Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1036163	03/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Ssm Health Medical Group	105 N Indian Meridian Rd, Pauls Valley, OK	

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	The recertification survey was performed on 03/11/2020. The laboratory was found out of compliance with the following CLIA regulations: 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory director and lead lab tech /testing person #1 at the conclusion of the survey.
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 a review of records, manufacturer's instructions, and interview with lead lab tech/testing person #1 and the laboratory director, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed for 14 of 14 months. Findings include: (1) The laboratory failed to perform two levels of quality control materials each day of PSA and TSH testing. Refer to D5447; (2) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479; (3) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791.
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 a review of records and interview with lead lab tech/testing person #1 and the laboratory director, the laboratory failed to perform two levels of quality control materials each day of PSA and TSH testing for 14 of 14 months. Findings include: (1) At the beginning of the survey, lead lab tech/testing person #1, stated the following to the surveyor: (a) PSA (Prostate Specific Antigen) and TSH (Thyroid Stimulating Hormone) testing were performed on the the NanoEntek FREND analyzer; (b) Two levels of Cliniqa Liquid QC Immunoassay Control quality control (QC) materials were performed every 30 days and with new shipments and/or new lot numbers of PSA and TSH test cartridges. (2) Later during the survey, the surveyor asked the laboratory director if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory director stated to the surveyor, the laboratory had not developed an IQCP. Therefore, the surveyor determined two levels of QC materials must be performed each day of patient testing; (3) The surveyor reviewed QC and patient testing records from January 2019 through June 2019; August 2019 through December 2019; and January 2020 through the day of the survey. The documentation showed two levels of QC testing had not been performed each day of patient PSA and TSH testing for 95 of 115 days of patient testing reviewed; (4) The surveyor reviewed the records with lead lab tech/testing person #1 and the laboratory director. Both stated two levels of QC materials had not been performed each day of patient PSA and TSH testing; (5) The following were examples of patient testing performed when two levels of QC materials had not been tested: (a) Patient #4 - PSA and TSH testing performed on 01/02/2019 (b) Patient #5 - PSA and TSH testing performed on 01/11/2019 (c) Patient #6 - TSH testing performed on 01/17/2019 (d) Patient #7 - PSA testing performed on 01/21/2019 (e) Patient #8 - TSH testing performed on 01/21/2019 (f) Patient #9 - TSH testing performed on 01/28/2019 (g) Patient #10 - TSH testing performed on 02/04/2019 (h) Patient #11 - PSA testing performed on 02/06/2019 (i) Patient #12 - PSA and TSH testing performed on 02/22/19 (j) Patient #13 - PSA testing performed on 03/01/2019 (k) Patient #14 - TSH testing performed on 03/05/2019 (l) Patient #15 - PSA testing performed on 03/05/2019 (m) Patient #3 - PSA and TSH testing performed on 03/13 /2019 (n) Patient #16 - TSH testing performed on 03/20/2019 (o) Patient #17 - PSA testing performed on 03/27/19 (p) Patient #18 - TSH testing performed on 03/27/19 (q) Patient #19 - TSH testing performed on 03/29/19 (r) Patient #20 - PSA testing performed on 04/02/2019 (s) Patient #21 - PSA testing performed on 04/03/209 (t) Patient #22 - TSH testing performed on 05/24/2019 (u) Patient #23 - PSA testing performed on 05/28/2019 (v) Patient #24 - TSH testing performed on 05/30/2019 (w) Patient #25 - PSA testing performed on 06/05/2019 (x) Patient #26 - PSA and TSH testing performed on 06/07/2019 (s) Patient #27 - TSH testing performed on 06/11 /2019 (t) Patient #28 - PSA testing performed on 06/13/2019 (u) Patient #29 - PSA testing performed on 06/24/2019 (v) Patient #30 - TSH testing performed on 06/24 /2019 (w) Patient #31 - TSH testing performed on 06/28/2019 (x) Patient #32 - PSA and TSH testing performed on 08/27/2019 (y) Patient #33 - TSH testing performed on 08/29/2019 (z) Patient #34 - PSA testing performed on 08/30/2019 (aa) Patient #35 - PSA testing performed on 09/05/2019 (bb) Patient #36 - TSH testing performed on 09 /17/2019 (cc) Patient #37 - PSA and TSH testing performed on 09/18/2019 (dd)

