| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 23D0371828 | 07/18/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Trinity Health Iha Medical Group Pediatrics - | 28300 Orchard Lake Road, Suite 100, Farmington Hills, 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 |
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| **D2128** | HEMATOLOGY<br>CFR(s): 493.851(e)<br><br>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the General Supervisor (GS), the laboratory failed to perform and document remedial action for unacceptable test scores for 2 (second and third events of 2018) of 6 testing events reviewed. Findings include: 1. A record review of College of American Pathologists proficiency testing results exposed the following results: a. 2018 FH2-B 1. Specimen FH2-05 unacceptable 2. Testing Event Score 83% b. 2018 FH2-C 1. Specimen FH2-05 unacceptable 2. Testing Event Score 93% 2. When requested on 7/18/19 at 10:36 am, the laboratory did not provide documentation of corrective actions taken for the unacceptable test scores. 3. An interview on 7/18/19 at 10:36 am with the GS confirmed corrective actions had not been performed and documented for the above testing events in 2018. This is a repeated deficiency from the 2/1/2013 survey. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the General Supervisor (GS), the laboratory failed to ensure test results are accurately and reliably sent from the point of data entry to the final report destination for 2 (July 2017 to July 2019) of 2 years. Findings include: 1. A record review exposed a lack of documentation of routine checks conducted to verify manual entry of results were being accurately and reliably conveyed to the final report destination. 2. An interview on 7/18/19 at 11:12 am with the GS confirmed that laboratory had not implemented routine checks to verify manual entry of results to the final report destination. |