

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0368418	<b>(X3) Date Survey Completed</b>  02/18/2021
<b>Name of Provider or Supplier</b>  Trinity Health Iha Medical Group Pediatrics	<b>Street Address, City, State</b>  990 W Ann Arbor Trail Suite 210, Plymouth, MI	
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>D2006</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by:  . Based on record review and interview with the Technical Consultant (TC) and Testing Personnel (TP) #4, the laboratory failed to test the chemistry bilirubin proficiency testing (PT) samples for 6 (1-3 events 2019 and 1-3 events 2020) of 6 events in the same manner as patient samples. Findings include: 1. A record review of the final graded American Proficiency Institute (API) proficiency testing reports for 6 (1-3 events 2019 and 1-3 events 2020) of 6 testing events revealed the laboratory did not document the proficiency testing samples on the "Bilirubin Log." 2. When queried on 2/18/2021 at 11:39 am, TP4 was not able to provide documentation to show the PT samples were tested in the same manner as patient samples. 3. A interview on 2/18 /2021 at 11:39 am, TC and TP4 confirmed the proficiency testing samples were not recorded on the "Bilirubin Log" like patient samples.</p>
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform</p>

test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC) and Testing Personnel (TP) #4, the TC failed to evaluate the competency of testing personnel performing the chemistry bilirubin testing for 6 (TP1 - TP6) of 6 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of testing personnel competency assessments revealed testing personnel competencies were assessed by a fellow TP for 6 (TP1 - TP6) of 6 testing personnel listed on the CMS-209 who do not qualify as a Technical Consultant to perform competency assessments as follows: a. TP1 assessed by TP4, assessment dates of 8/16/2019, 12/16/2019, and 1/2/2020 b. TP2 assessed by TP4, assessment dates of 2/25/2019, 12/16/2019, and 1/2/2020 c. TP3 assessed by TP4, assessment dates of 7/20/2020, 9/7/2020, 12/20/2020 d. TP4 assessed by TP5, assessment dates of 12/16/2019 and 1/2/2020 e. TP5 assessed by TP4, assessment dates of 12/16/2019 and 1/2/2020 f. TP6 assessed by TP4, assessment dates of 4/2/2019, 2/28/2019, and 1/2/2020 2. A interview on 2/18/2021 at 10:46 am, the TC and TP4 confirmed the competency assessments were completed by TP not qualified as a TC to perform competency assessments.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

. Based on lack of documentation and interview with the Technical Consultant (TC) and Testing Personnel (TP) #4, the Technical Consultant failed to evaluate the annual competency for 5 (TP1-2, TP4-6) of 6 TP performing the moderately complex chemistry bilirubin testing in 2021. Findings include: 1. A record review of the competency evaluations revealed lack of documentation for the annual competency for 5 (TP1-2, TP4-6) of 6 TP performing the chemistry bilirubin tests. 2. When queried on 2/18/2021 at 10:46 am, TP4 was not aware that she did not qualify as a TC to perform competency assessments. 3. During the interview on 2/18/2021 at 10:46 am, the TC and TP4 confirmed the annual competency assessments had not been performed and documented for 2021.