

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0674050	(X3) Date Survey Completed 12/19/2022
Name of Provider or Supplier Christus Jasper Memorial Hospital	Street Address, City, State 1275 Marvin Hancock Drive, Jasper, 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	An announced validation survey was performed on 12/19/2022. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, patient test reports, and confirmed in interview, the laboratory failed to have a preanalytical quality assurance (QA) policy in place to monitor collection and run times to ensure patient results did not exceed manufacturer limits on the RAPIDPoint 500 blood gas analyzer for one of three random patients reviewed from August to October 2022. The findings include: 1. Review of the RAPIDPoint 500 blood gas analyzer operator's guide (ref 10844830), section "System Operation", subsection "Collection Patient Samples" stated the following: "Plastic syringes should not be iced, but kept at room temperature as long as the blood is analyzed within 30 minutes of collection." 2. Review of patient test records from August and October 2022 had the following patient that exceeded the 30-minute analysis window: Patient ID: AP0801072424 Collection Date Time: 8/29/2022 at 0911 Analysis Time: 09:47 Elapsed Time: 36 minutes 3. Review of the laboratory policy titled "Quality Management Program Policy" stated the following components monitored: "2. The following will be components of the QM Program: - Includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases of testing." Surveyor queried for documentation that the laboratory was monitoring, and rejecting, patient specimens</p>

that were unable to analyze within the 30-minutes from collection, and none was provided. 4. In an interview on 12/19/2022 at 13:35 hours, testing person (TP) 1 confirmed that the laboratory did not have a QA plan in place to ensure that patients collected were analyzed within the 30 minutes as specified by the manufacturer.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy, verification records, patient test records from 2022, and confirmed in interview, the laboratory failed to document a complete verification study for three of three Blood gas testing (pH, pCO₂, and pO₂) on the Siemens Rapidpoint 500 blood gas analyzer. (normal reference range study for venous specimen) Findings were: 1. Review of the laboratory policy Reference Range and Critical Values Blood Gas and pH analysis (Policy #452101-11-001) revealed the following normal reference range for venous blood gas specimen. pH: 7.30-7.4 pCO₂: 42.0-48.0 mmHg pO₂: 35.0 - 45.0 mmHg 2. Review of the verification studies for the Siemens Rapidpoint 500 blood gas analyzer revealed no documentation to verify the above reference range for venous blood gas. Lab records indicate the laboratory began testing on the Siemens Rapidpoint 500 blood gas analyzer in January 2021. 3. Random review of patient test records from August 2022 to October 2022 revealed the laboratory performed the following two venous blood gas testing. Specimen ID: BG00014Z Specimen ID: BG00032Z 4. An interview with the technical consultant on 12/19/2022 at 1330 hours in the conference room confirmed the above findings.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of laboratory proficiency testing (PT) records, laboratory policy, and confirmed in interview the laboratory director failed to document the review Blood Gas PT results for two out of five events reviewed from 2021 and 2022. The findings include: 1. Review of proficiency testing records had the following performance summary review sheets without documentation of the laboratory directors, or designee, review in 2022: 2022:BloodGas1: No signature or date reviewed

documented. 2022:BloodGas2: No signature or date reviewed documented. 2. Review of the laboratory policy titled "Proficiency Testing", section "Procedure" stated the following: "4. Recording Results of PT a. Signs and date the attestation form (testing personnel and Lab Director or designee). b. Submit results by the date noted on the result form. c. Maintain copy of the results in the Survey binder under designated section d. Review results of PT. e. If there are any ungraded PT Challenges, they will be assessed and evaluated using the CAP Laboratory Accreditation Manual guidelines for listing of PT exception codes and actions. f. Identify any problems and document actions taken." 3. In an interview on 12/19/2022 at 13:05 hours, in the conference room, testing person (TP) 1 confirmed that the PT results for the Blood Gas events 1 and 2 did not have the documentation of review from the laboratory director, or designee.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of the CMS form 209, personnel records for 2022 and confirmed in interview, the Technical Consultant failed to perform the annual competency evaluations for one of five testing personnel (TP#8) in the year 2022. Findings included: 1. Review of the CMS form 209 revealed the laboratory had 13 testing personnel. 2. A review of the laboratory competency assessments for 2022 revealed the technical consultant failed to document the annual competencies for one of five testing personnel (TP#8). Testing Person #8 had his 2022 competency assessment performed at their main lab on 04/01/2022, not this laboratory. 3. An interview with the technical consultant on 12/19/2022 at 1410 hours in the conference room confirmed the above findings. He stated that all personnel perform their competencies at their main laboratory despite working at other locations. key: CMS - Centers for Medicaid and Medicare Services