Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2113773	05/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Total Men's Primary Care	180 E Whitestone Blvd Suite # 162, Cedar Park, 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
D0000	As a result of the initial CLIA certification inspection performed on Tuesday, May 15, 2018, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493. D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant;
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 review of laboratory policies and procedures, competency assessment documentation, and interview with facility personnel, the laboratory failed to follow written procedures to assess the competency of 2 of 2 testing personnel between June 2016 and May 2018. The findings included: 1. Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document direct observation of routine patient test performance, including patient preparation, specimen handling, processing, and testing for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. Refer to D6047. Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document monitoring the recording and reporting of test results for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. Refer to D6048. Based on the testing personnel competency assessment documentation and interview

	with facility personnel, the Technical Consultant failed to perform and document the review of quality control records, proficiency testing records or preventative maintenance records for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. Refer to D6049. Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document direct observation of performance of instrument maintenance and function checks for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. Refer to D6050. Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. Refer to D6051. Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document assessment of problem solving skills for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. Refer to D6052. Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to evaluate the performance of Testing Person 2 semi-annually in the first year of testing patient specimens between June 12, 2016 and June 12, 2017. Refer to D6053. 2. In an interview at 09:52 hours on 5/15/2018 in the laboratory, the Director of Operations stated the laboratory had used the manufacturer provided training worksheets as evidence of competency assessment by the Technical Consultant.
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 twice annual accuracy assessment records, laboratory policies and procedures, and interview with facility personnel, the laboratory failed to assess the accuracy twice annually in 2 of 2 times in 2017 for the Frend PSA assay and the Qualigen Testosterone assay. The findings included: 1. At 10:44 hours on 5/15/2018 in the laboratory, the twice annual accuracy assessment records for the Frend PSA assay and the Qualigen testosterone assay were requested. The laboratory provided documentation of assessing the accuracy for the Frend PSA assay and the Qualigen testosterone assay on May 9, 2018. 2. In an interview at 10:44 hours on 5/15/2018 in the laboratory, the Director of Operations stated the laboratory was unable to find documentation of twice annual accuracy assessment for the year 2017.
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 laboratory's policies and procedures, twice annual accuracy assessment records, and PSA assay instructions for use, the laboratory failed to establish and follow written policies and procedures to monitor, assess, and correct problems identified in general laboratory system requirements at 493.1231 through 493.1236 for 2016. The findings included: 1. The laboratory's quality assurance activities failed to detect and correct that the laboratory failed to assess testing personnel competency twice in the first year of testing and include the following: Direct observation of routine patient testing, including patient preparation, specimen handling, processing and testing. Monitor the recording and reporting of results Review intermediate results or worksheets, quality control records, proficiency testing records, and preventative maintenance records Direct observation of instrument maintenance and function checks Assessment of test performance through previously analyzed specimens, internal blind testing samples, external proficiency testing samples; and Assessment of problem solving skills Refer to D5209. 2. The laboratory's quality assurance activities failed to detect and correct that the laboratory failed to verify the accuracy of the analytes PSA and Testosterone twice annually for 2017. Refer to D5217. Key: PSA (prostate specific antigen)
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 surveyor observations, Cliniqa control instructions for use, review of quality control records, laboratory policies and procedures including Individualized Quality Control Plans (IQCP), patient records, and interview with facility personnel, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Refer to D5417, D5437, D5439, D5447, D5445, D5469, and D5791.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on quality control instructions for use, quality control records, patient records, and interview with facility personnel, the laboratory failed to ensure that expired quality control material was not used to assess the performance of the Frend PSA assay between April 1, 2018 and May 15, 2018. The findings included: 1. Based on review of the Cliniqa Liquid QC Immunoassay Control instructions for use (32928 06,

