Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2062544	05/13/2022
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory did not have competency check records for the technical supervisor and the technical consultant. Findings: 1. The laboratory did not have competency check records for the technical supervisor and technical consultant for the years 2021 and 2020; and 2. Testing person number three stated during interview on the afternoon of February 25, 2022, that the laboratory did not have competency records for the two laboratory staff.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of "Appendix O" received on 05/12/2022, Quality Management Plan (QMP), and interview with the laboratory director, the laboratory failed to verify the accuracy of the Biofilm, Neutrophil Lysis, Red Blood Cell Inclusions (BNR) slide analysis performed at least twice annually. Findings: 1. "Appendix O" is titled "BNR Split Specimen QA Summary and Log." This summary states that 1 out of every 20 specimens is to undergo a split specimen QA analysis. The data that was reviewed was from June 2019 through February 2022. 2. The proficiency testing section of the

	QMP stated "These formal reviews are done at least twice a year, however, our team does meet with our independent reviewers every 1-3 weeks to review any unusual image findings or other irregularities." 3. During the survey on 05/13/22 at 3:00 PM, the LD confirmed that the records reviewed show that the split samples were not being reviewed twice a year.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the spreadsheet used to document proficiency checks for the biofilm, neutrophil, red blood cell test (BNR) made by an independent reviewer (for proficiency or accuracy checks), the laboratory records were incomplete and did not include intermediate records made by the outside independent reviewer. Findings: 1. The spread sheet documenting the split sampling of patient specimens for BNR with an outside independent reviewer as a proficiency check (dated June 19, 2019 to March 24, 2022) did not include the dates the outside reviewer examined the split samples, the name of the outside reviewer, or intermediate worksheets showing the outside reviewer's findings and interpretations.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the written policies and procedures and interview with the laboratory director (LD), the laboratory failed to have written policies and procedures for the investigation of specimens that failed to meet the laboratory's criteria for acceptability. Findings 1. The laboratory used a worksheet titled "Specimen Incident Report" to document the findings of investigations of specimen issues. The laboratory documented the "specimen identification number, incident description and adverse events, outcome, and actions, if any" on the "Specimen Incident Report." 2. During the survey on 05/13/22 at 3:00 PM, the LD confirmed that there were no established policies and procedures that instruct the laboratory personnel to collect information and document the description of the problem, reasons for the deviation, actions taken and implementation of protocols to prevent reoccurrence of the problem.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and

	rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the procedure, stability studies, and specimen incident reports, and interview with the testing personnel (TP) and laboratory director (LD), the laboratory failed to establish a procedure and validate the criteria for specimen acceptability for the age of the specimens received for the laboratory developed test (LDT). Findings: 1. The laboratory performed a LDT that evaluated peripheral blood slides for morphological features to characterize and semi-quantify the presence of biofilms, neutrophil extracellular trap formation and red blood cell inclusions. 2. Patient results were reported as either Indeterminate, Positive-Low or Positive-High based on defined criteria. 3. The procedure titled "Receiving and Accessioning of Shipped Blood Samples" included specimen rejection criteria for the temperature of received blood specimens but did not address acceptability for the age of the blood specimens. 4. In documentation that was received via email on 05/12/2022, the laboratory stated that specimens were viable for at least 24 hours after collection and referred to a stability study. The stability study compared specimen imaging results from directly after collection to 24 hours later when stored at different temperatures. The stability study results stated "it was determined that time after draw and temperature effected red blood cell morphology in a way that made quantitative scoring more difficult. To account for this, the scoring guidelines were amended to include fewer possible results." 5. An incident report dated 02/07/2022 stated that specimen 4596 was received four days after specimen collection due to shipping delays and "The integrity of the specimen was not compromised. Therefore, the specimen was viable for testing. The specimen was processed as normal." There was no documentation explaining how it was determined that the integrity of the specimen was not compromised. 6. There was no documentation of stability studies performed to assess whether the observed morphological features and final result interpretation would be affected in a specimen received four days after collection. 7. During the survey on 05/13/2022 at 3: 00 PM, the TP and LD confirmed that the specimen acceptability procedure did not include criteria for age of specimen and the stability studies did not include an evaluation of specimens older than 24 hours.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.

