Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2069305	07/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
T Off Mens Health Fort Worth	3500 West 7th, 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
D0000	Based on an announced validation inspection, the laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; 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;
D2098	ENDOCRINOLOGY CFR(s): 493.843(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 the proficiency testing records and interview, the laboratory failed to attain an acceptable score of 80% or higher for the analyte Thyroid Stimulating Hormone (TSH) in the 1st event of 2023 resulting in unsatisfactory analyte performance. Findings follow. A. Review of the American Proficiency Institute (API) proficiency testing records from the 1st event of 2023, the 1st, 2nd, and 3rd events of 2022, and the 3rd event of 2021 showed in the 2023 Chemistry Core 1st Event the laboratory obtained a score of 60% for TSH. B. Interview with testing personnel #1 on June 29, 2023 at 1625 hours confirmed the laboratory repeated the samples, but didn't re-evaluate the results.
D2099	ENDOCRINOLOGY CFR(s): 493.843(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

	This STANDARD is not met as evidenced by: Review the CMS 155, proficiency testing records, and interview showed that the laboratory failed to attain a satisfactory score of at least 80% in the 1st event of 2023 resulting in unsatisfactory performance for Endocrinology. Findings follow. A. Review the CMS 155 proficiency testing scores found that the laboratory obtained an overall testing event score of 60% for Endocrinology. B. Review of the American Proficiency Institute (API) proficiency testing records showed in the 2023 Chemistry Core 1st Event the laboratory obtained a score of 60% for Thyroid Stimulating Hormone (TSH) when the laboratory failed to submit acceptable results for 2 of 5 specimens. C. Interview with testing personnel #1 on June 29, 2023 at 1625 hours confirmed the laboratory repeated the samples, but didn't re-evaluate the results.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the maintenance logs, and interview, the laboratory failed to retain all maintenance logs for the Beckman Coulter UniCel DxI 600 for four of 23 months reviewed. Findings follow. A. Review of the Beckman Coulter UniCel DxI 600 Maintenance Logs from July 2021 to May 2023 showed missing logs: 1. August 2021 2. September 2021 3. December 2021 4. February 2022 B. Interview with testing personnel #1 on June 30, 2023 at 1100 hours confirmed the findings.
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 the proficiency testing records and interview, the laboratory failed to verify the accuracy of its testing when the laboratory failed to attain an acceptable score of 80% or higher for the analytes Vitamin B12, PSA (Prostate Specific Antigen) Folate, Prolactin, and Vitamin D in the 1st event of 2023, and for Vitamin B12 in the 1st event of 2022, and for Vitamin B12 and Prolactin for the 3rd event of 2021: three out of five testing events reviewed. Findings follow. A. Review of the American Proficiency Institute (API) proficiency testing records from the 1st event of 2023, the 1st, 2nd, and 3rd events of 2022, and the 3rd event of 2021 showed: 1. 2023 Chemistry Core 1st Event the laboratory obtained a score of 50% for the analytes: a. Vitamin B12 b. PSA c. Folate d. Prolactin and e. Vitamin D 2. 2022 Chemistry Core 1st Event the laboratory obtained a score of 50% for: a. Vitamin B12 3. 2021 Chemistry Core 3rd Event the laboratory obtained a score of 50% for: a. Vitamin B12 the laboratory obtained a score of 0% for: b. Prolactin. B. Interview with testing

	personnel #1 on June 29, 2023 at 1625 hours confirmed the failures. Phone interview with testing personnel #1 on July 21, 2023 at 1040 hours confirmed the failures and confirmed the laboratory never ceased testing.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, observation, query of testing records, and interview, the laboratory failed to monitor and evaluate the overall quality of the preanalyitic systems and correct identified problems in Chemistry and Endocrinology(see D5311).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, observation, query of testing records, request of collection date and times, and interview, the laboratory failed to ensure specimens were stored at the appropriate temperature for Ferritin, Folate, Prolactin, Prostate Specific Antigen (PSA), Total Testosterone, Vitamin B12, and Sensitive Estradiol on the Beckman Coulter UniCel DxI 600 from July 19, 2023 - July 27, 2023. Findings follow. A. Review of the Beckman Coulter Access Instructions for Use for: 1. Ferritin (C64647A Dec 2021) under Specimen stated, "If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20 degrees Celsius or colder." 2. Folate (B03897H Dec 2021) under Specimen stated, "If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20 degrees Celsius or colder." 3. Prolactin (C64671A Dec 2021) under Specimen stated, "If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20 degrees Celsius or colder." 4. Prostate Specific Antigen (A85067P Feb 2022), under Specimen stated, "Specimen Collection and Preparation...If the serum sample is to be assayed within 24 hours after collection, the specimen should be stored in a refrigerator at 2 to 8 degrees Celsius. Specimens held for longer times (up to 5 months) should be frozen at -20 degrees Celsius or colder." 5. Total Testosterone (C64673A April 2022) under Specimen stated, "If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20 degrees Celsius or colder." 6. Vitamin B12 (C64657B Oct 2022) under Specimen stated, If the assay will not be

completed within 24 hours, or for shipment of samples, freeze at -20 degrees Celsius or colder." 7. Estradiol (A56077T May 2020) under Specimen stated, "If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20 degrees Celsius or colder." B. Surveyor observed on June 30, 2023 at 1030 hours in the laboratory, half a rack of tubes stored in the refrigerator waiting to be tested: no specimens were stored in the freezer. C. Review of a query of patient testing performed and request of collection date and times showed for testing performed on 06/24/2023 and 06/27/2023 the following samples listed by accession #, time of collection in hours, analyzer reported time in hours, total elapsed time: Accession # Collection Time Reported Time Elapsed time 1. Ferritin: Manufacturer required specimens not tested within 48 hours be frozen a. 99052404 06/21/2023 @ 0738 06/27/2023 @ 1421 6 days, 6 hours b. 99052417 06/22/2023 @ 0841 06/27/2023 @ 1504 5 days, 6 hours c. 99052409 06/21/2023 @ 0945 06/27/2023 @ 1438 6 days, 4 hours d. 99052424 06/21/2023 @ 1320 06/27/2023 @ 1458 6 days, 1 hour e. 99052401 06/20/2023 @ 0903 06/27/2023 @ 1445 7 days, 5 hours f. 99052386 06/19/2023 @ 1033 06/27/2023 @ 1406 8 days, 3 hours g. 99052399 06/20/2023 @ 0826 06/27/2023 @ 1457 7 days, 6 hours h. 99052405 06/21/2023 @ 0819 06/27/2023 @ 1454 6 days, 6 hours i. 99052410 06/21/2023 @ 0925 06/27/2023 @ 1406 6 days, 4 hours j. 99052419 06/22/2023 @ 0906 06/27/2023 @ 1442 5 days, 5 hours k. 99052426 06/22/2023 @ 0834 06/27/2023 @ 1453 5 days, 6 hours l. 99052434 06/23/2023 @ 0715 06/27/2023 @ 1424 4 days, 7 hours m. 99052437 06/23/2023 @ 0858 06/27/2023 @ 1431 4 days, 5 hours n. 99052379 06/19/2023 @ 0737 06/24/2023 @ 1137 5 days, 4 hours o. 99052384 06/19/2023 @ 1010 06/24/2023 @ 1211 5 days, 2 hours p. 99052385 06/19/2023 @ 0827 06/24/2023 @ 1155 5 days, 3 hours q. 99052387 06/19/2023 @ 0940 06/24/2023 @ 1305 5 days, 3 hours r. 99052388 06/19/2023 @ 1336 06/24/2023 @ 1147 4 days, 22 hours s.99052393 06/19/2023 @ 1527 06/24/2023 @ 1323 4 days, 21 hours t. 99052395 06/19/2023 @ 1011 06/24/2023 @ 1305 5 days, 2 hours u. 99052397 06/20/2023 @ 0731 06/24/2023 @ 1137 4 days, 4 hours v. 99052398 06/20/2023 @ 0908 06/24/2023 @ 1227 4 days, 3 hours w. 99052400 06/20/2023 @ 0922 06/24/2023 @ 1204 4 days, 2 hours x. 99052402 06/20/2023 @ 1134 06/24/2023 @ 1234 4 days, 1 hour y. 99052403 06/21/2023 @ 0720 06/24/2023 @ 1330 3 days, 6 hours z. 99052406 06/21/2023 @ 0853 06/24/2023 @ 1138 3 days, 2 hours aa. 99052407 06/21/2023 @ 0914 06/24/2023 @ 1203 3 days, 2 hours bb. 99052408 06/21/2023 @ 0930 06/24/2023 @ 1205 3 days, 2 hours cc. 99052411 06/21/2023 @ 1030 06/24/2023 @ 1220 3 days, 1 hour dd. 99052412 06/21/2023 @ 1351 06/24/2023 @ 1130 2 days, 21 hours ee. 99052432 06/21/2023 @ 0845 06/24/2023 @ 1148 3 days, 3 hours ff. 99052414 06/22/2023 @ 0822 06/24/2023 @ 1314 2 days, 4 hours gg. 99052418 06/22/2023 @ 0857 06/24/2023 @ 1328 2 days, 4 hours hh. 99052428 06/22/2023 @ 1016 06/24/2023 @ 1255 2 days, 2 hours 2. Folate: Manufacturer required specimens not tested within 48 hours be frozen. a. 99052404 06/21/2023 @ 0738 06/27/2023 @ 1421 6 days, 6 hours b. 99052417 06/22/2023 @ 0841 06/27/2023 @ 1504 5 days, 6 hours c. 99052409 06/21/2023 @ 0945 06/27/2023 @ 1438 6 days, 4 hours d. 99052424 06/21/2023 @ 1320 06/27/2023 @ 1458 6 days, 1 hour e. 99052401 06/20/2023 @ 0903 06/27/2023 @ 1445 7 days, 5 hours f. 99052386 06/19/2023 @ 1033 06/27/2023 @ 1406 8 days, 3 hours g. 99052399 06/20/2023 @ 0826 06/27/2023 @ 1457 7 days, 6 hours h. 99052405 06/21/2023 @ 0819 06/27/2023 @ 1454 6 days, 6 hours i. 99052410 06/21/2023 @ 0925 06/27/2023 @ 1406 6 days, 4 hours j. 99052419 06/22/2023 @ 0906 06/27/2023 @ 1442 5 days, 5 hours k. 99052426 06/22/2023 @ 0834 06/27/2023 @ 1453 5 days, 6 hours l. 99052434 06/23/2023 @ 0715 06/27/2023 @ 1424 4 days, 7 hours m. 99052437 06/23/2023 @ 0858 06/27/2023 @ 1431 4 days, 5 hours 3. Prolactin: Manufacturer required specimens not tested within 48 hours be frozen. a. 99052404 06/21/2023 @ 0738 06/27/2023 @ 1421 6 days, 6 hours b. 99052417 06/22/2023 @ 0841 06/27/2023 @

