Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0368418	(X3) Date Survey Completed 07/27/2022
Name of Provider or Supplier Trinity Health Iha Medical Group Pediatrics	**Street Address, City, State** 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) 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. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to test the American Proficiency Institute (API) samples like a patient sample and record on the daily "Bilirubin Log" for 2 (3rd event 2021 and 1st event 2022) of 5 events reviewed. Findings include: 1. A review of the API proficiency testing final reports revealed a lack of documentation on the bilirubin testing log to show that testing and results of the proficiency testing samples are treated like a patient. 2. When queried on 7/27/2022 at 11:14 am, the TC was unaware of the lack of documentation on the daily "Bilirubin Log" for 2 (3rd event 2021 and 1st event 2022) of 5 events. 3. A interview on 7/27/2022 11:14 am, the TC confirmed the API proficiency testing samples were not recorded on the daily "Bilirubin Log." ***Repeat Deficiency from 2/18/2021 survey ***
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the

	laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the Laboratory Director and/or designee failed to attest to the routine integration of the chemistry bilirubin American Proficiency Institute (API) proficiency testing samples into the patient workload for 2 (2nd and 3rd events in 2021) of 5 events reviewed. Findings include: 1. A record review of the API proficiency testing documents revealed the laboratory director did not sign the attestation statement sheets for the chemistry bilirubin testing as follows: a. 2nd event 2021 - no Laboratory Director or designee signature b. 3rd event 2021 - no Laboratory Director or designee signature 2. A interview on 7/27/2022 at 11:14 am, the TC confirmed the attestation statement sheet was not signed by the Laboratory Director and/or designee.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure the results manually entered into the laboratory information system (LIS) was accurate from the "Bilirubin Log" for 1 (#1 tested on 3/08/2021) of 20 patient test results reviewed. Findings include: 1. A record review for 1 (#1 tested on 3/08/2021) of 20 patient test results revealed the bilirubin result was inaccurate as follows: a. "Bilirubin Log" - 18.2 b. result in the LIS - 18.5 2. An interview on 7/27 /2022 at 11:48 am, the TC confirmed the manually entered bilirubin results were transcribed incorrectly into the LIS system.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel met the qualification requirements at 493.1423. Findings include: 1. The laboratory failed to ensure testing personnel were qualified. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

	(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on a lack of documentation and record review, the laboratory failed to ensure testing personnel were qualified for 2 (Testing Personnel (TP) #4 and TP #5) of 5 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel records revealed a lack of qualification documentation for TP #4 and TP #5 listed on the CMS-209 form performing moderate complexity testing. 2. The surveyor requested qualification documentation for TP #4 and TP #5 to show they were qualified to perform moderate complexity testing on 7/27/2022 at 9:14 am and it was not made available. 3. The laboratory was provided 7 days to supply documentation and it was not made available.