	1/18/13), under LIMITATIONS OF PROCEDURES, the manufacturer instructions state: "CLINIQA Liquid QC Immunoassay Control should not be used past the expiration date on the vial label." 2. Based on review of the Quality Control Plan portion of the laboratory's Individualized Quality Control Plan (IQCP), the document states: "External two-level liquid QC is run monthly or more often when needed. See "FREND Control Runs" section of this procedure manual". 3. Based on the laboratory's quality control records: Quality Control Lot 1411070, expiration 3/31 /2018 was run on 4/12/2018 Elapsed expiration: 12 days Quality Control Lot 1411071, expiration 3/31/2018 was run on 4/12/2018 Elapsed expiration: 12 days The previous in-date control values were run on 3/12/2018. 4. Based on review of patient testing records, the following 37 patients tested for on the FREND PSA assay since the previous control material expired. Date of testing Patient Identification 04/02/2018 7171985 04/04/2018 6181983 04/06/2018 2011956 04/11/2018 4041964 04/11/2018 7111962 04/12/2018 2031977 04/13/2018 12161959 04/13/2018 9301987 04/16/2018 6021982 04/16/2018 11081966 04/16/2018 8161967 04/16/2018 1241954 04/17/2018 5301983 04/17/2018 6181977 04/20/2018 12031987 04/20/2018 11071980 04/20 /2018 1071966 04/24/2018 10191980 04/24/2018 4101979 04/24/2018 9121962 04/25 /2018 3221962 04/26/2018 11061956 04/26/2018 9161967 04/27/2018 10261976 04 /27/2018 1281974 04/30/2018 10181983 04/30/2018 10191969 05/01/2018 2231978 05/01/2018 4241972 05/01/2018 12191962 05/08/2018 4221969 05/09/2018 9111972 05/09/2018 9271971 05/09/2018 8081982 05/11/2018 2211981 05/14/2018 7021971 05/14/2018 7061987 5. In an interview at 11:32 hours on 5/15/2018 in the laboratory, the Director of Operations acknowledged the quality control material had exceeded the manufacturer's expiration date when it was run on 4/12/2018. Key: PSA (prostate specific antigen)
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 review of the Qualigen operator's manual, calibration records for the Qualigen testosterone assay, and interview with facility personnel, the laboratory failed to perform calibration at least every 15 days 2 of 9 times between January 12, 2018 and May 15, 2018. The findings included: 1. Based on review of the Qualigen FastPack System Procedure manual, on page 19, the operator's manual states the following: "When is Calibration Required? The analyzer display will prompt you automatically when a calibration is due. this prompt will occur for two reasons: 1. When attempting to use new lots of Fastpacks or Calibrators. 2. When it's Time to Recalibrate Calibration expires every 15 days for the following assays: TSH, Free T4, Testo (Testosterone)." 2. Based on the Timestamp documentation the laboratory provided for FastPack testosterone calibrations, the laboratory calibrated the

	testosterone assay on the following dates: 1/12/2018 2/26/2018 3/23/2018 3/26/2018 4/9/2018 4/23/2018 5/8/2018 5/9/2018 5/15/2018 The calibration exceeded 15 days on the following 2 of 9 date intervals: Between 1/12/2018 and 2/26/2018 Elapsed time: 45 days Between 2/26/2018 and 3/23/2018 Elapsed time: 25 days 3. In an interview at 14:03 hours on 5/15/2018 in the laboratory, the Director of Operations stated that the lab missed the 15-day calibration interval a few times since January 12, 2018.
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 review of Qualigen testosterone calibration verification records and interview with facility personnel, the laboratory failed to perform calibration verification procedures at least once every 6 months 1 of 3 times between September 12, 2016 and May 15, 2018. The findings included: 1. Based on review of the calibration verification records from September 12, 2016 through May 15, 2018, the laboratory performed calibration verification procedures on the following dates: 9/12/2016 06/30/2017 01/03/2018 Between 9/12/2016 and 06/30/2017, the laboratory exceeded 6 months Elapsed time: 9 months and 18 days 2. In an interview at 14:00 hours on 5/15/2018 in the laboratory, the Director of Operations stated the laboratory had made recent adjustments to the calibration verification schedule to ensure the lab did not exceed 6 months in the future.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when