1504 5 days, 6 hours c. 99052409 06/21/2023 @ 0945 06/27/2023 @ 1438 6 days, 4 hours d. 99052424 06/21/2023 @ 1320 06/27/2023 @ 1458 6 days, 1 hour e. 99052401 06/20/2023 @ 0903 06/27/2023 @ 1445 7 days, 5 hours f. 99052386 06/19/2023 @ 1033 06/27/2023 @ 1406 8 days, 3 hours g. 99052399 06/20/2023 @ 0826 06/27/2023 @ 1457 7 days, 6 hours h. 99052405 06/21/2023 @ 0819 06/27/2023 @ 1454 6 days, 6 hours i. 99052410 06/21/2023 @ 0925 06/27/2023 @ 1406 6 days, 4 hours j. 99052419 06/22/2023 @ 0906 06/27/2023 @ 1442 5 days, 5 hours k. 99052426 06/22/2023 @ 0834 06/27/2023 @ 1453 5 days, 6 hours l. 99052434 06/23/2023 @ 0715 06/27/2023 @ 1424 4 days, 7 hours m. 99052437 06/23/2023 @ 0858 06/27/2023 @ 1431 4 days, 5 hours 4. PSA: Manufacturer required specimens not tested within 24 hours be frozen. a. 99052404 06/21/2023 @ 0738 06/27/2023 @ 1421 6 days, 6 hours b. 99052417 06/22/2023 @ 0841 06/27/2023 @ 1504 5 days, 6 hours c. 99052409 06/21/2023 @ 0945 06/27/2023 @ 1438 6 days, 4 hours d. 99052424 06/21/2023 @ 1320 06/27/2023 @ 1458 6 days, 1 hour e. 99052401 06/20/2023 @ 0903 06/27/2023 @ 1445 7 days, 5 hours f. 99052386 06/19/2023 @ 1033 06/27/2023 @ 1406 8 days, 3 hours g. 99052399 06/20/2023 @ 0826 06/27/2023 @ 1457 7 days, 6 hours h. 99052405 06/21/2023 @ 0819 06/27/2023 @ 1454 6 days, 6 hours i. 99052410 06/21/2023 @ 0925 06/27/2023 @ 1406 6 days, 4 hours j. 99052419 06/22/2023 @ 0906 06/27/2023 @ 1442 5 days, 5 hours k. 99052426 06/22/2023 @ 0834 06/27/2023 @ 1453 5 days, 6 hours l. 99052434 06/23/2023 @ 0715 06/27/2023 @ 1424 4 days, 7 hours m. 99052437 06/23/2023 @ 0858 06/27/2023 @ 1431 4 days, 5 hours n. 99052379 06/19/2023 @ 0737 06/24/2023 @ 1137 5 days, 4 hours o. 99052384 06/19/2023 @ 1010 06/24/2023 @ 1211 5 days, 2 hours p. 99052385 06/19/2023 @ 0827 06/24/2023 @ 1155 5 days, 3 hours q. 99052387 06/19/2023 @ 0940 06/24/2023 @ 1305 5 days, 3 hours r. 99052388 06/19/2023 @ 1336 06/24/2023 @ 1147 4 days, 22 hours s.99052393 06/19/2023 @ 1527 06/24/2023 @ 1323 4 days, 21 hours t. 99052395 06/19/2023 @ 1011 06/24/2023 @ 1305 5 days, 2 hours u. 99052397 06/20/2023 @ 0731 06/24/2023 @ 1137 4 days, 4 hours v. 99052398 06/20/2023 @ 0908 06/24/2023 @ 1227 4 days, 3 hours w. 99052400 06/20/2023 @ 0922 06/24/2023 @ 1204 4 days, 2 hours x. 99052402 06/20/2023 @ 1134 06/24/2023 @ 1234 4 days, 1 hour y. 99052403 06/21/2023 @ 0720 06/24/2023 @ 1330 3 days, 6 hours z. 99052406 06/21/2023 @ 0853 06/24/2023 @ 1138 3 days, 2 hours aa. 99052407 06/21/2023 @ 0914 06/24/2023 @ 1203 3 days, 2 hours bb. 99052408 06/21/2023 @ 0930 06/24/2023 @ 1205 3 days, 2 hours cc. 99052411 06/21/2023 @ 1030 06/24/2023 @ 1220 3 days, 1 hour dd. 99052412 06/21/2023 @ 1351 06/24/2023 @ 1130 2 days, 21 hours ee. 99052432 06/21/2023 @ 0845 06/24/2023 @ 1148 3 days, 3 hours ff. 99052414 06/22/2023 @ 0822 06/24/2023 @ 1314 2 days, 4 hours gg. 99052418 06/22/2023 @ 0857 06/24/2023 @ 1328 2 days, 4 hours hh. 99052428 06/22/2023 @ 1016 06/24/2023 @ 1255 2 days, 2 hours ii. 99052429 06/22/2023 @ 1512 06/24/2023 @ 1318 1 day, 22 hours jj. 99052430 06/22/2023 @ 1556 06/24/2023 @ 1140 1 day, 19 hours 5. Total Testosterone: Manufacturer required specimens not tested within 48 hours be frozen. a. 99052404 06/21/2023 @ 0738 06/27/2023 @ 1421 6 days, 6 hours b. 99052417 06/22/2023 @ 0841 06/27/2023 @ 1504 5 days, 6 hours c. 99052409 06/21/2023 @ 0945 06/27/2023 @ 1438 6 days, 4 hours d. 99052424 06/21/2023 @ 1320 06/27/2023 @ 1458 6 days, 1 hour e. 99052401 06/20/2023 @ 0903 06/27/2023 @ 1445 7 days, 5 hours f. 99052386 06/19/2023 @ 1033 06/27/2023 @ 1406 8 days, 3 hours g. 99052399 06/20/2023 @ 0826 06/27/2023 @ 1457 7 days, 6 hours h. 99052405 06/21/2023 @ 0819 06/27/2023 @ 1454 6 days, 6 hours i. 99052410 06/21/2023 @ 0925 06/27/2023 @ 1406 6 days, 4 hours j. 99052419 06/22/2023 @ 0906 06/27/2023 @ 1442 5 days, 5 hours k. 99052426 06/22/2023 @ 0834 06/27/2023 @ 1453 5 days, 6 hours l. 99052434 06/23/2023 @ 0715 06/27/2023 @ 1424 4 days, 7 hours m. 99052437 06/23/2023 @ 0858 06/27/2023 @ 1431 4 days, 5 hours n. 99052379 06/19/2023 @ 0737 06/24/2023 @

