Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2179381	04/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Kindbody - St Louis	347 N Lindbergh Blvd, Saint Louis, MO	

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
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 review of freezer temperature logs, Beckman Coulter Dxl 600 Access analyzer verification of performance specifications, Beckman Coulter Dxl 600 Access chemistry analyzer quality control (QC) logs, package inserts and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to ensure freezer was within acceptable criteria (Refer to D5413); failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population (Refer to D5421); failed to include two control materials of different concentrations each day of patient testing (Refer to D5447); and failed to establish or verify the criteria for acceptability of chemistry QC (Refer to D5469).
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 of chemistry freezer, review of 2020/2021 temperature logs, and interview with laboratory director, the laboratory failed to define and ensure acceptable storage criteria for chemistry reagents. Review of freezer temperature logs showed 12 of 90 testing days the freezer temperature was not within manufacturer's acceptable criteria. Findings: 1. Observation of chemistry freezer showed one box of Access Prolactin calibrator lot number 922725 expiration date October 3, 2021 with a manufacturer's acceptable storage temperature of negative 20 degrees Celsius. 2. Review of 2020 freezer temperature logs showed the freezer did not reach the temperature of negative 20 degrees Celsius on 11/16, 11/18, 11/19, 12/29, and 12/30. 3. Review of 2021 freezer temperature logs showed the freezer did not reach the temperature of negative 20 degrees Celsius on 01/04, 01/05, 01/06, 01/07, 01/08, 01 /27, and 03/01. 4. Interview with laboratory director on March 31, 2021 at 9:00 AM confirmed the laboratory failed to ensure proper freezer storage for prolactin calibrator.
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: Based on review of Beckman Coulter Dxl 600 Access analyzer verification of performance specifications and interview with the laboratory director, the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Findings: 1. Review of Beckman Coulter Dxl 600 Access analyzer verification of performance specifications showed the laboratory failed to verify the manufacturer's reference intervals (normal values) for: 25 Hydroxy Vitamin D Anti-Mullerian hormone (AMH) Beta hCG Dehydroepiandrosterone-Sulfate (DHEA-S) Estradiol Follicle-stimulating hormone (FSH) Luteinizing hormone (LH) Prolactin Rubella, IgG Thyroxine Free, (Free T4) Thyroid Peroxidase Antibodies (TPO) Thyroid-stimulating hormone (TSH) Progesterone Testosterone Vitamin B12 2. Interview with laboratory director on March 31, 2021 at 9:30 AM confirmed the laboratory failed to verify that the manufacturer's reference intervals (normal values) for the Beckman Coulter Dxl 600 Access analyzer.
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 2020/2021 Beckman Coulter Dxl 600 Access chemistry analyzer quality control (QC) logs for estradiol, and interview with laboratory director, the laboratory failed to include two control materials of different concentrations each day of patient testing for 4 of 46 patient testing days. Findings: 1. Review of November 2020 estradiol chemistry QC logs showed no documentation of level 3 QC for 2 of 23 days. (Laboratory policy is to perform level 1 and level 3 of BioRad QC each day of patient testing.) The laboratory was unable to provide the number of patients tested for estradiol for the 2 testing days. 2. Review of February 2021 estradiol chemistry QC logs showed no documentation of level 3 QC for 2 of 23 days. (Laboratory policy is to perform level 1 and level 3 of BioRad QC each day of patient testing.) The laboratory performed 112 patient tests for estradiol in February 2021. 