Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0366595	06/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Trinity Health Iha Medical Group Pediatrics	4350 Jackson Road Suite 100, Ann Arbor, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant (TC) #1, the laboratory failed to retain 1) the hematology quality control documents for 2 months (10/1/2019 to 11/25/2019) of 2 years and 2) the calibration documents for 1 (June-December 2019) of 4 every six months for two years. Findings include: 1. A record review of the hematology Beckman Coulter AcT diff quality control records revealed a note on the documents stating the material for 2 months (10/01/2019 to 11/25/2019) of 2 years was in the possession of TC1. 2. A record review of the hematology Beckman Coulter AcT diff calibrations records revealed a lack of documentation present for the calibration performed for 1 (June-December 2019) of 4 every six months calibrations in 2 years. 3. An interview on 6/21/2021 at approximately 12:45 pm, TC1 confirmed the above documentation was not available to the surveyor on the day of the survey.
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 Testing Personnel (TP) #1, the laboratory failed to ensure test results were accurately entered into the laboratory information system (LIS) from the patients printed report from the hematology analyzer for 1 (#10) of 13 patient test reports reviewed. Findings include: 1. A record review of the manually transcribed results into the LIS revealed for 1 (#10) of 13 patient test reports reviewed the monocytes percent was entered rather than the monocytes absolute result. 2. An interview on 6/21/2021 at approximately 12:45 pm, TP1 confirmed patient #10 final test report had a incorrect result reported out for the monocytes absolute count. ***Repeat Deficiency from the 5/31/2017 and 11?27/2018 surveys***