1137 5 days, 4 hours o. 99052384 06/19/2023 @ 1010 06/24/2023 @ 1211 5 days, 2 hours p. 99052385 06/19/2023 @ 0827 06/24/2023 @ 1155 5 days, 3 hours q. 99052387 06/19/2023 @ 0940 06/24/2023 @ 1305 5 days, 3 hours r. 99052388 06/19 /2023 @ 1336 06/24/2023 @ 1147 4 days, 22 hours s.99052393 06/19/2023 @ 1527 06/24/2023 @ 1323 4 days, 21 hours t. 99052395 06/19/2023 @ 1011 06/24/2023 @ 1305 5 days, 2 hours u. 99052397 06/20/2023 @ 0731 06/24/2023 @ 1137 4 days, 4 hours v. 99052398 06/20/2023 @ 0908 06/24/2023 @ 1227 4 days, 3 hours w. 99052400 06/20/2023 @ 0922 06/24/2023 @ 1204 4 days, 2 hours x. 99052402 06/20 /2023 @ 1134 06/24/2023 @ 1234 4 days, 1 hour y. 99052403 06/21/2023 @ 0720 06 /24/2023 @ 1330 3 days, 6 hours z. 99052406 06/21/2023 @ 0853 06/24/2023 @ 1138 3 days, 2 hours aa. 99052407 06/21/2023 @ 0914 06/24/2023 @ 1203 3 days, 2 hours bb. 99052408 06/21/2023 @ 0930 06/24/2023 @ 1205 3 days, 2 hours cc. 99052411 06/21/2023 @ 1030 06/24/2023 @ 1220 3 days, 1 hour dd. 99052412 06/21 /2023 @ 1351 06/24/2023 @ 1130 2 days, 21 hours ee. 99052432 06/21/2023 @ 0845 06/24/2023 @ 1148 3 days, 3 hours ff. 99052414 06/22/2023 @ 0822 06/24/2023 @ 1314 2 days, 4 hours gg. 99052418 06/22/2023 @ 0857 06/24/2023 @ 1328 2 days, 4 hours hh. 99052428 06/22/2023 @ 1016 06/24/2023 @ 1255 2 days, 2 hours 6. Vitamin B12: Manufacturer required specimens not tested within 24 hours be frozen. a. 99052404 06/21/2023 @ 0738 06/27/2023 @ 1421 6 days, 6 hours b. 99052417 06 /22/2023 @ 0841 06/27/2023 @ 1504 5 days, 6 hours c. 99052409 06/21/2023 @ 0945 06/27/2023 @ 1438 6 days, 4 hours d. 99052424 06/21/2023 @ 1320 06/27 /2023 @ 1458 6 days, 1 hour e. 99052401 06/20/2023 @ 0903 06/27/2023 @ 1445 7 days, 5 hours f. 99052386 06/19/2023 @ 1033 06/27/2023 @ 1406 8 days, 3 hours g. 99052399 06/20/2023 @ 0826 06/27/2023 @ 1457 7 days, 6 hours h. 99052405 06/21 /2023 @ 0819 06/27/2023 @ 1454 6 days, 6 hours i. 99052410 06/21/2023 @ 0925 06 /27/2023 @ 1406 6 days, 4 hours j. 99052419 06/22/2023 @ 0906 06/27/2023 @ 1442 5 days, 5 hours k. 99052426 06/22/2023 @ 0834 06/27/2023 @ 1453 5 days, 6 hours l. 99052434 06/23/2023 @ 0715 06/27/2023 @ 1424 4 days, 7 hours m. 99052437 06/23/2023 @ 0858 06/27/2023 @ 1431 4 days, 5 hours 7. Estradiol: Manufacturer required specimens not tested within 48 hours be frozen. a. 99052404 06 /21/2023 @ 0738 06/27/2023 @ 1421 6 days, 6 hours b. 99052417 06/22/2023 @ 0841 06/27/2023 @ 1504 5 days, 6 hours c. 99052409 06/21/2023 @ 0945 06/27 /2023 @ 1438 6 days, 4 hours d. 99052424 06/21/2023 @ 1320 06/27/2023 @ 1458 6 days, 1 hour e. 99052401 06/20/2023 @ 0903 06/27/2023 @ 1445 7 days, 5 hours f. 99052386 06/19/2023 @ 1033 06/27/2023 @ 1406 8 days, 3 hours g. 99052399 06/20 /2023 @ 0826 06/27/2023 @ 1457 7 days, 6 hours h. 99052405 06/21/2023 @ 0819 06/27/2023 @ 1454 6 days, 6 hours i. 99052410 06/21/2023 @ 0925 06/27/2023 @ 1406 6 days, 4 hours j. 99052419 06/22/2023 @ 0906 06/27/2023 @ 1442 5 days, 5 hours k. 99052426 06/22/2023 @ 0834 06/27/2023 @ 1453 5 days, 6 hours l. 99052434 06/23/2023 @ 0715 06/27/2023 @ 1424 4 days, 7 hours m. 99052437 06/23 /2023 @ 0858 06/27/2023 @ 1431 4 days, 5 hours n. 99052379 06/19/2023 @ 0737 06/24/2023 @ 1137 5 days, 4 hours o. 99052384 06/19/2023 @ 1010 06/24/2023 @ 1211 5 days, 2 hours p. 99052385 06/19/2023 @ 0827 06/24/2023 @ 1155 5 days, 3 hours q. 99052387 06/19/2023 @ 0940 06/24/2023 @ 1305 5 days, 3 hours r. 99052388 06/19/2023 @ 1336 06/24/2023 @ 1147 4 days, 22 hours s.99052393 06/19 /2023 @ 1527 06/24/2023 @ 1323 4 days, 21 hours t. 99052395 06/19/2023 @ 1011 06/24/2023 @ 1305 5 days, 2 hours u. 99052397 06/20/2023 @ 0731 06/24/2023 @ 1137 4 days, 4 hours v. 99052398 06/20/2023 @ 0908 06/24/2023 @ 1227 4 days, 3 hours w. 99052400 06/20/2023 @ 0922 06/24/2023 @ 1204 4 days, 2 hours x. 99052402 06/20/2023 @ 1134 06/24/2023 @ 1234 4 days, 1 hour y. 99052403 06/21 /2023 @ 0720 06/24/2023 @ 1330 3 days, 6 hours z. 99052406 06/21/2023 @ 0853 06 /24/2023 @ 1138 3 days, 2 hours aa. 99052407 06/21/2023 @ 0914 06/24/2023 @ 1203 3 days, 2 hours bb. 99052408 06/21/2023 @ 0930 06/24/2023 @ 1205 3 days, 2

	hours cc. 99052411 06/21/2023 @ 1030 06/24/2023 @ 1220 3 days, 1 hour dd. 99052412 06/21/2023 @ 1351 06/24/2023 @ 1130 2 days, 21 hours ee. 99052432 06 /21/2023 @ 0845 06/24/2023 @ 1148 3 days, 3 hours ff. 99052414 06/22/2023 @ 0822 06/24/2023 @ 1314 2 days, 4 hours gg. 99052418 06/22/2023 @ 0857 06/24 /2023 @ 1328 2 days, 4 hours hh. 99052428 06/22/2023 @ 1016 06/24/2023 @ 1255 2 days, 2 hours D. Interview with the owner on June 30, 2023 at 1520 hours acknowledged they were freezing tubes prior to the new technical consultant's arrival who started June 10, 2023, and stopped around June 19, 2023 when the new testing person (hired by the technical consultant) told them they didn't need to freeze the samples, and now only tested once a week on Saturdays.
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 observation, review of the verification of performance specification records, manufacturer's instructions, laboratory's policies and procedures, maintenance logs, quality control (QC) records, query, pre-survey paperwork and interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct problems in testing performed in Chemistry and Endocrinology. Findings follow. 1. The laboratory failed to have a written procedure for the performance of corrective actions taken when QC results fail to meet the acceptable criteria on the Beckman Coulter UniCel DxI 600 for two of two years reviewed (see D5403 I). 2. The laboratory failed to have a written procedure to establish control limits on the Beckman Coulter UniCel DxI 600 for two of two years reviewed (see D5403 II). 3. The laboratory failed to store Bio-Rad Liquichek Control material and calibrators in a non frost-free freezer for one of one freezer reviewed (see D5413). 4. The laboratory failed to verify the performance specifications for Luteinizing Hormone (LH) on the Beckman Coulter UniCel DxI 600 for normal reference ranges for 11 of 11 months reviewed (see D5421). 5. The laboratory failed to verify the performance specifications for Ferritin, Folate, Prolactin, Prostate Specific Antigen (PSA), Total Testosterone, Thyroid Stimulating Hormone (TSH), Vitamin B12, Sensitive Estradiol, Sex Hormone Binding Globulin (SHBG), and Vitamin D on the Beckman Coulter UniCel DxI 600 for precision and accuracy, and perform normal reference range studies for 2 of 2 years reviewed (see D5421 II). 6. The laboratory failed to perform maintenance on the Beckman Coulter UniCel DxI 600 as defined by the manufacturer for two out of six 5,000 test intervals reviewed from March 8, 2022 to May 30, 2023 (see D5429). 7. The laboratory failed to monitor over time the accuracy and precision of the test system for Ferritin, Folate, Prolactin, PSA, Total Testosterone, TSH, Vitamin B12, Sensitive Estradiol, SHBG, LH, and Vitamin D performed on the Beckman Coulter UniCel DxI 600 for 2 of 2 years reviewed (see D5441). 8. The laboratory failed to ensure two levels of QC were within range on the Beckman Coulter UniCel DxI 600 prior to reporting patient samples for 15 out of 17 days of testing reviewed. (see D5447).