	they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's Individualized Quality Control Plan for the Frend PSA assay, and interview with facility personnel, the laboratory failed to define frequency and impact of each potential risk identified in the Risk Assessment portion of the Individualized Quality Control Plan (IQCP). The findings included: 1. Based on review of the FREND IQCP (approved on 5/10/2018) Risk Assessment, the laboratory identified the following risks: Risk: Incorrect results due to reagent deterioration during shipment The laboratory failed to evaluate the frequency and impact of this source of failure on test quality. Risk: Incorrect results due to spectrophotometric drift. The laboratory failed to evaluate the frequency and impact of this source of failure on test quality. Risk: Incorrect results due to sample data entry error. The laboratory failed to evaluate the frequency and impact of this source of failure on test quality. Risk: Incorrect results due to operating the measuring system outside of manufacturer's environmental specifications. The laboratory failed to evaluate the frequency and impact of this source of failure on test quality. 2. In an interview at 11: 00 hours on 5/15/2018 in the laboratory, the Director of Operations stated the Risk assessment focused on mitigating sources of error but did not evaluate the frequency and impact of this source of failure on test quality. II. Based on review of the laboratory's Individualized Quality Control Plan for the Frend PSA assay and interview with facility personnel, the laboratory failed to perform external quality control at least as often as required by the manufacturer. The findings included: 1. Based on review of the laboratory's Individualized Quality Control Plan for the Frend PSA assay, under Quality Control Plan, the document states the following: "External two-level liquid QC is run monthly or more often when needed. See FREND Control Runs" section of this manual. The "FREND Control Runs" section of the manual does not indicate the frequency of the performance of external quality control. 2. Based on review of the FREND PSA Plus instructions for use (V.0.3.), under External quality control testing, states the following: "Commercially available controls that contain total PSA as a measure analyte are available for a variety of manufacturers. It is recommended that a minimum of two (2) levels be run at least once per month or once for each new lot, whichever comes earlier." 3. In an interview at 11:02 hours on 5/15 /2018 in the laboratory, the Director of Operations stated the laboratory performed external liquid quality control monthly. Key: PSA (prostate specific antigen)
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control records, patient testing records, and interview with facility personnel, the laboratory failed to perform two levels of quality control each day of patient testing for 2 of 5 days in July 2016 or develop an Individualized Quality Control Plan to modify the frequency of quality control testing. The findings included:

	1. Based on review of the FREND verification study, the FREND was approved for patient testing by the Laboratory Director on 4/22/2016. 2. Based on review of policies and procedures, the laboratory developed an Individualized Quality Control Plan to modify the quality control frequency from each day of patient testing to implement monthly quality control on 3/15/2017. In an interview at 14:32 hours on 5 /15/2018 in the laboratory, the Director of Operations confirmed the laboratory did not have documentation of implementing an IQCP between 4/22/2016 and 3/15/2017. 3. Based on a random sampling review of quality control records from July 2016, quality control assays were performed on the following dates: July 7th, 2016 July 13, 2016 July 25, 2016 4. Based on review of patient records, 11 patients were tested on 2 days in July 2016 when quality control was not performed each day of patient testing. Date of testing Patient Identification 07/21/2016 5151954 07/21/2016 9171942 07/21 /2016 8271975 07/21/2016 7201967 07/21/2016 10121954 07/21/2016 11271970 07 /21/2016 3041969 07/27/2016 3041993 07/27/2016 3041969 07/27/2016 9011968 07 /27/2016 11011972 5. In an interview at 14:32 hours on 5/15/2018 in the laboratory, the Director of Operations confirmed the laboratory did not have documentation of implementing an IQCP between 4/22/2016 and 3/15/2017, and would have been required to run quality control each day of patient testing.
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 review of Cliniqa Immunoassay control instructions for use, laboratory policy, laboratory quality control records, and confirmed in interview, the laboratory failed to establish parameters for the acceptability of controls for 1 of 1 lot of control material used between April 2016 through May 15, 2018. The findings included: 1. Review of the Cliniqa Immunoassay Liquid QC Control (Ref 94104), under ASSIGNMENT OF VALUES, states: "The Expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation." 2. Review of laboratory quality control records indicate that the laboratory used the following lot of control material between April 2016 and May 15, 2018: 1411070A and 1411071A 3. In an interview at 11:55 hours on 05/15/2018 in the laboratory, the Director of Operations confirmed that the laboratory had been using the Expected Range of Means to determine acceptability criteria instead of establishing acceptability criteria as required by both the manufacturer and laboratory policy and stated the laboratory had recently established acceptability criteria and would using the new acceptability criteria on 5/16/2018.

