

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0906103	(X3) Date Survey Completed 10/12/2023
Name of Provider or Supplier Columbus Regional Health Physicians	Street Address, City, State 2502 25th St, Columbus, IN	
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 Initial CLIA Certification survey was completed on 10/12/2023. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.801 Enrollment and Testing of Samples
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to enroll in an approved Proficiency Testing (PT) program in 2023 for one (Creatinine) of one non-waived analyte tested using the Stat Sensor (SN: 02-0377-22271) for the subspecialty of Routine Chemistry from May 2023 to 10/12/2023 and for six (PT#1-PT#6) of six patients reviewed. Findings include: 1. On 10/12/23 at 11:16am, SP-2 (Practice Manager) confirmed the laboratory was not enrolled in a Proficiency Test (PT) Program. 2. On 10/12/23 at 2:00 pm, during the tour of the laboratory a Stat Sensor analyzer was observed to be available for use in the laboratory. 3. Review of document titled, "CLIA Moderate Complexity Laboratory Requirements", with no signature by the laboratory director or date of review, indicated the following guideline for "Proficiency Testing (PT)" on page 22 of 23: "The laboratory must enroll in an approved PT testing program that covers each test found in Subpart I of the February 28, 1992, regulations. The test listed in Subpart I are considered</p>

"regulated analytes". 4. Review of medical records indicates the following patients were tested for Creatinine without PT being performed in 2023: PT# 1 on 05/16/23 - Result: Creatinine: 0.8 mg/dL PT# 2 on 05/25/23 - Result: Creatinine: 0.8 mg/dL PT# 3 on 08/22/23- Result: Creatinine: 1.22 mg/dL PT# 4 on 09/19/23- Result: Creatinine: 0.84 mg/dL PT# 5 on 10/03/23- Result: Creatinine: 0.84 mg/dL 5. Annual Test Volume for the subspecialty of Routine Chemistry is approximately 500.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director failed to sign and date a procedure manual before use for creatinine testing on analyzer Stat Sensor (SN: 02-0377-22271) for the subspecialty of Routine Chemistry from May 2023 to 10/12/2023 and for six (PT#1-PT#6) of six patients reviewed. Findings include: 1. Upon request for the laboratory's policy and procedure manual, on 10/12/23 at 12:18 pm, a binder was provided. The binder contained documents outlining "CLIA Moderate Complexity Laboratory Requirements". None of the documents provided had dates of initial use or signature of the laboratory director. 2. Review of document titled, "CLIA Moderate Complexity Laboratory Requirements", with no signature by the laboratory director or date of review, indicated the following three of eight guidelines for "Preparing the Procedure Manual" on page 15 of 23: 2) Manufacturer's literature (packet inserts/operator manuals) may be used, provided the instructions are followed in the unmodified form. When items are missing from the manufacturer, the laboratory must provide the information. 3) The date the procedure was put in place must be noted. 4) The current director must approve procedures and his/her signature, or designee's signature may be on the cover of the document. 3. Review of medical records indicates the following patients were tested for Creatinine without an approved procedure manual: PT# 1 on 05/16/23 - Result: Creatinine: 0.8 mg/dL PT# 2 on 05/25/23 - Result: Creatinine: 0.8 mg/dL PT# 3 on 08/22/23- Result: Creatinine: 1.22 mg/dL PT# 4 on 09/19/23- Result: Creatinine: 0.84 mg/dL PT# 5 on 10/03/23- Result: Creatinine: 0.84 mg/dL 4. Annual Test Volume for the subspecialty of Routine Chemistry is approximately 500.