3. Interview with laboratory director on March 31, 2021 at 9:30 AM confirmed the laboratory failed to include two control materials of different concentrations each day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of 2020/2021 Beckman Coulter Dxl 600 Access chemistry analyzer quality control (QC) logs, BioRad Liquichek Immunoassay Control package insert, and interview with laboratory director, the laboratory failed to establish or verify the criteria for acceptability of chemistry QC. Findings: 1. Review of QC on the Beckman Coulter Dxl 600 Access chemistry analyzer for November 2020 through March 2021 showed BioRad level 1 lot number 85231 and level 3 lot number 85233 did not match BioRad manufacturer's package insert for lot number 85321 and lot number 85233. The ranges in the Beckman Coulter Dxl 600 Access chemistry analyzer were: Beta hCG: Level 1 2.63 - 4.37 mIU/mL Level 3 309.50 - 408.5 mIU/mL Dehydroepiandrosterone-Sulfate (DHEA-S): Level 1 60.843 - 88.043 ug/dL Level 3 450.31 - 644.31 ug/dL Estradiol: Level 1 9.62 - 46.02 Level 3 591.36 - 856.16 Follicle-stimulating hormone (FSH): Level 1 6.57 - 9.89 mIU/mL Level 3 32.25 - 47.35 mIU/mL Luteinizing hormone (LH): Level 1 3.07 - 4.46 mIU/mL Level 3 46.3 - 66.3 mIU/mL Prolactin: Level 1 6.165 - 8.335 mIU/mL Level 3 34.3 - 45.1 mIU/mL Thyroxine Free, (Free T4): Level 1 0.667 - 0.998 ng/dL Level 3 2.805 - 4.035 ng/dL Thyroid-stimulating hormone (TSH): Level 1 0.558 - 0.821 mIU/mL Level 3 22.35 -

	33.25 mIU/mL Progesterone: Level 1 0.6 - 2.02 mIU/mL Level 3 21.15 - 35.45 mIU /mL Testosterone: Level 1 88.34 - 125.84 ug/dL Level 3 688.5 - 995.5 ug/dL 2. The ranges in the Beckman Coulter Dxl 600 Access chemistry analyzer did not match the BioRad Liquichek Specialty Immunoassay Control level 1 lot number 64911 and level 2 lot number 64912 package insert. The ranges in the Beckman Coulter Dxl 600 Access chemistry analyzer were: 25 Hydroxy Vitamin D: Level 1 11.45 - 24.75 ng /mL Level 3 30.9 - 65.5 ng/mL Thyroid Peroxidase Antibodies (TPO): Level 1 16.30 - 24.50 IU/mL Level 3 45.3 - 67.9 IU/mL 3. Review of BioRad Liquichek Immunoassay Plus Control package insert for level 1 lot number 85231 and level 3 lot number 85233 showed acceptable ranges: Beta hCG: Level 1 2.84 - 4.96 mIU/mL Level 3 303 - 423 mIU/mL Dehydroepiandrosterone-Sulfate (DHEA-S): Level 1 48.1 - 75.3 ug/dL Level 3 363 - 557 ug/dL Estradiol: Level 1 16.9 - 48.7 pg/mL Level 3 520 - 692 pg/mL Follicle-stimulating hormone (FSH): Level 1 6.72 - 10.8 mIU/mL Level 3 31.4 - 49.0 mIU/mL Luteinizing hormone (LH): Level 1 3.23 - 5.07 mIU/mL Level 3 47.8 - 73.1 mIU/mL Prolactin: Level 1 5.43 - 7.67 ng/mL Level 3 31.0 - 43.9 ng/mL Thyroxine Free, (Free T4): Level 1 0.671 - 1.12 ng/dL Level 3 2.74 - 4.21 ng /dL Thyroid-stimulating hormone (TSH): Level 1 0.480- 0.754 uIU/mL Level 3 25.3-38.4 uIU/mL Progesterone: Level 1 0.729 - 1.8 ng/mL Level 3 26.6 - >40 ng/mL Testosterone: Level 1 .756 - 1.18 ng/mL Level 3 5.98 - 9.65 ng/mL 4. Review of BioRad Liquichek Specialty Immunoassay Control package insert for level 1 lot number 64911 and level 2 lot number 64912 showed acceptable ranges: 25 Hydroxy Vitamin D: Level 13.2 - 29.3 ng/mL Level 3 34.2 - 74.4 ng/mL Thyroid Peroxidase Antibodies (TPO): Level 1 14.1 - 23.3 IU/mL Level 3 36.8 - 66 IU/mL 5. Review of November 2020, December 2020, January 2021 and February 2021 Beckman Coulter Dxl 600 Access chemistry analyzer QC logs for estradiol showed QC level 3 lot number 85233 was not within manufacturer's acceptable limits for 43 of 83 testing days. The laboratory performed 327 patient tests for estradiol from December 2020 to February 2021. 6. Review of November 2020, December 2020, January 2021 and February 2021 Beckman Coulter Dxl 600 Access chemistry analyzer QC logs for DHEA-S showed QC level 1 lot number 85231 was not within manufacturer's acceptable limits for 7 of 78 testing days. The laboratory performed 3 patient tests for DHEA-S in January 2021. 7. Review of November 2020, December 2020, January 2021 and February 2021 Beckman Coulter Dxl 600 Access chemistry analyzer QC logs for DHEA-S showed QC level 3 lot number 85233 was not within manufacturer's acceptable limits for 2 of 78 testing days. The laboratory performed 3 patient tests for DHEA-S in January 2021. 8. Interview with laboratory director on March 31, 2021 at 9:30 AM confirmed the laboratory failed to establish or verify the criteria for acceptability of chemistry QC.