(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
I. Based on record review, the laboratory written procedure for quality control procedures was not complete. Findings: 1. The laboratory quality assurance manual refers to the specimen preparation and staining procedure for quality control performance, but there is no quality control section that describes how positive and negative control reagents are selected, labeled and entered into the quality control records to identify them; 2. There was no quality control written procedure describing the staining patterns and observations required to interpret the negative and positive checks to ensure they reacted as required and 3. The written procedure did not state that the laboratory document stain quality control acceptability for each day patient specimens are stained. II. Based on review of written procedures and interview with laboratory staff, the laboratory did not have written procedures describing limitations of the biofilm, neutrophil, red blood cell test (BNR). Findings: 1. The laboratory performs a Jorvic Quick Dip stain on patient whole blood specimens; 2. The written procedure did not state the limitations the laboratory found during the validation of the BNR test and how to identify the interferences such as fibrin clot formation in the patient whole blood sample (causes include inadequate mixing or specimen age), artifacts due to dust or oil on microscope slides, hemolysis of the patient specimen and any other interfering factors identified by the laboratory that may affect the test; 3. The laboratory did not have written procedures to report interferences and if needed report rejection of specimens due to interference; and 4. This was confirmed with the laboratory director during the afternoon exit interview conducted May 13, 2022. 43123 III. Based on review of the standard operating procedure (SOP), validation report, and reference images and email communication, the laboratory's reporting SOP and reference images failed to define all criteria used for results reporting for the laboratory developed test (LDT). Findings: 1. The laboratory performed a LDT called "BNR" that evaluated peripheral blood slides for morphological features to characterize and semi-quantify the presence of biofilms (B), neutrophil extracellular trap formation (N) and red blood cell inclusions (R). 2. A request for documentation and a set of questions was emailed to the laboratory on 04/21/2022 at 2:23 pm. The requested documentation and response to the questions were received from the laboratory on 05/12/2022 at 10:48 am (response). 3. The procedure titled "Brightfield Microscopy Reporting SOP" (reporting SOP) stated that "results will be quantitatively reported as Indeterminate, Positive-Low, or Positive-High for three different categories: Biofilm, Neutrophil Degranulation Assessment, and Red Blood Cell Inclusions." 4. The laboratory's validation report revised on 02/03/2014 stated that "ambiguous results will not be reported as positive." The laboratory's response to the question of whether the laboratory had a visual guide to define what would be considered ambiguous stated that they "have a set of images that are agreed upon and used as a 'standard' that reviewers can rely upon" and referred to "Appendix S (BNR Example Images)" (Appendix S). 5. Appendix S contained a collection of reference images depicting biofilms, netosis, and RBC inclusions. The images did not contain any additional descriptions and did not identify the magnification the images were captured under. 6. The reporting SOP stated that for biofilms, "Indeterminate = none or few (1-2 small round per slide)", "Positive-Low = >2 per slide of a moderate size or larger", and "Positive-High = too numerous to count." The SOP did not define the measurements of a small and moderate size biofilm or if there was a cutoff value between ">2" and "too numerous to count" that distinguished a Positive-Low result from a Positive-High result. The biofilm reference images in Appendix S did not provide examples of what was considered a small versus a moderate size biofilm or

	how to count a single biofilm. 7. The reporting SOP stated that for neutrophil degranulation assessment, "Indeterminate = rare or none", "Positive-Low = >2 per slide", and "Positive-High = 2 or more per HPF [high powered field] and/or too numerous to count." The SOP did not define if there was a cutoff value between ">2 per slide" and "2 or more per HPF and/or too numerous to count" that distinguished a Positive-Low result from a Positive-High result. Neither the reporting SOP nor Appendix S defined how to count a neutrophil degranulation assessment which was labeled as "Netosis" in Appendix S. 8. The reporting SOP stated that for red blood cell (RBC) inclusions, "Indeterminate = none, or does not meet criteria", "Positive-Low = few RBCs may meet criteria, recommend further testing", and "Positive-High = too numerous to count." The SOP did not define the criteria used to identify a RBC inclusion, if there was a cutoff value between "few RBCs may meet criteria" and "too numerous to count" that distinguished a Positive-Low result from a Positive High result, or how to count a RBC inclusion. Appendix S did not include examples of what did and did not meet criteria or how to count RBC inclusions. 9. The reporting SOP stated that "Because results are recorded in a spreadsheet, for ease of data entry, we have been recording a negative nominally as a '0' and a positive nominally as a '1', '2', or '3'. A '1' is defined as a low-positive, and a '2' or '3' is defined as a high positive." Neither the reporting SOP nor Appendix S defined or gave examples of a '0', '1', '2', or '3' grading used for results interpretation.