Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1043906	02/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dr Todd's Pediatrics Pc	29526 Six Mile Road Suite B, Livonia, 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
D0000	D0000 493.3 Applicability (a) Basic rule. Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it- (1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or (2) Is CLIA-exempt. (b) Exception. These rules do not apply to components or functions of - (1) Any facility or component of a facility that only performs testing for forensic purposes; (2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or (3) Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. However, all other testing conducted by a SAMHSA- certified laboratory is subject to this rule. (c) Federal laboratories. Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate. This Basic Rule is not met as evidenced by: Based on record review of the Casper Report 0153D, the CLIA 116 Aspen Web database, observation during an unannounced complaint survey, and interview with the laboratory director (LD), the laboratory failed to have a current certificate of registration, certificate of compliance or certificate of accreditation to perform waived and moderately complex hematology testing since July 25, 2016. The findings include: 1. Record review of the Casper Report 0153D and the CLIA 116 Aspen Web database revealed the following: a. Casper Report 0153D, "Unsatisfactory (failed) and Unsuccessful (2 of 3) PT Report" , revealed the laboratory had unsatisfactory and/or unsuccessful proficiency testing results for five (2nd and 3rd event 2017 and 1st-3rd events 2018) events. b. CLIA 116 Aspen Web database revealed that the laboratory's CLIA certificate expired on July 25, 2016 and was terminated on July 26, 2016 for nonpayment of fees. 2. On February 5, 2019 during an unannounced complaint survey, the surveyor observed the laboratory performing waived and moderately complex hematology complete blood cell count

	testing. 3. Record review for 13 (#1 - #13) patient charts reviewed from January 3, 2017 to January 17, 2019 revealed the laboratory performing moderately complex hematology complete blood cell testing. 4. During the interview on February 5, 2019 at approximately 11:30 AM, the laboratory director stated the office was unaware that their CLIA certificate had expired and the laboratory has been performing patient testing.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: . Based on observation, record review, lack of documentation, and interview with testing personnel #1 (TP1), the laboratory failed to maintain copies of the handling, preparation, processing and examination of the testing specimens, the original proficiency testing documents, the hematology Beckman Coulter AcT diff analyzer printouts, the signed attestation statement sheets for five (2nd and 3rd in 2017 and 1st-3rd events in 2018) of six events in 2017 and 2018. Findings include: 1. On February 5, 2019 at approximately 12:30 PM, the surveyor observed a file that contained the proficiency testing (PT) documents for the 1st event of 2017. 2. Record review of the Casper Report 0153D revealed the laboratory was enrolled with American Proficiency Institute (API) proficiency testing program in 2017 and 2018. 3. No documentation was found for the five events on the day of the survey. 4. During the interview on February 5, 2019 at approximately 12:30 PM, TP1 confirmed the laboratory did not maintain records for two years.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent

	with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on Casper Report 0153D and record review of the American Proficiency Institute (API) graded proficiency testing reports it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the specialty of Hematology. Refer to D2131.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on record review of Casper Report 0153D and proficiency testing results from American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for the specialty of hematology in three of four consecutive testing events. Findings include: 1. Review of Casper Report 0153D and API proficiency testing results revealed the following scores for the specialty of hematology: Hematology PT Events Score 3rd event 2017 0% 1st event 2018 0% 3rd event 2018 0% Additional failures of analytes in the specialty of hematology during 2017 and 2018 included: Analyte PT Event Score Hematocrit 2nd event 2017 40% Red Blood Cell 2nd event 2018 60% White blood Cell 2nd event 2018 60% (differential)
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 testing personnel #1 (TP1), the laboratory failed to retain all daily Beckman Coulter AcT diff background counts, quality control records, and calibration records for two (2017 and 2018) of two years reviewed. Findings include: 1. Record review, for three (#5, #11, and #12) of 13 patient charts reviewed, revealed the daily background count printouts for the Beckman Coulter AcT diff were not consistently maintained. 2. Record review of the monthly quality control records (daily background count and the low, normal and high control material) revealed the laboratory was missing the instrument printouts from September to December 2018. 3. Record review of the Beckman Coulter AcT diff calibration reports revealed the laboratory did not maintain the instrument printouts for the calibrations performed on November 30, 2017 and December 29, 2017. 4. On February 5, 2019 at approximately 11:10 and 11:58 AM, TP1 confirmed the above findings.

D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1 (TP1), the laboratory failed to have a written request for patient testing from an authorized person for the routine hematology testing for one (#7) of 13 patient charts audited. Findings include: 1. Record review revealed for one of 13 patient charts audited the laboratory did not have a written request for the hematology complete blood cell count testing by an authorized person that was performed on February 16, 2018. 2. During the interview on February 5, 2019 at 12:12 PM, TP1 confirmed the patient chart did not have a written request for the testing completed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1 (TP1), the laboratory failed to perform the hematology calibration procedures at least every 6 months in 2018. Findings include: 1. Review of the calibration data for the hematology Beckman Coulter AcT diff hematology analyzer revealed the laboratory did not have any documentation to show the calibration procedure was performed every six months in 2018. 2. When requested, TP1 was not able to provide the surveyor with the documentation to demonstrate the calibrations had been performed every six months in 2018 for the Beckman Coulter AcT diff hematology analyzer. 3. During the interview on February 5, 2019 at 11:15 AM, TP1 confirmed calibrations were not performed in 2018.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1 (TP1), the laboratory failed to follow written policies and procedures to perform the monthly quality assurance (QA) checklist for eight (February, April, and May 2017 and August - December 2018) of 24 months reviewed. Findings include: 1. Review of the "CLIA Compliance Manual for AcT diff Series Analyzer" under section "Personnel Training Procedures" revealed the laboratory failed to perform and document the "Monthly QA Checklist" form for eight months. 2. During the interview on February 5, 2019 at 11: 10 AM, TP1 stated she did not follow their policy and procedure to perform the "Monthly QA Checklist".