

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0906103	<b>(X3) Date Survey Completed</b>  05/27/2025
<b>Name of Provider or Supplier</b>  Columbus Regional Health Physicians	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A proficiency testing desk review survey was completed on 5/27/2025. The following condition-level deficiencies were found to be out of compliance: D2016- 42 C.F.R. 493.803 Condition: Successful participation (proficiency testing) D6000-42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
<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 CONDITION is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologist (CAP) Evaluation Reports, Casper Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails</p>

from the Back Office Lead (SP-1) on 05/23/2025, the laboratory failed to achieve satisfactory performance in two consecutive events (Event 3 of 2024 and Event 1 of 2025) resulting in unsuccessful participation for the sub-specialty of Routine Chemistry and the analyte Whole Blood Creatinine in 2024 and 2025. Refer to D2096

**D2096**

**ROUTINE CHEMISTRY**  
CFR(s): 493.841(f)

(f) 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.

This STANDARD is not met as evidenced by:  
Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologist (CAP) Evaluation Reports, Casper Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Back Office Lead (SP-1) on 05/23/2025, the laboratory failed to achieve satisfactory performance in two consecutive events (Event 3 of 2024 and Event 1 of 2025) resulting in unsuccessful participation for the sub-specialty of Routine Chemistry and the analyte Whole Blood Creatinine in 2024 and 2025. Findings included: 1. Review of the "CASPER REPORT 0155D", run date 5/20/25 indicated a score of 60% for Event 3 2024, and 20% for Event 1 2025 for Routine Chemistry and Creatinine as reported by CAP. 2. On 05/23/2025 at 1:57, via email, SP-1 (Back Office Lead), confirmed that the scores, Event 3 2024-60% and Event 1 2025-20%, were correct for Routine Chemistry and Creatinine. 3. On 05/23/2025 at 11:58 pm, upon request, SP-1 (Back Office Lead) provided, via email, the CAP Original Evaluation and Performance Summary Proficiency Testing Reports for 2024 and 2025 for Creatinine. 4. Review of CAP Original Evaluation and Performance Summary Report for WBCR-C 2024 detailed the following: a.) Page 1 of 3, "Reviewed by" does not contain a signature. b.) Page 2 of 3 Original Evaluation 12/16/2024 Kit ID: 37426237 1.) Five samples were submitted: WBCR 11 through 15 2.) Two of the five samples were Unacceptable: WBCR-12 and WBCR-13 c.) Page 3 of 3 Performance Summary 1.) WBCR-C 2024 3/5 60% Unsatisfactory 5. Review of CAP Original Evaluation and Performance Summary Report for WBCR-A 2025 detailed the following: a.) Page 1 of 3, "Reviewed by" does not contain a signature. b.) Page 2 of 3 Original Evaluation 4/16/2025 Kit ID: 38918643 1.) Five samples were submitted: WBCR 01 through 05 2.) Four of the five samples were Unacceptable: WBCR-01 through WBCR-04 c.) Page 3 of 3 Performance Summary 1.) WBCR-C 2024 4/5 60% Unsatisfactory 2.) WBCR-A 2025 3/5 20% Unsatisfactory

**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 surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologist (CAP) Evaluation Reports, Casper Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails

from the Back Office Lead (SP-1) on 05/23/2025, the laboratory director failed to ensure that the laboratory successfully participated in two consecutive events (Event 3 of 2024 and Event 1 of 2025) resulting in unsuccessful participation for the sub-specialty of Routine Chemistry and the analyte Whole Blood Creatinine in 2024 and 2025. Refer to D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologist (CAP) Evaluation Reports, Casper Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Back Office Lead (SP-1) on 05/23/2025, the laboratory director failed to ensure that the laboratory successfully participated in an Health and Human Services (HHS) approved testing program for the sub-specialty of Routine Chemistry and the analyte Whole Blood Creatinine in 2024 and 2025. Refer to D2096.