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: 43123 I. Based on review of validation documentation and interview with the testing personnel (TP) and laboratory director (LD), the laboratory failed to establish performance specifications for precision by not evaluating the variability between multiple slides prepared from a single patient specimen for the laboratory developed test (LDT). Findings: 1. The laboratory performed a LDT that evaluated peripheral blood slides for morphological features to characterize and semi-quantify the presence of biofilms, neutrophil extracellular trap formation and red blood cell inclusions. 2. Patient results were reported as either Indeterminate, Positive-Low or Positive-High based on defined criteria. 3. The TP stated that a slide is prepared from a single drop of blood and the laboratory routinely prepared two slides from a single patient blood specimen tube, but only one of the two slides was imaged for evaluation and the other was stored as a backup slide. 4. The validation documentation did not include studies evaluating the variability and reproducibility of the observed morphological features and final result interpretation between multiple slides prepared from a single patient blood tube. 5. During the survey on 05/13/2022 at 3:00 PM, the LD confirmed that the laboratory only evaluated a single slide for each patient specimen received and did not

perform precision studies to evaluate the potential variability found between multiple slides prepared from a single specimen. II. Based on review of the manufacturer's instructions, quality assurance (QA) reports, and laboratory validation documentation , the laboratory failed to verify performance specifications when the manufacturer's procedure for blood smear staining was modified for the laboratory developed test (LDT). Findings: 1. The laboratory performed a LDT that evaluated peripheral blood slides for morphological features to characterize and semi-quantify the presence of biofilms, neutrophil extracellular trap formation and red blood cell inclusions. 2. Patient results were reported as either Indeterminate, Positive-Low or Positive-High based on defined criteria. 3. The laboratory stained the peripheral blood slides using the Jorvet Dip Quick Stain. Manufacturer's instructions stated that once the blood smear was prepared on the slide "The slide is allowed to air dry" prior to staining. 4. The laboratory QA report from "2015, 2016, & through May 2017" stated that in "the Fall of 2016, it was noted that temperature and humidity variability was affecting slide drying rates and thus, creating an artifact on the slide that impaired the ability to clearly image the RBCs. Thus a slide warmer drying step was introduced in November to provide consistency in the slide production and eliminate the artifact seen on the images. These too were reviewed in the QA process." 5. Based on the procedure titled "Diff Quick Procedure for Brightfield Microscopy", the laboratory modified the manufacturer's instructions by placing the prepared blood smear slides on a slide warmer for 15 minutes instead of allowing them to air dry prior to staining. 6. The document titled "Slide Warmer Temperature Change Validation Summary" stated that on 04/01/2021 the temperature setting for the slide warmer was changed from 40C to 45C. 7. There was no validation procedure or raw data for an evaluation of whether heating the slide up to 40C as compared to allowing the slide to air dry prior to staining affected the observed morphological features and final result interpretation. 8. The "Slide Warmer Temperature Change Validation Summary" stated that for two weeks following the temperature change, the laboratory "ran additional image analysis" for a total of 15 specimens and "results of those 15 specimens met or exceeded our validation criteria. The result compared favorably, similar in all respects, to those obtained when the slide warmer was set at 40 degrees Celsius." 9. The validation summary did not define what the acceptability criteria was, include instructions for how the validation study was performed, or include data for a comparison of the observed morphological features and final result interpretation between slides warmed at 40C to slides warmed at 45C for each of the 15 specimens referred to. III. Based on record review, the laboratory did not describe the procedure for validating the degranulation of neutrophils or NETS (neutrophil extracellular traps). Findings: 1. The validation study identified by the laboratory as the TMG blood smear for biofilm and intra-RBC morphology did not describe the procedure for validating the findings of NETS; 2. The study states that the goal of the test is to inspect for biofilms and intra-RBC (red blood cell) abnormalities, and degranulation or NETS was not included in this goal; and 3. The updated validation procedure dated May 10, 2022 did not include the procedures used to assess sensitivity, accuracy and specificity for NETS, even though NETS are reported as part of the BNR test. IV. Based on review of written procedures and interview with laboratory staff, the laboratory validation did not describe limitations of the biofilm, neutrophil, red blood cell test (BNR). Findings: 1. The laboratory performs a Jorvic Quick Dip stain on patient whole blood specimens; 2. The laboratory's validation study did not establish the limitations of the BNR (for example fibrin clot formation in the patient whole blood sample due to inadequate mixing or specimen age, artifacts due to dust or oil on microscope slides, hemolysis of the patient specimen); and 3. This was confirmed with the laboratory director during the afternoon exit interview conducted May 13, 2022.