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
I. Based on review of the validation records, laboratory's policies and procedures, quality control (QC) records and interview, the laboratory failed to have a written procedure for the performance of corrective actions taken when QC results fail to meet the acceptable criteria on the Beckman Coulter UniCel DxI 600 for two of two years reviewed. Findings follow. A. Review of the validation records showed the analyzer was installed 12/14/2017. B. The laboratory's policy and procedure for handling out of range QC results was requested on June 30, 2023 at 1115 hours but not provided. C. One of three controls were reviewed: Immunoassay Controls Levels 1 & 3 used for Ferritin, Folate, Prolactin, Prostate Specific Antigen (PSA), Total Testosterone, Thyroid Stimulating Hormone (TSH), Vitamin B12, Sensitive Estradiol, and Luteinizing Hormone (LH). Review of the QC Test Lot print-outs from January 2023 showed the laboratory's acceptable ranges for Levels 1 & 3: Ferritin were 45.97 -59.93 and 300.28 - 405.72 ng/mL Folate were 3.84 - 5.22 and 14.5 - 18.86 ng/mL Prolactin were 5.18 - 6.58 and 31.86 - 39.54 ng/mL PSA were 0.78 - 0.98 ng/mL and 20.18 and 25.34 ng/mL Testosterone were 101.66 - 131.34 ng/dL and 623.72 - 797.48 ng/dL TSH were 0.34 - 0.43 uIU/mL and 28.33 - 35.93 uIU/mL Vitamin B12 were 220.02 - 295.18 and 803.42 - 1095.18 pg/mL Estradiol were 76.03 - 97.35 pg/mL and 325.52 - 400.48 pg/mL LH were 0.88 - 1.24 uIU/mL and 55.84 - 71 uIU/mL 1. 01/05 /2023: a. Level 1 showed Folate was out of range 5.45 ng/mL, repeated out of range 5.45, calibrated, repeated in range, Level 3 not repeated after calibration. 2. 01/26 /2023: a. Level 1 showed Vitamin B12 was out of range 317 pg/mL repeated out of range 328 pg/mL, calibrated, repeated in range 268 pg/mL, Level 3 not repeated after calibration. b. Level 3 showed Folate was out of range 13.55 ng/mL, repeated out of range 13.40 ng/mL, calibrated, repeated out of range 13.18 ng/mL, accepted, Level 1 not repeated after calibration. 3. 02/07/2023: a. Level 1 showed Prolactin was out of range 7.04 ng/mL, repeated out of range 6.75 ng/mL, calibrated and repeated 7.45 ng /mL out of range, QC ranges changed, accepted, Level 3 not repeated after calibration. b. Level 1 showed TSH was out of range 0.700 uIU/mL, repeated out of range 0.686 uIU/mL, calibrated and repeated 0.714 uIU/mL, out of range, accepted, Level 3 not repeated after calibration. c. Level 1 showed LH was out of range 1.96 uIU/mL,

repeated out of range 1.64 uIU/mL, calibrated and repeated 1.75 uIU/mL, out of range, accepted, Level 3 not repeated after calibration. d. Level 3 showed Folate was out of range 12.96 ng/mL, repeated out of range 13.16 ng/mL, calibrated and repeated 12.92 ng/mL, out of range, QC ranges changed, accepted, Level 1 not repeated after calibration. Review of the QC Test Lot print-outs from 02/07/2023 showed the laboratory's acceptable ranges for Levels 1 & 3: Ferritin were 46.49 - 60.29 and 304.26 - 412.34 ng/mL Folate were 3.85 - 5.17 and 12.46 - 17.14 ng/mL Prolactin were 5.91 - 7.49 and 31.31 - 39.71 ng/mL PSA were 0.79 - 1.03 ng/mL and 20.15 - 25.27 ng/mL Testosterone were 103 - 131.4 ng/dL and 626.68 - 798.92 ng/dL TSH were 0.36 - 0.43 uIU/mL and 28.5 - 35.82 uIU/mL Vitamin B12 were 221.2 - 301.6 and 810.76 - 1094.64 pg/mL Estradiol were 75.36 - 95.44 pg/mL and 325.84 - 398.75 pg/mL LH were 0.78 - 1.18 uIU/mL and 55.78 - 70.22 uIU/mL 4: 02/09/2023: a. Level 3 showed Folate was out of range 12.45 ng/mL, repeated out of range 12.40 ng /mL, calibrated and repeated in range, Level 1 not repeated after calibration. b. Level 3 showed Vitamin B12 was out of range 1126 pg/mL, repeated out of range 1133 pg /mL, calibrated and repeated in range, Level 1 not repeated after calibration. 5. 02/14 /2023: a. Level 3 showed Prolactin was out of range 39.80 ng/mL, repeated out of range 40.83 ng/mL, calibrated and repeated in range, Level 1 not repeated after calibration. 6. 02/16/2023: a. Level 1 showed Vitamin B12 was out of range 343 pg /mL, repeated out of range 371 pg/mL, calibrated and repeated out of range 328 pg /mL, QC ranges changed, accepted, Level 3 was not repeated after calibration Review of the QC Test Lot print-outs from 02/16/2023 showed the laboratory's acceptable ranges for Levels 1 & 3: Vitamin B12 was changed to 259.8 - 340.2 and 810.76 - 1094.64 pg/mL 7. 02/21/2023: a. Level 1 showed Vitamin B12 was out of range 367 pg/mL, repeated out of range 342 pg/mL, calibrated and repeated out of range 366 pg /mL, repeated in range, Level 3 not repeated after calibration. D. Interview with testing personnel #1 on June 30, 2023 at 1115 hours confirmed she would run QC, and if anything was out would repeat, and calibrate if still out, and would change the acceptable QC ranges if still out. Interview with testing personnel #1 on June 30, 2023 at 1140 hours acknowledged the analyzer did not indicate whether control runs were in or out of range and she had to compare each result every day of patient testing to the ranges taken from the Unity report and confirmed she would change the mean and standard deviation to the Unity report when she was having trouble with QC, and had no reference or procedure. Interview with testing personnel #1 on June 30, 2023 at 1405 hours confirmed she would select a number within the range of the QC package insert to be the mean, and thought as long as she was within the acceptable range on the package insert, that was all right. She would run QC, and if anything was out would run in duplicate, if one was in-range, would accept the run, if both still out would then calibrate and repeat controls. If still out, would change the acceptable QC ranges, and had no procedure. II. Based on review of the manufacturer's instructions, validation records, laboratory's policies and procedures, quality control (QC) records, pre-survey paperwork, and interview, the laboratory failed to have a written procedure to establish control limits on the Beckman Coulter UniCel DxI 600 for two of two years reviewed. Findings follow. A. Review of the Biorad Lyphochek Immunoassay Plus Control package insert, 02/2023 1536-00S, under Assignment of Values stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this

