Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2078777	10/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Legend Internal Medicine	609 Hemphill Street Suite 101, Fort Worth, TX	

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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing results and interview with the Technical consultant the laboratory failed to score at least 80% on second testing event in 2018 for Erythrocytes. Findings Included: Review of API proficiency testing revealed a score of 60% for Erythrocytes in the specialty of Hematology in the 2nd testing event of 2018. During an interview on 10/17/18 at 11: 00 AM the Technical Consultant confirmed the proficiency testing failure.
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 record review and interview with the Technical Consultant the laboratory failed to have a competency evaluation on 1 out of 1 Technical Consultant reviewed. Findings Included: Review of employee competency evaluations revealed that the Technical Consultant did not have a competency evaluation from 2016-2017 on the abilities to be a Technical Consultant. During an interview on 10/17/18 at 12:00 PM the Technical Consultant revealed that a competency evaluation had not been performed on him since starting in 2016.

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 American Proficiency Institute (API) proficiency testing and interview with the Technical Consultant the laboratory failed to have correction action on results less than 100% in 5 (3rd testing event in 2016, 1st, 2nd, 3rd testing event in 2017 and 2nd testing event 2018) out of 6 (3rd testing event in 2016, 1st, 2nd, 3rd testing event in 2017 and 1st, 2nd testing event 2018) testing events reviewed. Findings Included: Review of API proficiency revealed 80% for White Blood Cell Differential in the 3rd testing event of 2016, 80% for Erythrocyte Count in the 1st testing event in 2017, 80% for Leukocyte Count in the 2nd testing event of 2017, 80% for Erythrocyte Count in the 3rd testing event in 2017, and 80% for Free Thyroxine in the 2nd testing event of 2018 all with no corrective action documented. During an interview on 10/17/18 at 11:00 AM the Technical Consultant confirmed that there was no corrective action documented for the aforementioned testing events.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the Technical Consultant and Testing Person #A the laboratory failed to perform required maintenance (See D5429), failed to perform calibration verification (See D5439), failed to perform lot to lot verification (See D5469), failed to perform calibrations (See DD5437), and reported patients when quality control was not acceptable (See D5481).
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant, the laboratory failed to document weekly maintenance since December 2016 on the chemistry analyzer that tests TSH (Thyroid Stimulating Hormone), Free T4 (Free Thyroxine), and PSA (Prostate Specific Antigen). Findings Included: Review of manufacturers

	instructions revealed that the chemistry analyzer maintenance requires a weekly USB data back-up. During an interview on 10/17/18 at 5:30 PM the technical consultant confirmed that the weekly maintenance was not documented.
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 the Technical Consultant the laboratory failed to calibrate the hematology analyzer every six months as required by the manufacturer for 2 out of 2 years (2016-2018) reviewed. Findings Included: Review of policy an procedures (last signed by the Lab Director 04/28/18) stated the calibrations on the hematology analyzer is calibrated "Every six months as required by the manufacturer." Review of calibration records revealed calibrations performed 12/16/16, 01/25/18, and 03/07/18. There were no calibrations performed in 2017 and would have been due 09/18. During an interview on 10/17/18 at 5:00 PM the Technical Consultant confirmed that the calibrations were not performed every 6 months.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant, the laboratory failed to perform calibration verification on the chemistry analyzer since December 2016. This is a repeat deficiency from the 05/04/16 recertification survey. Findings Included: Review of manufactures instructions for the chemistry analyzer performing testing on TSH (Thyroid Stimulating Hormone), Free T4 (Free Thyroxine), and PSA (Prostrate Specific Antigen) states that calibration verification must be performed every 6 months. No documentation of calibration verification for TSH, Free T4, or PSA was provided. During an interview on 10/17/18 at 5:30 PM the Technical Consultant confirmed that the calibration verification had not been performed for TSH, Free T4, or PSA. Review of the recertification survey conducted on 05/04/16 revealed that the laboratory was cited for no calibration verification of TSH and PSA.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant the laboratory failed to verify the quality control material for the hematology analyzer when lot numbers changed for 2 out of 2 years (2016-2018) reviewed. Findings Included: Review of quality control records for the hematology analyzer revealed no verification of the quality control materials when there was a change in lot numbers from 2016 to 2018. During an interview on 10/17/18 at 5:00 PM the Technical Consultant confirmed that lot to lot verification had not been performed.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (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 #A the laboratory reported patient results when the quality control was not within acceptable ranges for 201 patients reported. Findings Included: Manufacturers instructions require two levels of

	external quality control ran monthly. Thyroid Stimulating Hormone (TSH) level 1 control was 1.20 ng/mL on 01/05/17 (acceptable range was 1.21-1.81 ng/mL) 156 patients were reported during that time period. Prostate Specific Antigen (PSA) level 1 control was 1.37 ng/mL on 01/05/17 (acceptable range was 1.38-2.06 ng/mL) 6 patients were reported during that time period. Free Thyroxine (Free T4) level 1 was 1.58 ng/mL on 06/07/18 (acceptable range was 0.51-1.57 ng/mL) and level 2 was 2.22 ng/mL (acceptable range was 0.80-1.98 ng/mL) 1 patient was ran during that time period. Free T4 level 1 was 1.69 ng/mL on 07/10/18 (acceptable range was 0.51-1.57 ng/mL) 1 patient was reported during that time period. TSH level 2 was 15.97 ng/mL on 09/11/18 (acceptable range was 8.38-15.65 ng/mL) 37 patients were reported out during that time period. During an interview on 10/17/18 at 5:20 PM Testing Person #A confirmed that controls were not in range and the patients reported during the range of the unacceptable quality control.