	Patient #38 - TSH testing performed on 09/23/19 (ee) Patient #39 - PSA and TSH testing performed on 10/01/2019 (ff) Patient #40 - PSA testing performed on 11/15 /2019 (gg) Patient #41 - TSH testing performed on 11/15/209 (hh) Patient #42 - TSH testing performed on 11/18/2019 (ii) Patient #43 - PSA testing performed on 11/18 /2019 (jj) Patient #44 - TSH testing performed on 11/26/2019 (kk) Patient #45 - PSA and TSH testing performed on 11/27/2019 (ll) Patient #46 - PSA and TSH testing performed on 12/05/2019 (mm) Patient #47 - PSA testing performed on 12/16/2019 (nn) Patient #48 - TSH testing performed on 12/17/2019 (oo) Patient #49 - PSA and TSH testing performed on 12/19/2019 (pp) Patient #50 - PSA and TSH testing performed on 12/26/2019 (qq) Patient #51 - TSH testing performed on 12/30/2019 (rr) Patient #52 - PSA testing performed on 12/30/2019 (ss) Patient #53 - PSA testing performed on 01/02/2020 (tt) Patient #54 - TSH testing performed on 01/02/2020 (uu) Patient #55 - TSH testing performed on 01/03/2020 (vv) Patient #56 - PSA testing performed on 01/07/2020 (ww) Patient #57 - PSA and TSH testing performed on 01 /10/2020 (xx) Patient #58 - TSH testing performed on 01/14/2020 (yy) Patient #59 - PSA testing performed on 01/14/2020 (zz) Patient #60 - TSH testing performed on 01 /21/2020 (aaa) Patient #61 - PSA testing performed on 01/24/2020 (bbb) Patient #62 - TSH testing performed on 01/24/2020 (ccc) Patient #63 - PSA and TSH testing performed on 01/30/2020 (ddd) Patient #64 - PSA testing performed on 02/03/2020 (eee) Patient #65 - PSA and TSH testing performed on 02/06/2020 (fff) Patient #66 - TSH testing performed on 02/07/2020 (ggg) Patient #67 - PSA and TSH testing performed on 02/12/2020 (hhh) Patient #68 - TSH testing performed on 02/21/2020 (iii) Patient #69 - PSA testing performed on 02/24/2020 (jjj) Patient #70 - TSH testing performed on 02/25/2020 (kkk) Patient #71 - PSA testing performed on 02/28/2020 (lll) Patient #72 - TSH testing performed on 02/28/2020 (mmm) Patient #73 - PSA and TSH testing performed on 03/03/2020 (nnn) Patient #74 - PSA and TSH testing performed on 03/05/2020 (ooo) Patient #75 - PSA and TSH testing performed on 03 /06/2020 (ppp) Patient #76 - PSA testing performed on 03/06/2020 (qqq) Patient #77 - TSH testing performed on 03/09/2020
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with lead lab tech/testing person #1, the laboratory failed to follow the manufacturer's quality control specifications for 14 of 14 months. Findings include: (1) At the beginning of the survey, lead lab tech/testing person #1, stated the following to the surveyor: (a) PSA (Prostate Specific Antigen) and TSH (Thyroid Stimulating Hormone) testing were performed on the the NanoEntek FREND analyzer; (b) Two levels of Cliniqa Liquid QC Immunoassay Control quality control (QC) materials were performed every 30 days and with new shipments and/or new lot numbers of PSA and TSH test cartridges (refer to D5447 for not performing QC each day of patient testing). (2) Later during the survey, the surveyor reviewed the manufacturer's instructions for the QC materials which stated, "The Expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation. It is considered good laboratory practice for each laboratory to establish its own mean and

