30 opened 12/1/2021( received 10/1/2021) lot 1195582 expiration 2022/04/30 opened 10/30/2021 ( received 9/17/2021) lot 1125352 expiration 2022/02/28 ( no date of opening documented) lot 1041552 expiration 2021/11/30 opened 07/08/2021 lot 1014467 expiration 2021/10/31 opened 9/9/2021 lot 0329026 expiration 2021/09/30 opened 2/24/2021 lot 0274601 expiration 2021/07/31 opened 1/05/2021 c. BD BACTEC Standard Anaerobic/F culture vials - lot 1280544 expiration 2022/07/31 Opened 1/3/2022 lot 1245599 expiration 2022/06/30 opened 2/5/2022 lot 1125355 expiration 2022/02/28 opened 10/1/2021 lot 1061248 expiration 2021/12/31 opened 9/10/2021 lot 0336016 expiration 2021/09/30 opened 8/2/2021 lot 0281039 expiration 2021/07/11 opened 6/8/2021 lot 0281039 expiration 2021/07/31 opened 3/25/2021 lot 0267248 expiration 2021/07/31 opened 2/08/2021 d. The laboratory tested the following lot numbers using ATCC organisms on these dates when performing the weak light source check: January 11, 2021 BD BACTEC Peds Plus/F Culture Vials lot 0092360 expiration 01/31/2021 BD BACTEC Standard Aerobic/F culture vials lot 0195729 expiration 04/30/2021 BD BACTEC Standard Anaerobic/F culture vials lot 091273 expiration 05/31/2021 January 14, 2022 BD BACTEC Peds Plus/F Culture Vials lot 1202910 expiration 2022/05/31 BD BACTEC Standard Aerobic/F culture vials lot 1195582 expiration 2022/04/30 BD BACTEC Standard Anaerobic/F culture vials lot 1245599 expiration 2022/06/30 4. Review of patient records between January 1, 2021 and September 20,2022 indicated 408 blood cultures had been tested using the various media as described above without performing quality control procedures for each new lot and shipment of blood culture media used. 4. Interview of the general supervisor conducted on September 20, 2022 at 11:15 AM found that the laboratory had historically accepted the manufacturer's quality control certificate and had not performed end user quality control procedures for blood culture media, and does not document the condition of the media upon receipt.

**D6168**

TESTING PERSONNEL  
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:  
Based on a review of the Laboratory Personnel Report, personnel records and staff

interview, it was revealed that one of ten testing personnel performing high complexity testing did not have the appropriate education credentials. (refer to D6171)

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have

earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the laboratory failed to ensure one of ten testing personnel listed on the CMS report 209 met the minimum education requirements to perform High complexity testing in Bacteriology. The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report found the laboratory documented 10 individuals as testing personnel performing high complexity testing. 2. Review of personnel records found she was educated in the Phillipines with no evaluation of foreign education records available for review for testing person six ( hire date 11/23 /2018). 3. Interview of the general supervisor listed on the CMS report 209 Laboratory Personnel Report conducted September 21,2022 at 09:36 AM confirmed the laboratory did not have an evaluation of foreign education records to ensure the personnel met the minimum education requirements to perform high complexity testing.