

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0668729	<b>(X3) Date Survey Completed</b>  04/10/2024
<b>Name of Provider or Supplier</b>  Christus Santa Rosa Hospital- San Marcos	<b>Street Address, City, State</b>  1301 Wonder World Drive, San Marcos, 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>	Based on a validation survey performed on April 9, 2024, through April 10, 2024, the laboratory was found to be out of compliance based on the following <b>CONDITION LEVEL DEFICIENCIES</b> : D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This <b>CONDITION</b> is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists proficiency evaluation reports, the laboratory failed to achieve</p>

	<p>satisfactory performance in two of two consecutive testing events for the analyte Hematocrit in the specialty of Hematology in 2023, resulting in an initial unsuccessful performance. Refer to D2130 and D2131.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists proficiency evaluation reports, the laboratory failed to achieve satisfactory performance in two of two consecutive testing events for the analyte Hematocrit in 2023, resulting in an initial unsuccessful performance. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory received a score of 0 percent for the second and third events of 2023 for the analyte Hematocrit. 2023 Event 2 - Hematocrit - 0 percent 2023 Event 3 - Hematocrit - 0 percent 2. Based on review of the College of American Pathologists proficiency evaluation reports, the laboratory received a score of 0 percent for the second and third events of 2023 for the analyte Hematocrit. 2023 Event 2 - Hematocrit - 0 percent 2023 Event 3 - Hematocrit - 0 percent</p>
<p><b>D2131</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists proficiency evaluation reports, the laboratory failed to achieve satisfactory performance in two of two consecutive testing events for the specialty of Hematology in 2023, resulting in an initial unsuccessful performance. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory received a score of 50 percent for the second and third events of 2023 for the specialty of Hematology. 2023 Event 2 - Hematocrit - 50 percent 2023 Event 3 - Hematocrit - 50 percent 2. Based on review of the College of American Pathologists proficiency evaluation reports, the laboratory received a score of 50 percent for the second and third events of 2023 for the specialty of Hematology. 2023 Event 2 - Hematocrit - 50 percent 2023 Event 3 - Hematocrit - 50 percent</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the Roche Cobas chemistry analyzer operator's manual, laboratory maintenance records from 2023, and interview with laboratory personnel, the laboratory failed to perform and document the 2-month maintenance procedure for six of six months between March 2023 and August 2023 and failed to perform Quarterly maintenance for nine of nine months reviewed between January 2023 and September 2023. The findings included: 1. Based on review of the Roche Cobas chemistry analyzer operator's manual (Version 1.0), on page C-77, the manual stated: "Every two months maintenance - In this section, you will find all maintenance for the ISE unit of the c 501 module that is to be performed at least once every two months. Replace ISE measuring cartridges (Cl-, K+, Na+) - The electrical response level and the slope value (sensitivity of each measuring cartridge slightly decrease with time and use). Replace an ISE measuring cartridge if one of the following criteria is met: \*The cartridge has been in service beyond 2 months. \*The test count has reached 9000 tests. \*The slope value of the cartridge falls outside of the normal range" 2. Based on review of the Roche Cobas chemistry analyzer "C3" maintenance records, 2-Month maintenance was not performed and documented for six of six months between March 2023 and August 2023. The two-month maintenance was performed in February 2023 and was not performed again until September 2023. 3. Based on review of the Roche Cobas chemistry analyzer operator's manual (Version 1.0), on page C-82, the manual stated: "Quarterly maintenance - In this section you find all maintenance for the photometric unit of the c 501 module that is to be performed at least once every three months. Cleaning the ultrasonic mixers - Clean the ultrasonic mixers at least every three months. Contamination and precipitation on the surface of the ultrasonic mixers may cause inadequate mixing and thus lead to inaccurate results. (Page C-86) Replacing the ISE sipper tubing - After long use, the tubing will gradually wear out and the accuracy of sample aspiration will decrease. Replace the ISE sipper tubing once every three months. (Page C-87) Replace the syringe seals - Replace the syringe seal every three months. When the syringe seals get worn out, this may cause leakage and inaccurate pipetting. This is combined maintenance procedure for both ISE and photometric unit." 4. Based on review of the Roche Cobas chemistry analyzer "C3" maintenance records, quarterly maintenance was not performed and documented for nine of nine months between January 2023 and September 2023. 5. In an interview at 14:11 hours on 4/10/2024 in the laboratory, the Chemistry Section Lead (Technical Consultant 1 on the CMS-209 Laboratory Personnel Report) confirmed the laboratory would not have another place where the maintenance could be documented if it had been performed. Terms: ISE - Ion selective electrode Cl- - Chloride K+ - Potassium Na+ - Sodium

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit

of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of laboratory policy, calibration verification records from 2023, and interview with laboratory personnel, the laboratory failed to perform calibration verification at least every six months for the Precision Systems Osmolality instrument for one out of two times for 2023 and two for two times in 2022. The findings included: 1. Based on review of the laboratory policy "Osmolality Urine/Serum", under Linearity Testing, the procedure stated: A. Validate Osmolality Linearity for urine and serum is used to verify reportable range. B. Linearity testing is performed every six months by the Supervisor or assigned Tech. 1. If any standard is out of specification upon re-testing, the instrument should be calibrated. C. Record all results on the OSMO Linearity Worksheet. D. Linearity results are kept in the testing binder." 2. Based on a review of laboratory records, a calibration verification record was provided for 12/14/2023. No other records of linearity/calibration verification were found for 2023. No other records of linearity/calibration verification were found for 2022. 3. In an interview at 15:49 hours on 4/10/2024 in the laboratory, the Chemistry Section Supervisor (Technical Consultant 1 from the CMS-209 Laboratory Personnel report) stated the only other record of linearity that could be found was from April of 2021, when the instrument was verified and put into service.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists proficiency evaluation reports, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for two of two events for the analyte Hematocrit, in the specialty of Hematology for 2023. Refer to D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the College of American Pathologists proficiency evaluation records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for two of two events for the analyte Hematocrit, in the specialty of Hematology in 2023, resulting in an initial unsuccessful performance. Refer to D2130 and D2131.