control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications." Review of the Biorad Lyphochek Immunoassay Plus Control package insert, 02/2023 1536-00S showed the acceptable range for Level 1 for Prolactin was 4.71 - 7.24, and for Vitamin B12 was 187 - 335. B. Review of the validation records showed the analyzer was installed 12/14/2017. C. The laboratory's policy and procedure for establishing new means and ranges was requested on June 30, 2023 at 1140 hours but not provided. D. One of three controls were reviewed: Biorad Immunoassay Controls Levels 1 & 3 used for Ferritin, Folate, Prolactin, Prostate Specific Antigen (PSA), Total Testosterone, Thyroid Stimulating Hormone (TSH), Vitamin B12, Sensitive Estradiol, and Luteinizing Hormone. Review of the QC Test Lot print-outs from 02/07/2023 showed the laboratory's acceptable ranges for Levels 1 & 3: Ferritin were 46.49 - 60.29 and 304.26 - 412.34 ng/mL: matching the Unity report from December 2022, Level 1 mean = 53.39, SD = 3.45, Level 3 mean = 358.3, SD = 27.02 Folate were 3.85 - 5.17 and 12.46 - 17.14 ng/mL: matching the Unity report from December 2022, Level 1 mean = 4.51, SD = 0.33, Level 3 mean = 16.36, SD = 1.17 Prolactin were 5.91 - 7.49 and 31.31 - 39.71 ng/mL: Level 1 not matching the Unity report from December 2022, Level 1 mean = 5.80, SD = 0.394, Level 3 mean = 35.51, SD = 2.10; Level 1 mean set at 6.7 PSA were 0.79 - 1.03 ng/mL and 20.15 - 25.27 ng/mL: Level 1 & 3 not matching the Unity report from December 2022, Level 1 mean = 0.909, SD = 0.054, Level 3 mean = 22.93, SD = 1.32; Level 1 mean at 0.120, SD = 0.91, Level 3 mean at 22.71, SD = 1.28 Testosterone were 103 - 131.4 ng/dL and 626.68 - 798.92 ng/dL: matching the Unity report from December 2022, Level 1 mean = 117.2, SD = 7.1, Level 3 mean = 712.8, SD = 43.06 TSH were 0.36 - 0.43 uIU/mL and 28.5 - 35.82 uIU/mL: Level 1 & 3 not matching the Unity report from December 2022, Level 1 mean = 0.387, SD = 0.018, Level 3 mean = 32.16, SD = 1.83; Level 1 mean set at 0.392, Level 3 mean set at 31.83, SD at 2.03 Vitamin B12 were 221.2 - 301.6 and 810.76 - 1094.64 pg/mL: matching the Unity report from December 2022, Level 1 mean = 261.4, SD = 20.1, Level 3 mean = 952.7, SD = 70.97 Estradiol were 75.36 - 95.44 pg/mL and 325.84 - 398.75 pg/mL: Level 1 & 3 matching the Unity report from December 2022, Level 1 mean = 85.40, SD = 5.02, Level 3 mean = 362.3, SD = 18.23 LH were 0.78 - 1.18 uIU/mL and 55.78 - 70.22 uIU/mL: Level 1 not matching the Unity report from December 2022, Level 1 mean = 1.02, SD = 0.09, Level 3 mean = 61.4, SD = 3.61; Level 1 mean set at 0.98, SD at 0.1 Review of the QC Test Lot print-outs from 02/16/2023 showed the laboratory's acceptable ranges for Levels 1 & 3: Vitamin B12 was changed to 259.8 - 340.2 and 810.76 - 1094.64 pg/mL; Level 1 not matching the Unity report from January 2023, Level 1 mean = 258.9, SD = 22.06, Level 3 mean = 947.6, SD = 85.78; Level 1 mean set at 300, SD at 20.1 E. Interview with testing personnel #1 on June 30, 2023 at 1115 hours confirmed she would run QC, and if anything was out would repeat, and calibrate if still out, and would change the acceptable QC ranges if still out. Interview with testing personnel #1 on June 30, 2023 at 1140 hours acknowledged the analyzer did not indicate whether control runs were in or out of range and she had to compare each result every day of patient testing to the ranges taken from the Unity report and confirmed she would change the mean and standard deviation to the Unity report when she was having trouble with QC, and had no reference or procedure. Interview with testing personnel #1 on June 30, 2023 at 1405 hours confirmed she would select a number within the range of the QC package insert to be the mean, and thought as long as she was within the acceptable range on the package insert, that was all right. she would run QC, and if anything was out would run in duplicate, if one was in-range, would accept the run, if both still out would then calibrate and repeat controls. If still out, would change the acceptable QC ranges, and had no procedure. F. Review of the CMS form 116 showed approximately 27, 300

	chemistry and endocrinology tests combined were performed annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, and interview, the laboratory failed to store Bio-Rad Liquichek Control material in a non frost-free freezer for one of one freezer reviewed. Findings follow. A. During a tour of the laboratory on June 30, 2023 at 1030 hours, the surveyor observed in a Kenmore frost-free freezer: Bio-Rad Liquichek Specialty Immunoassay Controls - one box of each Lot 64981 and 64982, expiration 10/31/25. B. Review of the package insert for the Bio-Rad Liquichek Specialty Immunoassay Control, 2023-02 5450-00S, under Storage and Stability stated, "This product will be stable until the expiration date when stored unopened at -20 to -70 degrees Celsius. For optimum performance, avoid storing this product in a frost-free freezer." C. Interview with testing personnel #1 on June 30, 2023 at 1030 hours confirmed the findings and verified it was a frost-free freezer (and by definition a frost-free freezer goes through freeze thaw cycles to prevent ice buildup).
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on review of verification of performance specification records, interview, and query, the laboratory failed to verify the performance specifications for Luteinizing Hormone (LH) on the Beckman Coulter UniCel DxI 600 for normal reference ranges for 11 of 11 months reviewed. Findings follow. A. Review of the validation for LH, 08/02/22, on the Beckman Coulter UniCel DxI 600 showed no verification of the normal reference range. The normal range study was requested on June 29, 2022 at 1730 hours but not provided. B. Interview with testing personnel #1 on June 29, 2023 at 1730 hours confirmed the findings. C. A 60 day instrument query from 05/12/23 - 07/11/23 showed 13 patients were tested for LH. II. Based on review of verification of performance specification records, pre-survey paperwork, and interview, the laboratory failed to verify the performance specifications for Ferritin, Folate,