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 review of the laboratory's policies and procedures, Cliniqa control instructions for use, quality control records, surveyor observation, and staff interview, the laboratory failed to establish and follow written policies and procedures to monitor, assess and correct problems in the analytic laboratory systems specified at 493.1251 through 493.1283. The findings included: 1. The laboratory's quality assurance activities failed to monitor, assess, and correct that the laboratory failed to ensure that expired quality control material was not used to assess the performance of the Frend PSA assay between April 1, 2018 and May 15, 2018.Re.fer to D5417. 2.The laboratory's quality assurance activities failed to monitor, assess, and correct that the laboratory failed to perform calibration at least every 15 days 2 of 9 times between January 12, 2018 and May 15, 2018. Refer to D5437. 3. The laboratory's quality assurance activities failed to monitor, assess, and correct that the laboratory failed to perform calibration verification procedures at least once every 6 months 1 of 3 times between September 12, 2016 and May 15, 2018. Refer to D5439. 4. The laboratory's quality assurance activities failed to monitor, assess, and correct that the laboratory failed to define frequency and impact of each potential risk identified in the Risk Assessment portion of the Individualized Quality Control Plan (IQCP) for the FREND analyzer. Refer to D5445-I. 5. The laboratory's quality assurance activities failed to monitor, assess, and correct that the laboratory failed to perform external quality control at least as often as required by the manufacturer. Refer to D5445-II. 6. The laboratory's quality assurance activities failed to monitor, assess, and correct that the laboratory failed to perform two levels of quality control each day of patient testing for 2 of 5 days in July 2016 or develop an Individualized Quality Control Plan to modify the frequency of quality control testing. Refer to D5447. 7. The laboratory's quality assurance activities failed to monitor, assess, and correct that the laboratory failed to establish parameters for the acceptability of controls for 1 of 1 lot of control material used between April 2016 through May 15, 2018. Refer to D5469.
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 review of the laboratory's policies and procedures, quality control records, quality assessment records and staff interview, the laboratory director failed to provide overall management and direction of the laboratory. Refer to D6020 and D6021.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, operator's manuals, manufacturer instructions for controls, and staff interview, the laboratory director failed to ensure that the quality control program was maintained to assure the quality of laboratory services. The laboratory director failed to ensure: Based on review of the laboratory's Individualized Quality Control Plan for the Frend PSA assay, and interview with facility personnel, the laboratory failed to define frequency and impact of each potential risk identified in the Risk Assessment portion of the Individualized Quality Control Plan (IQCP). Refer to D5445-I. Based on review of the laboratory's Individualized Quality Control Plan for the Frend PSA assay and interview with facility personnel, the laboratory failed to perform external quality control at least as often as required by the manufacturer. Refer to D5445-II. Based on quality control records, patient testing records, and interview with facility personnel, the laboratory failed to perform two levels of quality control each day of patient testing for 2 of 5 days in July 2016 or develop an Individualized Quality Control Plan to modify the frequency of quality control testing. Refer to D5447. Based on review of Cliniqa Immunoassay control instructions for use, laboratory policy, laboratory quality control records, and confirmed in interview, the laboratory failed to establish parameters for the acceptability of controls for 1 of 1 lot of control material used between April 2016 through May 15, 2018. Refer to D5469.
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 review of the laboratory's quality assessment records, operator's manuals, patient test records, and staff interview, the laboratory director failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services. The findings included: 1. The laboratory director failed to ensure policies and procedures were established and followed to detect problems in general laboratory systems. Refer to D5291. 2. The laboratory director failed to ensure policies and procedures were established and followed to detect problems in analytic laboratory systems. Refer to D5791.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY

	CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, quality control records, patient test records, personnel and competency assessment records, and confirmed in interview with laboratory staff, the Technical Consultant failed to provide technical oversight to the laboratory. Refer to D6042, D6047, D6048, D6049, D6050, D6051, D6052, and D6053.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, operator's manuals, manufacturer instructions for controls, and staff interview, the Technical Consultant failed to establish and maintain the quality control program to assure the quality of laboratory services. The Technical Consultant failed to ensure: Based on review of the laboratory's Individualized Quality Control Plan for the Frend PSA assay, and interview with facility personnel, the laboratory failed to define frequency and impact of each potential risk identified in the Risk Assessment portion of the Individualized Quality Control Plan (IQCP). Refer to D5445-I. Based on review of the laboratory's Individualized Quality Control Plan for the Frend PSA assay and interview with facility personnel, the laboratory failed to perform external quality control at least as often as required by the manufacturer. Refer to D5445-II. Based on quality control records, patient testing records, and interview with facility personnel, the laboratory failed to perform two levels of quality control each day of patient testing for 2 of 5 days in July 2016 or develop an Individualized Quality Control Plan to modify the frequency of quality control testing. Refer to D5447. Based on review of Cliniqa Immunoassay control instructions for use, laboratory policy, laboratory quality control records, and confirmed in interview, the laboratory failed to establish parameters for the acceptability of controls for 1 of 1 lot of control material used between April 2016 through May 15, 2018. Refer to D5469.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