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 review of patient chemistry test report and interview with laboratory director, the laboratory failed to include the name and address of the laboratory location where the test was performed. Findings: 1. Review of patient chemistry test report showed no name and address of the laboratory location where the test was performed. 2. Interview with the laboratory director on March 31, 2021 at 9:00 AM confirmed the laboratory failed to include name and address of the laboratory location where the test was performed.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of 2020/2021 Beckman Coulter Dxl 600 Access chemistry analyzer quality control (QC) logs, BioRad Liquichek Immunoassay Control package insert, and interview with laboratory director, the laboratory director failed to ensure that the quality control and quality assessment programs were established and maintained to identify failures in quality as they occur. Findings: 1. Review of QC on the Beckman Coulter Dxl 600 Access chemistry analyzer for November 2020 through March 2021 showed BioRad level 1 lot number 85231 and level 3 lot number 85233 did not match BioRad manufacturer's package insert for lot number 85321 and lot number 85233. The ranges in the Beckman Coulter Dxl 600 Access chemistry analyzer were: Beta hCG: Level 1 2.63 - 4.37 mIU/mL Level 3 309.50 - 408.5 mIU/mL Dehydroepiandrosterone-Sulfate (DHEA-S): Level 1 60.843 - 88.043 ug/dL Level 3 450.31 - 644.31 ug/dL Estradiol: Level 1 9.62 - 46.02 Level 3 591.36 - 856.16 Follicle-stimulating hormone (FSH): Level 1 6.57 9.89 mIU/mL Level 3 32.25 - 47.35 mIU/mL Luteinizing hormone (LH): Level 1 3.07 - 4.46 mIU/mL Level 3 46.3 - 66.3 mIU/mL Prolactin: Level 1 6.165 - 8.335 mIU/mL Level 3 34.3 - 45.1 mIU/mL Thyroxine Free, (Free T4): Level 1 0.667 - 0.998 ng/dL Level 3 2.805 - 4.035 ng/dL Thyroid-stimulating hormone (TSH): Level 1 0.558 - 0.821 mIU/mL Level 3 22.35 - 33.25 mIU/mL Progesterone: Level 1 0.6 - 2.02 mIU/mL Level 3 21.15 - 35.45 mIU /mL Testosterone: Level 1 88.34 - 125.84 ug/dL Level 3 688.5 - 995.5 ug/dL 2. The ranges in the Beckman Coulter Dxl 600 Access chemistry analyzer did not match the BioRad Liquichek Specialty Immunoassay Control level 1 lot number 64911 and level 2 lot number 64912 package insert. The ranges in the Beckman Coulter Dxl 600 Access chemistry analyzer were: 25 Hydroxy Vitamin D: Level 1 11.45 - 24.75 ng /mL Level 3 30.9 - 65.5 ng/mL Thyroid Peroxidase Antibodies (TPO): Level 1 16.30 - 24.50 IU/mL Level 3 45.3 - 67.9 IU/mL 3. Review of BioRad Liquichek Immunoassay Plus Control package insert for level 1 lot number 85231 and level 3 lot number 85233 showed acceptable ranges: Beta hCG: Level 1 2.84 - 4.96 mIU/mL Level 3 303 - 423 mIU/mL Dehydroepiandrosterone-Sulfate (DHEA-S): Level 1 48.1 - 75.3 ug/dL Level 3 363 - 557 ug/dL Estradiol: Level 1 16.9 - 48.7 pg/mL Level 3 520 - 692 pg/mL Follicle-stimulating hormone (FSH): Level 1 6.72 - 10.8 mIU/mL Level 3 31.4 - 49.0 mIU/mL Luteinizing hormone (LH): Level 1 3.23 - 5.07 mIU/mL Level 3 47.8 - 73.1 mIU/mL Prolactin: Level 1 5.43 - 7.67 ng/mL Level 3 31.0 - 43.9 ng/mL Thyroxine Free, (Free T4): Level 1 0.671 - 1.12 ng/dL Level 3 2.74 - 4.21 ng

	/dL Thyroid-stimulating hormone (TSH): Level 1 0.480- 0.754 uIU/mL Level 3 25.3-38.4 uIU/mL Progesterone: Level 1 0.729 - 1.8 ng/mL Level 3 26.6 - >40 ng/mL Testosterone: Level 1 .756 - 1.18 ng/mL Level 3 5.98 - 9.65 ng/mL 4. Review of BioRad Liquichek Specialty Immunoassay Control package insert for level 1 lot number 64911 and level 2 lot number 64912 showed acceptable ranges: 25 Hydroxy Vitamin D: Level 13.2 - 29.3 ng/mL Level 3 34.2 - 74.4 ng/mL Thyroid Peroxidase Antibodies (TPO): Level 1 14.1 - 23.3 IU/mL Level 3 36.8 - 66 IU/mL 5. Review of Beckman Coulter Dxl 600 Access chemistry analyzer QC logs for estradiol showed no documentation by the laboratory director for failure of QC level 3 lot number 85233 for 43 of 83 testing days. 6. Review of Beckman Coulter Dxl 600 Access chemistry analyzer QC logs for DHEA-S showed no documentation by the laboratory director for failure of QC level 1 lot number 85231 for 7 of 78 testing days. 7. Review of Beckman Coulter Dxl 600 Access chemistry analyzer QC logs for DHEA-S showed no documentation by the laboratory director for failure of QC level 3 lot number 85233 for 2 of 78 testing days. 8. Review of November 2020 estradiol chemistry QC logs showed no documentation by the laboratory director for failure to perform two levels of estradiol QC for 2 of 23 days. 9. Review of February 2021 estradiol chemistry QC logs showed no documentation by the laboratory director for failure to perform two levels of QC for 2 of 23 days. 10. Interview with laboratory director on March 31, 2021 at 9:30 AM confirmed the laboratory director failed to ensure that the quality control and quality assessment programs were established and maintained to identify failures in quality as they occur.