	Prolactin, Prostate Specific Antigen (PSA), Total Testosterone, Thyroid Stimulating Hormone (TSH), Vitamin B12, Sensitive Estradiol, Sex Hormone Binding Globulin (SHBG), and Vitamin D on the Beckman Coulter UniCel DxI 600 for precision and accuracy, and perform normal reference range studies for 2 of 2 years reviewed. Findings follow. A. Review of the validation on 12/14/2017 on the Beckman Coulter UniCel DxI 600 showed no evaluation of the precision and accuracy studies, and no verification of the normal reference range. The normal range study was requested on June 30, 2022 at 0845 hours but not provided. B. Interview with testing personnel #1 on June 30, 2023 at 0845 hours confirmed the findings. C. Review of the CMS form 116 showed approximately 27, 300 tests combined were performed annually.
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 review of the manufacturer's instructions, maintenance logs, and interview, the laboratory failed to perform maintenance on the Beckman Coulter UniCel DxI 600 as defined by the manufacturer for two out of six 5,000 test intervals reviewed from March 8, 2022 to May 30, 2023. Findings follow. A. Review of the Beckman Coulter UniCel DxI 600 Instructions for Use, Rev October 2016, under Chapter 6 Maintenance at Test Interval Maintenance: 5,000 Tests stated, "Beckman Coulter recommends that you replace the duck bill valve after each 5,000 test interval. The duck bill valve prevents wash buffer from entering the RVs in the wash carousel during the aspirate probe wash. If the 10,000 and 5,000 test interval maintenance procedures are scheduled for the same day, begin with the 10,000 test interval maintenance procedures. The 10,000 test interval procedures include a step to perform 5,000 test interval maintenance." B. Review of the Beckman Coulter UniCel DxI 600 Maintenance Logs from March 2022 to May 2023 (see D3031) 5,000 Test Interval Maintenance was not performed per manufacturer's instructions for two of six events reviewed: November 3, 2023 performed at 166772 tests 1. March 2, 2023 performed at 175387 tests (8615 tests elapsed) 2. none as of May 30, 2023 at 181488 tests (6101 tests elapsed and counting) C. Interview with testing personnel #1 on June 30, 2023 at 1100 hours acknowledged she did not know she was supposed to do the 5,000 Test Interval Maintenance when she performed the 10,000 Test Interval Maintenance and had been alternating the maintenance.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control results (QC) and interview, the laboratory failed to monitor over time the accuracy and precision of the test system for Ferritin, Folate, Prolactin, Prostate Specific Antigen (PSA), Total Testosterone, Thyroid Stimulating Hormone (TSH), Vitamin B12, Sensitive Estradiol, Sex Hormone Binding Globulin (SHBG), Luteinizing Hormone (LH), and Vitamin D performed on the Beckman Coulter UniCel DxI 600 for 2 of 2 years reviewed. Findings follow. A. Review of quality control results from January and April 2023 showed mean and standard deviation (SD) were not calculated for the Ferritin, Folate, Prolactin, PSA, Total Testosterone, TSH, Vitamin B12, Sensitive Estradiol, SHBG, LH, and Vitamin D QC results. B. Interview with testing personnel #1 on June 30, 2023 at 1600 hours confirmed the laboratory was not monitoring over time the accuracy and precision of the tests.
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 review of quality control (QC) records, query, pre-survey paperwork, and interview, the laboratory failed to ensure two levels of QC were within range on the Beckman Coulter UniCel DxI 600 prior to reporting patient samples for 15 out of 17 days of testing reviewed. Findings follow. A. Review of the QC instrument print-outs from January to February 2023 for 15 out of 17 days of testing showed only one level of acceptable QC: One of three controls were reviewed: Immunoassay Controls Levels 1 & 3 used for Ferritin, Folate, Prolactin, Prostate Specific Antigen (PSA), Total Testosterone, Thyroid Stimulating Hormone (TSH), Vitamin B12, Sensitive Estradiol, and Luteinizing Hormone (LH). Review of the QC Test Lot print-outs from January 2023 showed the laboratory's acceptable ranges for Levels 1 & 3: Ferritin were 45.97 -59.93 and 300.28 - 405.72 ng/mL Folate were 3.84 - 5.22 and 14.5 - 18.86 ng/mL Prolactin were 5.18 - 6.58 and 31.86 - 39.54 ng/mL PSA were 0.78 - 0.98 ng/mL and 20.18 and 25.34 ng/mL Testosterone were 101.66 - 131.34 ng/dL and 623.72 - 797.48 ng/dL TSH were 0.34 - 0.43 uIU/mL and 28.33 - 35.93 uIU/mL Vitamin B12 were 220.02 - 295.18 and 803.42 - 1095.18 pg/mL Estradiol were 76.03 - 97.35 pg/mL and 325.52 - 400.48 pg/mL LH were 0.88 - 1.24 uIU/mL and 55.84 - 71 uIU/mL 1. 01/02/2023: a. Level 1 showed Ferritin was out of range 61.1 ng/mL, and accepted. b. Level 1 showed Prolactin was out of range 6.65 ng/mL, repeated out of range 6.64 ng/mL, and accepted. c. Level 3 showed PSA was out of range 25.65 ng /mL, and accepted. 2. 01/05/2023: a. Level 1 showed Folate was out of range 5.45 ng /mL, repeated out of range 5.45, calibrated, repeated in range, Level 3 not repeated after calibration. b. Level 3 showed LH was out of range 54.97 ng/mL, and accepted. 3. 01/09/2023: a. Level 1 showed Ferritin was out of range 61.3 ng/mL, and accepted. b. Level 1 showed Vitamin B12 was out of range 328 pg/mL, repeated out of range at 357 pg/mL, repeated out of range at 360 pg/mL, accepted. c. Level 3 showed Folate

was out of range 12.54 ng/mL and accepted. 4. 01/12/2023: a. Level 1 showed Vitamin B12 was out of range 317 pg/mL and accepted. 5. 01/16/2023: a. Level 3 showed PSA was out of range 25.79 ng/mL and accepted. 6. 01/19/2023: a. Level 3 showed PSA was out of range 26.01 ng/mL and accepted. 7. 01/24/2023: a. Level 3 showed Folate was out of range 14.17 ng/mL and accepted. 8. 01/26/2023: a. Level 1 showed Vitamin B12 was out of range 317 pg/mL repeated out of range 328 pg/mL, calibrated, repeated in range 268 pg/mL, Level 3 not repeated after calibration. b. Level 3 showed Folate was out of range 13.55 ng/mL, repeated out of range 13.40 ng /mL, calibrated, repeated out of range 13.18 ng/mL, accepted, Level 1 not repeated after calibration. 9. 01/31/2023: a. Level 3 showed Folate was out of range 14.06 ng /mL and accepted. 10. 02/03/2023: a. Level 1 showed Prolactin was out of range 6.59 ng/mL and accepted. b. Level 1 showed PSA was out of range 1.03 ng/mL, repeated out of range 1.06 ng/mL, repeated out of range 1.08 ng/mL, accepted. c. Level 1 showed LH was out of range 1.75 uIU/mL, repeated out of range 1.85 uIU/mL, repeated out of range 1.81 uIU/mL, accepted. d. Level 1 showed TSH was out of range 0.654 uIU/mL, repeated out of range 0.705 uIU/mL, repeated out of range 0.725 uIU/mL, accepted. e. Level 3 showed Folate was out of range 13.81 ng/mL, repeated out of range 14.30 ng/mL, accepted. 11. 02/07/2023: a. Level 1 showed Prolactin was out of range 7.04 ng/mL, repeated out of range 6.75 ng/mL, calibrated and repeated 7.45 ng/mL out of range, QC ranges changed, accepted, Level 3 not repeated after calibration. b. Level 1 showed TSH was out of range 0.700 uIU/mL, repeated out of range 0.686 uIU/mL, calibrated and repeated 0.714 uIU/mL, out of range, accepted, Level 3 not repeated after calibration. c. Level 1 showed LH was out of range 1.96 uIU /mL, repeated out of range 1.64 uIU/mL, calibrated and repeated 1.75 uIU/mL, out of range, accepted, Level 3 not repeated after calibration. d. Level 3 showed Folate was out of range 12.96 ng/mL, repeated out of range 13.16 ng/mL, calibrated and repeated 12.92 ng/mL, out of range, QC ranges changed, accepted, Level 1 not repeated after calibration. Review of the QC Test Lot print-outs from 02/07/2023 showed the laboratory's acceptable ranges for Levels 1 & 3: Ferritin were 46.49 - 60.29 and 304.26 - 412.34 ng/mL Folate were 3.85 - 5.17 and 12.46 - 17.14 ng/mL Prolactin were 5.91 - 7.49 and 31.31 - 39.71 ng/mL PSA were 0.79 - 1.03 ng/mL and 20.15 - 25.27 ng/mL Testosterone were 103 - 131.4 ng/dL and 626.68 - 798.92 ng/dL TSH were 0.36 - 0.43 uIU/mL and 28.5 - 35.82 uIU/mL Vitamin B12 were 221.2 - 301.6 and 810.76 - 1094.64 pg/mL Estradiol were 75.36 - 95.44 pg/mL and 325.84 - 398.75 pg/mL LH were 0.78 - 1.18 uIU/mL and 55.78 - 70.22 uIU/mL 12: 02/09/2023: a. Level 3 showed Folate was out of range 12.45 ng/mL, repeated out of range 12.40 ng /mL, calibrated and repeated in range, Level 1 not repeated after calibration. b. Level 3 showed Vitamin B12 was out of range 1126 pg/mL, repeated out of range 1133 pg /mL, calibrated and repeated in range, Level 1 not repeated after calibration. 13. 02/14 /2023: a. Level 3 showed Prolactin was out of range 39.80 ng/mL, repeated out of range 40.83 ng/mL, calibrated and repeated in range, Level 1 not repeated after calibration. 14. 02/16/2023: a. Level 1 showed Vitamin B12 was out of range 343 pg /mL, repeated out of range 371 pg/mL, calibrated and repeated out of range 328 pg /mL, QC ranges changed, accepted, Level 3 was not repeated after calibration. Review of the QC Test Lot print-outs from 02/16/2023 showed the laboratory's acceptable ranges for Levels 1 & 3: Vitamin B12 was changed to 259.8 - 340.2 and 810.76 - 1094.64 pg/mL 15. 02/21/2023: a. Level 1 showed Vitamin B12 was out of range 367 pg/mL, repeated out of range 342 pg/mL, calibrated and repeated out of range 366 pg /mL, repeated in range, Level 3 not repeated after calibration. B. Review of query of four panels (New patient TRT, 3 month panel, 4-6 week panel, Established Physical TRT, (may not represent all testing performed on a given day) run in the laboratory showed patient testing reported on the following dates of testing by accession number with one level of QC within range: 1. 1/02/2023: a. Ferritin: 99046350, 99046305,