	This STANDARD is not met as evidenced by: Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document direct observation of routine patient test performance, including patient preparation, specimen handling, processing, and testing for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. The findings included: 1. At 09:50 hours on 5/15/2018 in the laboratory, the Director of Operations was asked to provide documentation of competency assessments performed since 5/18/2016, when the Qualigen testosterone assay was approved for patient testing, for Testing Person 1 and Testing Person 2 (as listed on the CMS-209 Laboratory Personnel Report). Based on review of the document "FastPack IP System Training Checklist", that was provided as documentation of competency assessment, the Technical Consultant did not document direct observation of routine patient test performance, including patient preparation, specimen handling, processing, and testing for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2. Testing Person 1 Date of hire: 12/01/2016 Dates of competency assessments: 12/20 /2016, 09/25/2017, 3/7/2018 Testing Person 2 Date of Hire: 6/5/2016 Dates of competency assessments: 06/12/2016, 09/25/2017, 3/7/2018 2. In an interview at 09: 52 hours on 5/15/2018 in the laboratory, the Director of Operations stated the laboratory had used the manufacturer provided training worksheets as evidence of competency assessment by the Technical Consultant and did not document direct observation of routine test performance including patient preparation, specimen handling, processing, and patient testing,
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document monitoring the recording and reporting of test results for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. The findings included: 1. At 09:50 hours on 5/15/2018 in the laboratory, the Director of Operations was asked to provide documentation of competency assessments performed since 5/18/2016, when the Qualigen testosterone assay was approved for patient testing, for Testing Person 1 and Testing Person 2 (as listed on the CMS-209 Laboratory Personnel Report). Based on review of the document "FastPack IP System Training Checklist", that was provided as documentation of competency assessment, the Technical Consultant did not perform and document monitoring the recording and reporting of test results for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2. Testing Person 1 Date of hire: 12/01/2016 Dates of competency assessments: 12/20/2016, 09/25/2017, 3/7/2018 Testing Person 2 Date of Hire: 6/5/2016 Dates of competency assessments: 06/12 /2016, 09/25/2017, 3/7/2018 The "FastPack IP System Training Checklist" states "Knowing and using proper reporting systems (including abnormal and panic results" under the heading "Attained proficiency In:" There is no documentation of the Technical Consultant monitoring the recording and reporting of any patient test results. 2. In an interview at 09:52 hours on 5/15/2018 in the laboratory, the Director of Operations stated the laboratory had used the manufacturer provided training

	worksheets as evidence of competency assessment by the Technical Consultant and did not perform and document monitoring the recording and reporting of test results.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document the review of quality control records, proficiency testing records or preventative maintenance records for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. The findings included: 1. At 09: 50 hours on 5/15/2018 in the laboratory, the Director of Operations was asked to provide documentation of competency assessments performed since 5/18/2016, when the Qualigen testosterone assay was approved for patient testing, for Testing Person 1 and Testing Person 2 (as listed on the CMS-209 Laboratory Personnel Report). Based on review of the document "FastPack IP System Training Checklist", that was provided as documentation of competency assessment, the Technical Consultant did not perform and document the review of quality control records, proficiency testing records or preventative maintenance records for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2. Testing Person 1 Date of hire: 12/01/2016 Dates of competency assessments: 12/20/2016, 09/25/2017, 3/7/2018 Testing Person 2 Date of Hire: 6/5/2016 Dates of competency assessments: 06/12/2016, 09/25/2017, 3 /7/2018 2. In an interview at 09:52 hours on 5/15/2018 in the laboratory, the Director of Operations stated the laboratory had used the manufacturer provided training worksheets as evidence of competency assessment by the Technical Consultant and did not perform and document the review of quality control records, proficiency testing records or preventative maintenance records.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document direct observation of performance of instrument maintenance and function checks for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. The findings included: 1. At 09:50 hours on 5/15/2018 in the laboratory, the Director of Operations was asked to provide documentation of competency assessments performed since 5/18/2016, when the Qualigen testosterone assay was approved for patient testing, for Testing Person 1 and Testing Person 2 (as listed on the CMS-209 Laboratory Personnel Report). Based on review of the document "FastPack IP System Training Checklist", that was provided as

