Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2285210	12/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Level Up Men's Health, Llc	4095 Mallory Ln, Franklin, TN	

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	During an initial survey completed on 12/04/23, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 of the laboratory, review of seven patient test reports, the Laboratory Personnel Policies, the lack of records, and interview with the Technical Consultant (TC), the laboratory failed to document initial competency for the Technical Consultant and Testing Personnel. The findings include: 1. Observation of the laboratory on 11.27.23 at 10:40 am revealed the Qualigen Fast Pack System (SN0230) in use for total testosterone testing. 2. Review of patient test reports revealed that the first patient total testosterone test was reported on 8.17.23 (specimen id #20), and that seven patient tests had been performed since implementation of the test system. 3. Review of the Laboratory Personnel Policies revealed a the following: "Ongoing personnel competency is assessed by visual observation, adherence to written procedures, and proficiency testing performance. The laboratory director evaluates the competency of testing personnel: When a new method has begun by using the System Training Checklist (QA Log) For annual evaluations, use the Competency Assessment (QA Log)" 4. There were no competency assessment documents for surveyor review. 5. Interview with the Technical Consultant on 11.27.23 at 1:30 pm confirmed the laboratory failed to follow their own policy by not documenting initial competency assessments for the TC, and one of one TP performing total testosterone patient testing.

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 observation, review of seven patient test reports, and interview with the Technical Consultant, the laboratory failed to have patient reference ranges (normal values) available to the provider using the test result from implementation of the test system on 8.17.23 to the date of the survey, 11.27.23. The findings include: 1. Observation of the laboratory on 11.27.23 at 10:40 am revealed the Qualigen Fast Pack System (SN0230) in use for total testosterone testing. 2. Review of patient test reports revealed that the first patient total testosterone test was reported on 8.17.23 (specimen id #20), and that seven patient tests had been performed since implementation of the test system. Seven of seven patient test reports did not have a reference range available to the provider. 3. Interview with the Technical Consultant on 11.27.23 at 1:30 pm confirmed the lack of reference range availability for total testosterone testing.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of final patient test reports, review of the laboratory's policy and procedure manual, review of laboratory quality records, review of personnel records, and staff interview, the laboratory director failed to ensure the laboratory's competency assessment policy was followed (Refer to D5209), verify performance characteristics for total testosterone using the Qualigen Fast Pack System prior to patient testing (Refer to D5807 and D6013), failed to ensure the laboratory's quality assessment programs were maintained (Refer to D6021), and failed to review and approve the laboratory's policies and procedures (Refer to 6031).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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:

	Based on observation of the laboratory, review of validation records, patient test records and interview with the technical consultant, the laboratory director failed to review and approve the accuracy and precision performance specifications data for the Qualigen Fast Pack System prior to the start of patient testing on 8.17.23. The findings include: 1. Observation of the laboratory on 11.27.23 at 10:40 am revealed the Qualigen Fast Pack System (SN0230) in use for total testosterone testing. 2. Review of the validation of performance specifications studies performed for the Qualigen Fast Pack System revealed the presence of raw data with no formal evaluation of the data by the laboratory director. 3. Review of final patient test reports revealed seven total testosterone patient results were reported from 8.17.23 to the date of the survey, 11.27.23. 4. Interview with the technical consultant on 11.27.23 at 1:30 pm confirmed validation studies for the Qualigen Fast Pack System (SN0230) had not been approved by the laboratory director prior to patient testing that began 8.17.23.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of seven patient test records, the Quality Assurance Assessment Program, and interview with the Technical Consultant (TC), the laboratory failed to follow its own policy for performing and documenting monthly Quality Assurance (QA) reviews. The findings include: 1. Observation of the laboratory on 11.27.23 at 10:40 am revealed the Qualigen Fast Pack System (SN0230) in use for total testosterone testing. 2. Review of patient test reports revealed that the first patient total testosterone test was reported on 8.17.23 (specimen id #20), and that seven patient tests had been performed since implementation of the test system. 3. Review of the Quality Assurance Assessment Program revealed a requirement for monthly assessment of the QA plan stating, "Our laboratory assesses the QA plan monthly, using the QA Assessment, which (1) evaluates and monitors the overall quality of our testing; (2) helps evaluate how well our policies and procedures are working; and (3) minimizes the possibility of recurrent problems." 4. There was no QA Assessment documentation for August, September, or October 2023 for surveyor review. 5. Interview with the Technical Consultant on 11.27.23 at 1:30 pm confirmed the laboratory director failed to document and sign monthly QA assessments for three of three months since testing began on 8.17.23.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) 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 observation of the laboratory, review of patient test records, laboratory procedure manual, and interview with the technical consultant, the laboratory director failed to ensure an approved procedure manual was available to testing personnel for use of the Qualigen Fast Pack System for total testosterone testing prior to the start of patient testing on 8.17.23. The findings include: 1. Observation of the laboratory on 11.27.23 at 10:40 am revealed the Qualigen Fast Pack System (SN0230) in use for total testosterone testing. 2. Review of the patient test records revealed the first patient total testosterone test was reported on 8.17.23 (specimen id #20). 3. Review of the the laboratory's procedure manual revealed no approval by the laboratory director. 4. Interview with the Technical Consultant on 11.27.23 at 1:30 pm confirmed the lab director failed to ensure an approved procedure manual was available to testing personnel for use of the Qualigen Fast Pack System since testing began on 8.17.23 until the date of the survey on 11.27.23.