	99046306, 99046329, 99046333, 99046323, 99046336, 99046312, 99046328, 99046331, 99046334, 99046322, 99046324, 99046325, 99046326, 99046337, 99046335, 99046344 b. Prolactin: 99046350, 99046305, 99046306, 99046329, 99046333, 99046323, 99046336 c. PSA: 99046350, 99046305, 99046306, 99046329, 99046333, 99046323, 99046336, 99046312, 99046328, 99046331, 99046334, 99046322, 99046324, 99046325, 99046326, 99046337, 99046335, 99046344 2. 01/05 /2023: a. Folate: 99046348, 99046356, 99046365 LH: 3. 01/09/2023 a. Ferritin: 99046396, 99046404, 99046386, 99046392, 99046400, 99046397, 99046395, 99046398, 99046393, 99046403, 99046410, 99046416, 99046418, 99046420, 99046421, 99046422 b. Vitamin B12: 99046396, 99046404 c. Folate: 99046396, 99046404 4. 01/12/2023 a. Vitamin B12: 99046459, 99046455, 99046457, 99046461, 99046456, 99046462 5. 01/16/2023: a. PSA: 99046470, 99046463, 99046467, 99046483, 99046472, 99046476, 99046479, 99046477, 99046468, 99046473, 99046471, 99046504, 99046481, 99046482, 99046485, 99046490, 99046489, 99046484, 99046488, 99046487, 99046486, 99046498, 99046505, 99046506, 6. 01/19 /2023: a. PSA: 99046541, 99046518, 99046523, 99046520, 99046522, 99046521, 99046524, 99046526, 99046527, 99046531, 99046538, 99046532, 99046535, 99046533, 99046528, 99046537, 99046539, 99046508, 99046510, 99046543, 99046545, 99046546, 99046547, 99046548, 99046549, 99046550, 99046507, 99046519, 99046534 7. 01/24/2023: a. Folate: 99046563 8. 01/26/2023: a. Vitamin B12: 99046632, 99046640, 99046627 b. Folate: 99046632, 99046640, 99046627 9. 01 /31/2023: a. Folate: 10. 02/03/2023: a. Prolactin: 99046694, 99046695 b. PSA: 99046694, 99046695, 99046651, 99046652, 99046679, 99046655, 99046656, 99046688, 99046682, 99046683, 99046684, 99046689, 99046685, 99046686, 99046657, 99046659, 99046697, 99046696, 99046693, 99046702, 99046707, c. LH: 99046651, 99046652, 99046679, 99046655, 99046656, 99046688, 99046682, 99046683, 99046684, 99046689, 99046685, 99046686, 99046657, 99046659, 99046697, 99046696, 99046693, 99046702, 99046707 d. TSH: 99046694, 99046695 e. Folate: 99046694, 99046695 11. 02/07/2023: a. Prolactin: b. TSH: c. LH: 99046714, 99046749 d. Folate: 12: 02/09/2023: a. Folate: 99046728, 99046757, 99046768, 99046771, 99046716, 99046767 b. Vitamin B12: 99046728, 99046757, 99046768, 99046771, 99046716, 99046767 13. 02/14/2023: a. Prolactin: 99046832, 99046817, 99046804, 99046818 14. 02/16/2023: a. Vitamin B12: 99046860, 99046858, 99046864 15. 02/21/2023: a. Vitamin B12: 99046867, 99046881, 99046885, 99046905 C. Review of the CMS form 116 showed approximately 27,300 tests combined were performed annually. D. Interview with testing personnel #1 on June 30, 2023 at 1140 hours acknowledged the analyzer did not indicate whether control runs were in or out of range and she had to compare each result every day of patient testing to the ranges taken from the Unity report, and confirmed she would change the mean and standard deviation to the Unity report when she was having trouble with QC. Interview with testing personnel #1 on June 30, 2023 at 1430 hours confirmed the findings after a review of the findings.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on review of instrument print-outs and interview, the laboratory failed to retain instrument print-outs on the Beckman Coulter UniCel DxI 600 for Chemistry and

	Endocrinology testing for two of two years reviewed. Findings follow. A. Review of instrument print-outs showed none for patient testing. Patient instrument print-outs were requested on June 30, 2023 at 1345 hours but not provided. B. Interview with the owner on June 30, 2023 at 1345 hours confirmed instrument print-outs for patients were not retained. Interview with testing personnel #1 on July 17, 2023 confirmed the instrument printed the patient results, but the lab was throwing them away after they transmitted to the EHR (electronic health record).
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, review of the verification of performance specification records, manufacturer's instructions, laboratory's policies and procedures, maintenance logs, quality control (QC) records, query, pre-survey paperwork and interview, the Laboratory Director failed to provide technical and scientific oversight of the laboratory for two of two years reviewed. Findings follow. 1. Based on observation, review of the verification of performance specification records, manufacturer's instructions, laboratory's policies and procedures, maintenance logs, quality control (QC) records, query, pre-survey paperwork and interview, the laboratory director failed to monitor and evaluate the overall quality of the preanalytic and analytic systems; and correct problems in testing performed in Chemistry and Endocrinology (refer to D6007). 2. Based on review of the verification of performance specification records, manufacturer's instructions, laboratory's policies and procedures, quality control (QC) records, pre-survey paperwork, and interview, the Laboratory Director failed to ensure the quality control program is established and maintained to assure the quality of Chemistry and Endocrinology results (refer to D6020).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on observation, review of the verification of performance specification records, manufacturer's instructions, laboratory's policies and procedures, maintenance logs, quality control (QC) records, query, pre-survey paperwork and interview, the laboratory director failed to monitor and evaluate the overall quality of the preanalytic and analytic systems; and correct problems in testing performed in Chemistry and Endocrinology. Findings follow. 1. The laboratory failed to ensure specimens were

	stored at the appropriate temperature for Ferritin, Folate, Prolactin, Prostate Specific Antigen (PSA), Total Testosterone, Vitamin B12, and Sensitive Estradiol on the Beckman Coulter UniCel DxI 600 from July 19, 2023 - July 24, 2023 (see D5311). 2. The laboratory failed to have a written procedure for the performance of corrective actions taken when QC results fail to meet the acceptable criteria on the Beckman Coulter UniCel DxI 600 for two of two years reviewed (see D5403 I). 3. Thelaboratory failed to have a written procedure to establish control limits on the Beckman Coulter UniCel DxI 600 for two of two years reviewed (see D5403 II). 4. The laboratory failed to store Bio-Rad Liquichek Control material and calibrators in a non frost-free freezer for one of one freezer reviewed (see D5413). 5. The laboratory failed to verify the performance specifications for Luteinizing Hormone (LH) on the Beckman Coulter UniCel DxI 600 for normal reference ranges for 11 of 11 months reviewed (see D5421). 6. The laboratory failed to verify the performance specifications for Ferritin, Folate, Prolactin, PSA, Total Testosterone, Thyroid Stimulating Hormone (TSH), Vitamin B12, Sensitive Estradiol, Sex Hormone Binding Globulin (SHBG), and Vitamin D on the Beckman Coulter UniCel DxI 600 for precision and accuracy, and perform normal reference range studies for 2 of 2 years reviewed (see D5421 II). 7. The laboratory failed to perform maintenance on the Beckman Coulter UniCel DxI 600 as defined by the manufacturer for two out of six 5,000 test intervals reviewed from March 8, 2022 to May 30, 2023 (see D5429). 8. The laboratory failed to monitor over time the accuracy and precision of the test system for Ferritin, Folate, Prolactin, PSA, Total Testosterone, TSH, Vitamin B12, Sensitive Estradiol, SHBG, LH, and Vitamin D performed on the Beckman Coulter UniCel DxI 600 for 2 of 2 years reviewed (see D5441). 9. The laboratory failed to ensure two levels of QC were within range on the Beckman Coulter UniCel DxI 600 prior to reporting patient samples for 15 out of 15 days of testing reviewed (see D5447).
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 verification of performance specification records, manufacturer's instructions, laboratory's policies and procedures, quality control (QC) records, pre-survey paperwork, and interview, the Laboratory Director failed to ensure the quality control program is established and maintained to assure the quality of Chemistry and Endocrinology results. Findings follow. 1. The laboratory failed to have a written procedure for the performance of corrective actions taken when QC results fail to meet the acceptable criteria on the Beckman Coulter UniCel DxI 600 for two of two years reviewed (refer to D5403 I). 2. The laboratory failed to have a written procedure to establish control limits on the Beckman Coulter UniCel DxI 600 for two of two years reviewed (refer to D5403 II).
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 observation, review of the verification of performance specification records, manufacturer's instructions, laboratory's policies and procedures, maintenance logs, quality control (QC) records, query, pre-survey paperwork, competency evaluations, educational credentials and interview, the Technical Consultant failed to provide the required technical oversight of the laboratory for two of two years reviewed. Findings follow. 1. The technical consultant failed to provide technical and scientific oversight of the laboratory for two of two years reviewed (refer to D6036). 2. The technical consultant failed to ensure verification of the test procedures for precision and accuracy, and perform normal reference range studies for 11 out of 11 analytes reviewed (refer to D6040). 3. The technical consultant failed to establish a QC program appropriate for the testing performed and establishing acceptable levels of analytic performance (refer to D6042). 4. The technical consultant failed to perform the direct observation of routine patient test performance for three of three testing personnel for two of two years reviewed (refer to D6047). 5. The technical consultant failed to perform the direct observation of maintenance for one of one testing personnel for two of two years reviewed (refer to D6050). 6. The technical consultant failed to evaluate and document the performance of individuals for the use of the Qualigen for testosterone testing at least semiannually for one of one testing personnel reviewed for one of one years reviewed (refer to D6053). 7. The technical consultant failed to evaluate and document the performance of individuals for the use of the Qualigen for testosterone testing for one of one testing personnel reviewed for two of two years reviewed (refer to D6054).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, review of the verification of performance specification records, manufacturer's instructions, laboratory's policies and procedures, maintenance logs, quality control (QC) records, query, pre-survey paperwork and interview, the technical consultant failed to provide technical and scientific oversight of the laboratory for two of two years reviewed. Findings follow. 1. The laboratory failed to ensure specimens were stored at the appropriate temperature for Ferritin, Folate, Prolactin, Prostate Specific Antigen (PSA), Total Testosterone, Vitamin B12, and Sensitive Estradiol on the Beckman Coulter UniCel DxI 600 from July 19, 2023 - July 24, 2023 (see D5311). 2. The laboratory failed to have a written procedure for the performance of corrective actions taken when QC results fail to meet the acceptable criteria on the Beckman Coulter UniCel DxI 600 for two of two years reviewed (see D5403 I). 3. The laboratory failed to have a written procedure to establish control limits on the Beckman Coulter UniCel DxI 600 for two of two years reviewed (see D5403 II). 4. The laboratory failed to store Bio-Rad Liquichek Control material and calibrators in a non frost-free freezer for one of one freezer reviewed (see D5413). 5.

