

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2138575	(X3) Date Survey Completed 02/23/2021
Name of Provider or Supplier Trinity Health Medical Group	Street Address, City, State 801 Broadway Street Ne Suite 105, Grand Rapids, MI	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant (TC) 2, the laboratory failed to maintain a copy of the American Academy of Family Physicians (AAFP) final proficiency testing (PT) report, signed attestation statement sheet by the testing personnel (TP), and review of the final graded PT results for 6 (A-C events in 2019 and 2020) of 6 events reviewed. Findings include: 1. A record review of the AAFP proficiency testing documents revealed the laboratory failed to maintain a copy of the AAFP final PT report, signed attestation statement sheet by the TP, and review of the final graded PT results for 6 (A-C events in 2019 and 2020) of 6 events as follows: a. No AAFP final report for event C 2019 and event A in 2020 b. Events A-C in 2019 and 2020 the attestation statement sheet was not signed by the individual testing personnel (TP 3 and TP4). c. Lack of documentation for TP3 and TP4 reviewing the final graded results. 2. A interview on 02/23/2021 at 12:21 pm, TC2 confirmed the laboratory did not maintain all the documentation listed above for 2019 and 2020. .</p>

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

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

This STANDARD is not met as evidenced by:

. Based on lack of documentation and interview with Technical Consultant (TC) #2, the TC failed to evaluate the competency of testing personnel (TP) performing the moderately complex Potassium hydroxide (KOH), wet prep, microscopic urinalysis, parasitology (Scabies), and the fern testing for 3 (TP #1, #3, and #4) of 3 TP during the 2019 and 2020 testing years. Findings include: 1. Lack of documentation of competency assessments for 3 (TP #1, #3, and #4) of 3 TP performing the KOH, wet prep, microscopic urinalysis, scabies, and fern testing was revealed. 2. When queried on 2/23/2021 at 9:52 am, TC2 was not aware of competency assessments for physicians and physician assistant. 3. A interview on 2/23/2021 at 9:52 am, TC2 confirmed there was no documentation of competency assessments for TP1, TP3, and TP4 for 2019 and 2020.