D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory's written Quality Management Plan, the laboratory did not have procedures for checking the slide warmer thermometer to ensure that the thermometer was reading the temperature in an accurate manner. Findings: 1. The laboratory performs a Wright's stain on patient whole blood affixed to microscope slides; and 2. The slide warmer used to dry patient slides before and after staining had a thermometer attached to the warmer. The laboratory did not have records showing that the thermometer readings were periodically checked for accuracy.
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 record review and interview with testing person #3, the laboratory did not document each quality control check (positive and negative) made for stain acceptability each day of staining for the biofilm, neutrophil, red blood cell test (BNR). Findings: 1. The worksheet used to document the stain quality control checks showed that quality control checks were documented one time each week and that date corresponds to the date that the patient slides were reviewed microscopically and not for the dates that quality control slides were stained with every daily batch of patient specimens; and 2. During survey in the afternoon of February 25, 2022, Testing person #3 stated that on the day patient specimens arrive in the laboratory for BNR testing, they are prepared and stained.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on review of the "Responses to CLIA Survey Questions May 2022" document, final report and interview with the laboratory director (LD), the laboratory failed to ensure that the final test report included the date of the final report, specimen source, units of measurement or interpretation, and any information regarding the condition of the patient specimen when it was received by the laboratory. Findings: 1. The "Responses to CLIA Survey Questions May 2022" document stated that the laboratory required a fresh specimen, 24 hours old, be used when preparing a slide for interpretation. The "Specimen Incident Report" for specimen #4596 stated that the specimen was collected on 02/03/21 and received on 02/07/21. "The integrity of the specimen was not compromised. Therefore, the specimen was viable for testing." The report was signed 02/07/22 by the LD. 2. The final report for specimen #4596 was reviewed. The final report failed to include the date the specimen was reported, the source of the specimen, units of measurement or interpretative information, and any information regarding the condition of the patient specimen. 3. The final report failed to identify the specimen as compromised since it was not received within the required 24 hours. 4. During the survey on 05/13/2022 at 3:00 PM, the LD confirmed that the final patient test report did not include all the required information. The LD also confirmed that there was an error with the recorded collection and received dates. The correct collection date was 02/03/22 and the received date was 02/07/22.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the "Brightfield Microscopy Reporting SOP [Standard Operating Procedure]", final patient report, and interview with the laboratory director (LD), the laboratory's final report failed to define reference intervals for normal and abnormal patient values. Findings: 1. The "Brightfield Microscopy Reporting SOP" defined "quantitatively" results as "Biofilms", "Neutrophil Degranulation Assessment", and "Red Blood Cell Inclusions." The procedure defined the reference intervals for normal and abnormal as a numeric value for each category as "Intermediate", "Positive-Low", and "Positive-High." 2. The procedure manual included an example of a revised final report dated "2017 01 27" that included interpretative information defining "Normal", "Indeterminate", "Positive Moderate", and "Positive High." 3. The final report failed to provide the numeric value which corresponded to normal and abnormal patient results. 4. During the survey on 05/13/22 at 3:00 PM, the LD confirmed that the laboratory had revised the final patient report and failed to include the interpretative information of normal and abnormal patient values.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