	documentation of competency assessment, the Technical Consultant did not perform and document direct observation of performance of instrument maintenance and function checks for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2. Testing Person 1 Date of hire: 12/01/2016 Dates of competency assessments: 12/20/2016, 09/25/2017, 3/7/2018 Testing Person 2 Date of Hire: 6/5 /2016 Dates of competency assessments: 06/12/2016, 09/25/2017, 3/7/2018 2. In an interview at 09:52 hours on 5/15/2018 in the laboratory, the Director of Operations stated the laboratory had used the manufacturer provided training worksheets as evidence of competency assessment by the Technical Consultant and did not perform and document direct observation of performance of instrument maintenance and function checks.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. The findings included: 1. At 09:50 hours on 5/15/2018 in the laboratory, the Director of Operations was asked to provide documentation of competency assessments performed since 5/18/2016, when the Qualigen testosterone assay was approved for patient testing, for Testing Person 1 and Testing Person 2 (as listed on the CMS-209 Laboratory Personnel Report). Based on review of the document "FastPack IP System Training Checklist", that was provided as documentation of competency assessment, the Technical Consultant did not perform and document assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples 6 of 6 competency assessments of Testing Person 1 and Testing Person 2. Testing Person 1 Date of hire: 12/01/2016 Dates of competency assessments: 12/20/2016, 09/25/2017, 3 /7/2018 Testing Person 2 Date of Hire: 6/5/2016 Dates of competency assessments: 06 /12/2016, 09/25/2017, 3/7/2018 2. In an interview at 09:52 hours on 5/15/2018 in the laboratory, the Director of Operations stated the laboratory had used the manufacturer provided training worksheets as evidence of competency assessment by the Technical Consultant and did not perform and document assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by:

	Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to perform and document assessment of problem solving skills for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2 between June 2016 and May 2018. The findings included: 1. At 09:50 hours on 5/15/2018 in the laboratory, the Director of Operations was asked to provide documentation of competency assessments performed since 5/18 /2016, when the Qualigen testosterone assay was approved for patient testing, for Testing Person 1 and Testing Person 2 (as listed on the CMS-209 Laboratory Personnel Report). Based on review of the document "FastPack IP System Training Checklist", that was provided as documentation of competency assessment, the Technical Consultant did not perform and document assessment of problem solving skills for 6 of 6 competency assessments of Testing Person 1 and Testing Person 2. Testing Person 1 Date of hire: 12/01/2016 Dates of competency assessments: 12/20 /2016, 09/25/2017, 3/7/2018 Testing Person 2 Date of Hire: 6/5/2016 Dates of competency assessments: 06/12/2016, 09/25/2017, 3/7/2018 2. In an interview at 09: 52 hours on 5/15/2018 in the laboratory, the Director of Operations stated the laboratory had used the manufacturer provided training worksheets as evidence of competency assessment by the Technical Consultant and did not perform and document assessment of problem solving skills.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the testing personnel competency assessment documentation and interview with facility personnel, the Technical Consultant failed to evaluate the performance of Testing Person 2 semi-annually in the first year of testing patient specimens between June 12, 2016 and June 12, 2017. The findings included: 1. At 09:50 hours on 5/15 /2018 in the laboratory, the Director of Operations was asked to provide documentation of competency assessments performed since 5/18/2016, when the Qualigen testosterone assay was approved for patient testing, for Testing Person 2 (as listed on the CMS-209 Laboratory Personnel Report). Based on review of the document "FastPack IP System Training Checklist", that was provided as documentation of competency assessment, the Technical Consultant did not evaluate the performance of Testing Person 2 semi-annually in the first year of testing patient specimens between June 12, 2016 and June 12, 2017. Testing Person 2 Date of Hire: 6 /5/2016 Dates of competency assessments: 06/12/2016 09/25/2017 3/7/2018 2. In an interview at 10:09 hours on 5/15/2018 in the laboratory, the Director of Operations stated the Technical Consultant did not evaluate the performance of Testing Person 2 semi-annually in the first year of testing patient specimens between June 12, 2016 and June 12, 2017 and that the second competency assessment was late on September 25, 2017.