

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0928366	<b>(X3) Date Survey Completed</b>  10/24/2023
<b>Name of Provider or Supplier</b>  Norton Children's Medical Group - Jeffersonville	<b>Street Address, City, State</b>  3118 E 10th Suite B, Jeffersonville, 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 10/24/2023. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.803(a)(b)(c) Successful Participation 42 CFR 493.1403 Moderate Complexity 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: Repeat deficiency Based on document review and interview, the laboratory failed to successfully participate in the American Academy of Family Physicians (AAFP) and American Proficiency Institute (API) proficiency testing (PT) programs for one of one analyte (bilirubin, total) tested in the subspecialty of Routine Chemistry. The</p>

	<p>laboratory had 0 percent PT testing scores for three out of four PT testing events 2022 (Event C), 2023 (Event 2), and 2023 (Event 3) for both bilirubin and routine chemistry (Refer to D2096).</p>
<p><b>D2096</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(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: Repeat Deficiency Based on document review and interview, the laboratory failed to successfully participate in American Academy of Family Physicians (AAFP) and American Proficiency Institute (API) proficiency testing (PT) programs for one of one analyte (bilirubin, total) tested in the subspecialty of Routine Chemistry. The laboratory had 0 percent PT testing scores for three out of four PT testing events 2022 (Event C), 2023 (Event 2), and 2023 (Event 3) for both bilirubin and routine chemistry. Findings include: 1. Review of the AAFP "Proficiency Testing Evaluation AAFP PT 2002-C" indicated the laboratory received 0 percent scores for chemistry and bilirubin (total). 2. Review of the API "Proficiency Summary 2023 Chemistry-Core- 2nd Event" indicated 0 percent scores for chemistry and bilirubin, total. Notes stated, "Failure to Participate". 3. Patients' records indicated the following patients reviewed had testing performed when the PT failures occurred: Patient Date Test PT6 12/28/22 Bilirubin PT8 6/05/23 Bilirubin 4. Annual Test Volume for Routine Chemistry is approximately 100. 5. Review of the API 2023 "Proficiency Testing Performance Evaluation 2023 Chemistry-Core-3rd Event" indicated 0 percent scores for chemistry and bilirubin, total. Notes states, "Failure to Participate". 6. On 10/24 /2023 at 5:33 pm, SP1 acknowledged that the laboratory received 0 percent scores for chemistry and bilirubin, total for event C, 2022; event 2, 2023; and event 3, 2023.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure the laboratory successfully participated in American Academy of Family Physicians (AAFP) and American Proficiency Institute (API) proficiency testing (PT) programs for one of one analyte (bilirubin, total) tested in the subspecialty of Routine Chemistry. The laboratory had 0 percent PT testing scores for three out of four PT testing events 2022 (Event C), 2023 (Event 2), and 2023 (Event 3) for both bilirubin and routine chemistry (Refer to D6017).</p>
<p><b>D6017</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory director failed to ensure the laboratory returned proficiency testing results within established time frames for the American Academy of Family Physicians (AAFP) and American Proficiency Institute (API) proficiency testing (PT) programs for one of one analyte (bilirubin, total) tested in the subspecialty of Routine Chemistry. The laboratory had 0 percent PT testing scores for three out of four PT testing events 2022 (Event C), 2023 (Event 2), and 2023 (Event 3) for both bilirubin and routine chemistry due to failure to participate. Findings include: 1. Review of the AAFP "Proficiency Testing Evaluation AAFP PT 2002-C" indicated the laboratory received 0 percent scores for chemistry and bilirubin (total). 2. Review of the API "Proficiency Summary 2023 Chemistry- Core- 2nd Event" indicated 0 percent scores for chemistry and bilirubin, total. Notes stated, "Failure to Participate". 3. Review of the API 2023 "Proficiency Testing Performance Evaluation 2023 Chemistry-Core-3rd Event" indicated 0 percent scores for chemistry and bilirubin, total. Notes states, "Failure to Participate". 4. On 10/24/2023 at 5:33 pm, SP1 acknowledged that the laboratory received 0 percent scores for chemistry and bilirubin, total for event C, 2022; event 2, 2023; and event 3, 2023.