	This STANDARD is not met as evidenced by: I. Based on review of the "TMG Blood Smear for Biofilm & intra-RBC Morphology Validation Report", "Responses to CLIA Survey Questions May 2022" and interview with the laboratory director (LD), the LD failed to define the acceptable age of a specimen received in an ethylenediamine tetraacetic acid (EDTA) tube used for the preparation of fresh peripheral blood smears for review and interpretation. Findings: 1. The "TMG Blood Smear for Biofilm & intra-RBC Morphology Validation Report" stated: "b. The goal of the present test is to allow the in-office inspection of fresh peripheral blood." The procedure failed to define the acceptable age of a "fresh peripheral blood" specimen that will be used to prepare a slide once it is received. 2. The "Responses to CLIA Survey Questions May 2022" document provided to the surveyors on 05/12/22 stated "The specimens are immediately processed and stained on the day the specimen is received (by overnight express mail within 24 hours of collection)." 3. The "Specimen Incident Report" forms from 02/17/21 to 02/03/22 showed that five specimens were received and reported that were greater than 24 hours and the final report failed to indicate that the specimen failed to meet the required criteria defined in the "Responses to CLIA Survey Questions May 2022" document. 4. During the survey on 05/13/22 at 3:00 PM, the LD confirmed that the procedure for peripheral blood smears failed to define the acceptable age of a specimen received in an EDTA tube used for the preparation of fresh peripheral blood smears for review and interpretation. II. Based on review of the "Specimen Incident Report" and interview with the LD, the LD failed to provide the clients with a final report when the specimens were received and found to be unacceptable due to hemolysis. Findings: 1. Review of the "Specimen Incident Report" forms from 02/17 /21 to 02/03/22 showed that three specimens were received as hemolyzed and no final report was issued. The records did not include notification of the hemolyzed specimen to the client so that the specimen could be recollected and tested. 2. During the survey on 05/13/22 at 3:00 PM, the LD confirmed that there was no final report sent to the client when the specimen was received and found to be unacceptable due to hemolysis.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: The laboratory director failed to ensure that verification procedures were available and followed to validate the stability of specimens older than 24 hours, establish variability between multiple slides prepared from a single patient specimen, and verify performance specifications when the manufacturer's staining procedure was modified. Cross-refer to tags D5311 and D5423 I and II.
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: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 06/28/2019 for not defining the mean of the temperature of the slide warmer as 40 degrees Celsius and the range for the slide warmer used for making patient blood slides. The plan of correction stated that this would be corrected by 10/07 /2019. Based on review of the previous statement of deficiencies, the current procedures and interview with the laboratory director (LD), the LD failed to put in place the plan of correction (POC) from the previous survey, and define the mean of the temperature of the slide warmer and the range for the slide warmer used for making patient blood slides. Findings: 1. The current "Diff Quick Procedure for Brightfield Microscopy" procedure step vi stated to heat fix peripheral smears for 15 minutes, but did not define the temperature that the slide warmer must be set at. 2. The LD stated that the patient blood smears were to be heat fixed using a slide warmer set at 45 degrees Celsius for 15 minutes. 3. The laboratory's written procedures failed to include the updated procedure defining the mean of the temperature and the acceptable range for the slide warmer used for making patient blood slides that was referred to in the POC. 4. The laboratory's current written procedures failed to include the mean of the temperature as 45 degrees Celsius and the acceptable range for the slide warmer used for making patient blood slides. 5. During the survey on 05/13/22 at 3:00 PM, the LD confirmed that the procedure for patient blood smears had not been updated to include heat fixing the slide at 40 degrees Celsius cited during the previous survey and did not include the updated temperature of 45 degrees Celsius for 15 minutes reviewed during the current survey.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: The technical supervisor failed to ensure that stability of specimens older than 24 hours was validated, variability between multiple slides prepared from a single patient specimen was established, and performance specifications when the manufacturer's staining procedure was modified were verified. Cross-refer to tags D5311 and D5423 I and II.