	The laboratory failed to verify the performance specifications for Luteinizing Hormone (LH) on the Beckman Coulter UniCel DxI 600 for normal reference ranges for 11 of 11 months reviewed (see D5421). 6. The laboratory failed to verify the performance specifications for Ferritin, Folate, Prolactin, PSA, Total Testosterone, Thyroid Stimulating Hormone (TSH), Vitamin B12, Sensitive Estradiol, Sex Hormone Binding Globulin (SHBG), and Vitamin D on the Beckman Coulter UniCel DxI 600 for precision and accuracy, and perform normal reference range studies for 2 of 2 years reviewed (see D5421 II). 7. The laboratory failed to perform maintenance on the Beckman Coulter UniCel DxI 600 as defined by the manufacturer for two out of six 5,000 test intervals reviewed from March 8, 2022 to May 30, 2023 (see D5429). 8. The laboratory failed to monitor over time the accuracy and precision of the test system for Ferritin, Folate, Prolactin, PSA, Total Testosterone, TSH, Vitamin B12, Sensitive Estradiol, SHBG, LH, and Vitamin D performed on the Beckman Coulter UniCel DxI 600 for 2 of 2 years reviewed (see D5441). 9. The laboratory failed to ensure two levels of QC were within range on the Beckman Coulter UniCel DxI 600 prior to reporting patient samples for 15 out of 17 days of testing reviewed (see D5447).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of verification of performance specification records, pre-survey paperwork, query, and interview the technical consultant failed to ensure verification of the test procedures for precision and accuracy, and perform normal reference range studies for 11 out of 11 analytes reviewed. Findings follow. 1. The laboratory failed to verify the performance specifications for Luteinizing Hormone (LH) on the Beckman Coulter UniCel DxI 600 for normal reference ranges for 11 of 11 months reviewed (refer to D5421 I). 2. The laboratory failed to verify the performance specifications for Ferritin, Folate, Prolactin, Prostate Specific Antigen (PSA), Total Testosterone, Thyroid Stimulating Hormone (TSH), Vitamin B12, Sensitive Estradiol, Sex Hormone Binding Globulin (SHBG), and Vitamin D on the Beckman Coulter UniCel DxI 600 for precision, accuracy, or perform a normal reference range study for 2 of 2 years reviewed (refer to D5421 II).
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 validation records, manufacturer's instructions, laboratory's policies and procedures, quality control (QC) records, query, pre-survey paperwork,

	and interview, the technical consultant failed to establish a QC program appropriate for the testing performed and establishing acceptable levels of analytic performance. Findings follow. 1. The laboratory failed to have a written procedure for the performance of corrective actions taken when QC results fail to meet the acceptable criteria on the Beckman Coulter UniCel DxI 600 for two of two years reviewed (refer to D5403 I). 2. The laboratory failed to have a written procedure to establish control limits on the Beckman Coulter UniCel DxI 600 for two of two years reviewed (refer to D5403 II). 3. The laboratory failed to ensure two levels of QC were within range on the Beckman Coulter UniCel DxI 600 prior to reporting patient samples for 15 out of 17 days of testing reviewed (refer to D5447).
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 review of the competency evaluations and interview, the technical consultant failed to perform the direct observation of routine patient test performance for three of three testing personnel for two of two years reviewed. Findings follow. A. Competency evaluations: 1. Review of the 04/30/2023 & 04/18/2022 competency evaluations for testing personnel number one, on the CMS form 209 showed chart reviews instead of direct observation of patient testing on the Beckman Coulter UniCel DxI 600 for chemistry and endocrinology testing and the Qualigen for testosterone testing. 2. Review of the 04/25/2023 & 09/14/2022 competency evaluations for testing personnel number three showed chart reviews instead of direct observation of patient testing on the Qualigen for testosterone testing. 3. Review of the 09/14/2022 & 03/31/2022 competency evaluations for testing personnel number four showed chart reviews instead of direct observation of patient testing on the Qualigen for testosterone testing. B. Interview with testing personnel #1 on June 29, 2023 at 1510 hours confirmed the competency evaluations were retroactive chart reviews of the results reported in the chart and did not include direct observation of patient testing. For Qualigen testing, they review what is resulted is the same as what is charted: they keep a binder with the patient results and compares it to the result in the chart.
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 review of the competency evaluations and interview, the technical consultant failed to perform the direct observation of maintenance for one of one testing personnel for two of two years reviewed. Findings follow. A. Competency evaluations: 1. Review of the 04/30/2023 & 04/18/2022 competency evaluations for testing personnel number one, on the CMS form 209 showed maintenance log reviews

	instead of the direct observation of maintenance on the Beckman Coulter UniCel DxI 600 used for chemistry and endocrinology testing. B. Interview with testing personnel #1 on June 29, 2023 at 1510 hours confirmed the competency evaluations for maintenance was the review of the maintenance log and did not include the direct observation of the performance of maintenance.
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 review of competency evaluations, educational credentials, and interview, the technical consultant failed to evaluate and document the performance of individuals for the use of the Qualigen for testosterone testing at least semiannually for one of one testing personnel reviewed for one of one years reviewed. Findings follow. A. Review of the 09/14/2022 & 03/31/2022 competency evaluations for testing personnel number four using the Qualigen for testosterone testing showed the competency evaluation was performed by a former testing person. B. Review of the educational credentials for the former testing person showed she had a high school diploma and did not qualify for technical consultant. C. Interview with testing personnel #1 on June 29, 2023 at 1520 hours confirmed the findings.
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 review of competency evaluations, educational credentials, and interview, the technical consultant failed to evaluate and document the performance of individuals for the use of the Qualigen for testosterone testing for one of one testing personnel reviewed for two of two years reviewed. Findings follow. A. Review of the 04/25/2023 & 09/14/2022 competency evaluations for testing personnel number three using the Qualigen for testosterone testing showed the competency evaluation was performed by testing personnel #1 (04/25/2023) and a former testing person (09/14 /2022). B. Review of the educational credentials for the former testing person showed she had a high school diploma and did not qualify for technical consultant. C. Interview with testing personnel #1 on June 29, 2023 at 1520 hours confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

	This STANDARD is not met as evidenced by: Based on review of training records, pre-survey documents, and interview, the laboratory failed to provide documentation of training on the Beckman Coulter UniCel DxI 600 for one of one testing personnel reviewed. Findings follow. A. Review of training records showed no documentation of training for testing personnel #1 as listed on the CMS form 209. B. Interview with testing personnel #1 on June 29, 2023 at 1500 hours acknowledged she was the sole testing personnel since another testing personnel left in Jan of 2023, and confirmed there was no documentation of training, and testing personnel #1 started testing on the DxI 600 approximately 05/30 /2022. C. Review of the CMS form 116 showed approximately 27,300 tests were performed annually.