Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2062544	06/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
T Lab Inc	910 Clopper Rd Suite 220s, Gaithersburg, MD	

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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) record review and interview with the laboratory staff and the laboratory director (LD), the laboratory did not record the results of the "Jorvet Dip Quick Stain" hematology QC, documenting that the staining characteristics observed on patient slides were acceptable each day of testing. Findings: 1. The laboratory uses the "Jorvet Dip Quick Stain" to stain patient blood slides for hematology testing. During an interview at 11:30 AM on the day of the survey, the laboratory staff stated that a "QC slide" is stained with each batch of patient slides, and the QC slide is evaluated for acceptable staining characteristics when the doctor performs patient testing. Laboratory staff stated that patient testing is performed "every 1-2 weeks." 2. A review of slide QC logs from July, 2017 to June, 2019 showed that slide QC was recorded once a month. 3. During an interview on 6/28 /19 at 12:45 PM, the LD confirmed that slide QC was not documented on each day of patient testing.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) and quality assurance (QA) record review and interview with the laboratory director (LD), the LD did not ensure that the QA review included updating written laboratory procedures to reflect the actual practice in the laboratory. Findings: 1. The procedure, "Slide Interpretation," "Quality Control" states that "Each batch of slides stained will contain as controls" a "Blind Control," "Negative Control," and a "Positive Control." During an interview at 11:30 AM, laboratory staff stated that they "run a positive slide only"; and 2. The procedure, "Slide Interpretation," "Interpretation Guidelines" states, "All results will be qualitatively reported as positive or negative. Quantitative reporting is not allowed." The procedure, "Split Specimen Analysis" states that 5 slides are sent to an external lab for proficiency testing purposes and that the slides are to be evaluated as "Negative" or "Positive." During an interview at 9:30 AM, the LD stated that the slides are graded numerically as 0, 1, 2, or 3, not as "negative" or "positive." 3. During an interview, laboratory staff stated that after making patient blood slides, the slides are placed on a slide warmer to dry, and that the temperature should be 40 degrees Celsius. The SOP did not state a temperature range and the LD confirmed that slide warmer temperatures were not recorded. 4. The procedure, "Quality Assurance" states, "a chart review will be conducted quarterly on a random sampling of patient charts to verify that all test ordered have been reported and filed correctly in the EMR. Staff will review at least 20 patient charts and present their findings to the Lab Director." The LD stated that this procedure is not followed because each patient is checked as they are read. A review of "Lab Director QA Summary-Quarterly" report forms from June, 2017 to June, 2019 showed that this chart review was not documented. 5. During an interview on 6/28/19 at 12:45 PM, the LD confirmed that the laboratory SOPM did not reflect the current practice of the laboratory.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with the laboratory director (LD), the laboratory did not ensure that all of the written procedures in the SOPM were signed and dated by the LD. Findings: 1. A review of the current SOPM showed that approximately 20 of 24 procedures were not approved (signed and dated) by the LD. 2. During an interview on 6/28/19 at 12:45 PM, the LD confirmed that all of the written procedures in the current SOPM were not signed and dated.