	standard deviation for its test methods"; (3) The surveyor reviewed records for testing performed from January 2019 through June 2019; August 2019 through December 2019; and January 2020 through the day of the survey. For 2 of 2 lot numbers, it was identified the laboratory had used the package insert guideline ranges instead of laboratory established ranges to determine acceptability of QC results. The package insert ranges had been used during the review period as follows: (a) Cliniqa Liquid QC Immunoassay Control (level 1 lot #1706090A and level 2 lot #1706091A) (i) PSA - The laboratory used the manufacturer's range of 0.59-1.92 ng/ml for level 1 and 8.03-17.64 ng/ml for level 3; (ii) TSH - The laboratory used the manufacturer's range of 0.72-1.61 mIU/L for level 1 and 8.38-15.65 mIU/L for level 3. (4) The surveyor reviewed the findings with lead lab tech/testing person #1, who stated at 4:50 pm that the laboratory had used the manufacturer's provided ranges for determining acceptability of the results, as indicated above, and did not establish their own ranges; (5) Refer to D5447 for examples of patient testing performed.
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 a review of records, manufacturer's instructions, and interview with lead lab tech/testing person #1 and the laboratory director, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment for 14 of 14 months. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to perform two levels of quality control materials each day of PSA and TSH testing. Refer to D5447; (b) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479.
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 a review of records and interview with lead lab tech/testing person #1, the laboratory failed to ensure patient test reports included either the patient's name and identification number, or a unique patient identifier and identification number; and the name of the laboratory location for 3 of 3 patient reports. Findings include: (1) During

	the survey, the surveyor reviewed 3 patient test reports as follows: (a) Patient #1 - TSH (Thyroid Stimulating Hormone) testing was performed with the results reported on 03/10/2020; (b) Patient #2 - CBC (Complete Blood Count) and TSH testing were performed with the results reported on 03/10/2020; (c) Patient #3 - CBC, PSA (Prostate Specific Antigen), and TSH testing were performed with the results reported on 03/11/2020. (2) The surveyor identified the following: (a) The reports did not include a second unique identifier (only the patient's first and last name and date of birth were on the reports); (b) The name of the laboratory on the reports did not match the name on the Clia certificate. The name on patient report #1 was "Allee Family Medicine" and the name on patient report #2 and patient #3 was "Brian A. Allee, D.O. - SSM Medical". The name on the Clia certificate was "SSM Medical Group Pauls Valley"; (3) The surveyor reviewed the reports with lead lab tech/testing person #1, who stated the reports did not include a second unique identifier and the name on the reports did not match the name on the Clia certificate.
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 a review of records and interview with lead lab tech/testing person #1, the laboratory failed to make appropriate reference ranges available for 3 of 3 PSA and/or TSH patient reports and 2 of 2 CBC patient reports. Findings include: PSA AND TSH TESTING (1) At the beginning of the survey, lead lab tech/testing person #1 stated to the surveyor PSA (Prostate Specific Antigen) and TSH (Thyroid Stimulating Hormone) testing were performed using the NanoEntek FREND analyzer; (2) Later during the survey, the surveyor reviewed three patient reports containing PSA and/or TSH test results. The reports did not include reference ranges for PSA and TSH as follows: (a) Patient #1 - TSH testing performed on 03/10/2020 (b) Patient #2 - TSH testing performed on 03/10/2020 (c) Patient #3 - PSA and TSH testing performed on 03/11/2020 (3) The surveyor reviewed the reports with lead lab tech/testing person #1, who stated to the surveyor the reports did not include the reference ranges for PSA and TSH testing. CBC TESTING (1) At the beginning of the survey, lead lab tech /testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Beckman Coulter ACT Diff 2 analyzer;(2) Later during the survey, the surveyor reviewed two patient CBC reports: (a) Patient #2 - An adult female with the testing performed on 03/10/2020 at 11:54 (b) Patient #3 - An adult male with the testing performed on 03/11/2020 at 09:36 (3) Both reports included the same reference intervals (not gender specific) for the CBC parameters of RBC (Red Blood Cell) and Hemoglobin which were: (a) RBC - 4.00 - 6.00 10^6/L (b) Hemoglobin - 11.0 - 18.0 g/dL (c) Hematocrit - 35.0-60.0 % (4) The surveyor reviewed the findings with lead lab tech/testing person #1 who stated the patient reports did not include gender specific reference ranges for RBC, Hemoglobin, and Hematocrit; NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
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 a review of records, manufacturer's instructions, and interview with lead lab tech/testing person #1 and the laboratory director, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (2) The laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Refer to D6016; (3) The laboratory director failed to ensure proficiency testing reports were reviewed. Refer to D6018; (4) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (5) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (6) The laboratory director failed to ensure test reports included pertinent information required for interpretation. Refer to D6026.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with lead lab tech/testing person #1, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported for 14 of 14 months. Findings include: (1) The laboratory director failed to ensure the laboratory followed the manufacturer's quality control specifications. Refer to D5479.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with lead lab tech/testing person #1, the

	laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 1 of 6 Chemistry Miscellaneous events. Findings include: (1) The surveyor reviewed 2018 and 2019 Chemistry Miscellaneous proficiency testing records. It was identified for 1 of 6 events, the attestation statement had been signed approximately 2 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2019 Chemistry Miscellaneous Event - The sample testing had been completed on 04/29/2019 and the attestation statement had not been signed by the laboratory director until 06/09/2019. (2) The surveyor reviewed the findings with lead lab tech/testing person #1 and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with lead lab tech/testing person #1, the laboratory director failed to ensure proficiency testing reports were reviewed for 1 of 6 Chemistry Core events. Findings include: (1) The surveyor reviewed 2018 and 2019 Chemistry Core proficiency testing records. The Performance Evaluations included a space for the laboratory director or designee signature and date (indicating review of the graded evaluation). The following events had not been signed and dated as reviewed by the laboratory director or designee: (a) Second 2019 Chemistry Core Event (2) The surveyor reviewed the records with lead lab tech/testing person #1, who stated the graded evaluation, as indicated above, had not been signed and dated as reviewed by the laboratory director or designee.
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 a review of records and interview with lead lab tech/testing person #1 and the laboratory director, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include:

	(1) The laboratory director failed to ensure two levels of quality control materials had been performed each day of PSA and TSH testing. Refer to D5447.
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 a review of records, manufacturer's instructions, and interview with lead lab tech/testing person #1 and the laboratory director, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on a review of records and interview with lead lab tech/testing person #1, the laboratory director failed to ensure test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure patient test reports included either the patient's name and identification number, or a unique patient identifier and identification number; and the name of the laboratory location. Refer to D5805; (2) The laboratory director failed to ensure appropriate reference ranges were available. Refer to D5807.
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 a review of records, manufacturer's instructions, and interview with lead lab tech/testing person #1 and the laboratory director, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings

	include: (1) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (2) The technical consultant failed to ensure evaluations included all moderate complexity testing performed. Refer to D6054.
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 a review of records, manufacturer's instructions, and interview with lead lab tech/testing person #1 and the laboratory director, the technical consultant failed to establish a quality control program which ensured the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure two levels of quality control materials had been performed each day of PSA and TSH testing. Refer to D5447; (2) The technical consultant failed to ensure the laboratory followed the manufacturer's quality control specifications. Refer to D5479.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with lead lab tech/testing person #1, the technical consultant failed to ensure evaluations included all moderate complexity testing performed. Findings include: (1) At the beginning of the survey, lead lab tech /testing person #1 stated to the surveyor the following were performed in the laboratory: (a) PSA (Prostate Specific Antigen) and TSH (Thyroid Stimulating Hormone) testing using the NanoEntek FREND analyzer; (b) CBC (Complete Blood Count) testing using the Beckman Coulter AcT Diff 2 analyzer. (2) The surveyor reviewed personnel records for 3 persons performing the above testing during 2018 and to date (lead lab tech/testing person #1, testing person #2, and testing person #3). The records showed that annual competency evaluations had been performed as follows: (a) Lead Lab Tech/Testing Person #1 - Performed on 12/24/18 and 12/14/19 for CBC testing; and performed on 12/28/18 and 12/30/19 for the specimen collection portion of PSA and TSH testing; (b) Testing Person #2 - Performed on 12/24/18 and 12/14/19 for CBC testing; and performed on 12/28/18 and 12/30/19 for the specimen collection portion of PSA and TSH testing; (c) Testing Person #3 - Performed on 12 /08/18 and 12/14/19 for CBC testing; and performed on 12/28/18 and 12/30/19 for the specimen collection portion of PSA and TSH testing. (3) There was no evidence the evaluations performed for the above persons, included an assessment of the analytical portion for PSA and TSH testing; (4) The surveyor reviewed the findings with lead

	lab tech/testing person #1, who stated the above evaluations did not include PSA and TSH testing.