

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2110069	(X3) Date Survey Completed 03/03/2022
Name of Provider or Supplier Stripes Primary Care	Street Address, City, State 750 S Ironwood Dr Suite 101, Apache Junction, AZ	
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
D2016	<p>SUCCESSFUL PARTICIPATION 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 CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) reports for 2021 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the regulated analytes, TSH and Free TY (Thyroxine), and failed to successfully participate in a PT program for the sub-specialty of Endocrinology. Findings include: 1. The laboratory's PT performance was unsatisfactory for the second event of 2021 for the regulated analyte, Free TY (Thyroxine), with a score of 0%. 2. The laboratory's PT performance was unsatisfactory for the third event of 2021 for the regulated analyte, Free TY (Thyroxine), with a score of 0%. 3. The laboratory's PT performance was unsatisfactory for the second event of 2021 for the regulated analyte,</p>

	<p>TSH, with a score of 0%. 4. The laboratory's PT performance was unsatisfactory for the third event of 2021 for the regulated analyte, TSH, with a score of 0%. 5. The laboratory's PT performance was unsatisfactory for the second event of 2021 for the sub-specialty of Endocrinology with a score of 0%. 6. The laboratory's PT performance was unsatisfactory for the third event of 2021 for the sub-specialty of Endocrinology with a score of 0%.</p>
<p>D2107</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in 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 Proficiency Testing (PT) reports for 2021 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the regulated analytes, Free TY (Thyroxine), for the 2nd and 3rd events of 2021; and TSH, for the 2nd and 3rd events of 2021, resulting in unsuccessful PT performance. See D2016 for findings.</p>
<p>D2108</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(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 information furnished to the State Agency by the Proficiency Testing (PT) provider, the laboratory failed to achieve an overall testing event score of satisfactory performance for the sub-specialty of Endocrinology for the 2nd and 3rd events of 2021, resulting in unsuccessful PT performance. See D2016 for findings.</p>
<p>D3031</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation for testing performed on the Sysmex XP300 analyzer and the Alfa Wassermann Chemistry analyzer, review of Quality Assessment (QA) documentation and interview with the Technical Consultant, the laboratory failed to retain QC documentation for at least 2 years. Findings include: 1. The laboratory began patient testing in the specialities of Chemistry and Hematology on April 15, 2020, with an approximate annual test volume of 97,310. 2. The laboratory utilizes a Laboratory Information System (LIS), Medicus, in which QC results from the analyzers indicated above electronically</p>

interface into Medicus, where they are stored indefinitely. 3. During the survey conducted on March 3, 2022, patient test records (patient ID# 24189) were reviewed for testing performed on May 24, 2021 on the Sysmex XP300 and Alfa Wassermann analyzer. 4. No documentation of QC records were presented for review for the testing date indicated above (5/24/2021), from either analyzer. 5. During the survey, it was determined that QC records were not available in the LIS, on the analyzer or in printed form for the following dates: QC data missing from May 17, 2021 through June 1, 2021 for testing performed on the Sysmex XP300; QC data missing from May 3, 2021 through May 31, 2021 for testing performed on the Alfa Wassermann analyzer. 6. At approximately 3:10pm on March 3, 2022, the Technical Consultant stated during an interview that QC results were performed and reviewed on each analyzer by the Technical Consultant for each day of patient testing that occurred in May 2021, but the QC results failed to interface to the LIS and the lab failed to print the QC data. The Technical Consultant confirmed that QC results were available for review during May 2021 on each analyzer, however the QC data was purged from the analyzers by the date of the survey. 7. The laboratory's QA documentation from May 2021 reviewed during the survey confirmed that the laboratory identified the problem at the time as evidenced in the QA comments section stating, "QC files not updated by lot number in Medicus. Daily QC is to be printed", however the Testing Personnel at the time failed to print the QC records as instructed. 8. The number of patients tested on the Sysmex XP300 analyzer from May 17, 2021 through June 1, 2021 and the number of patients tested on the Alfa Wassermann analyzer from May 3, 2021 through May 31, 2021 could not be determined at the time of the survey.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
 CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
 Based on lack of calibration records from the Sysmex XP300 hematology analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration procedures as required. Findings include: 1. The laboratory utilizes the Sysmex XP300 hematology analyzer to perform patient testing, with an approximate annual test volume of 21,860. Patient testing began on 4/15/2020. 2. No documentation was presented for review during the survey conducted on March 3, 2022 to indicate the laboratory performed and documented calibration procedures every 6 months as required by the manufacturer for the analyzer indicated above. Calibration records reviewed during the survey indicated the analyzer was calibrated on 8/28/20 and was not calibrated again until 5/28/21. 3. The facility personnel confirmed the laboratory failed to perform a calibration in February 2021 as required.

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:

Due to the number and severity of deficient practices identified during the survey conducted on February 24, 2021, the Condition of Laboratory Director was found to be not met as evidenced by: D6016 - ensuring that the proficiency testing samples are tested as required under Subpart H and D6020 - failure to ensure the quality control program is maintained to assure the quality of laboratory services provided.

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 information furnished to the State Agency by the Proficiency Testing (PT) provider, it was determined that the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a proficiency testing program for the regulated analytes, TSH and Free TY (Thyroxine), and for the sub-specialty of Endocrinology. See D2016 and D6000 for findings.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on the number and severity of deficient practices identified during the survey related to the retention of Quality Control (QC) records, the laboratory director failed to ensure that the laboratory's QC program is maintained to assure the quality of laboratory services provided. See D3031 for findings.