

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2331972	(X3) Date Survey Completed 08/06/2026
Name of Provider or Supplier Kbmo Molecular Diagnostics	Street Address, City, State 1640 North Cornington Avenue, Kansas City, 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 laboratory procedures, policies, calibration records from January 2026 to date August 5, 2026, temperature and humidity logs for November 17, 2025 to date August 5, 2026, Centers for Medicare and Medicaid Services Form 116 (CMS-116), performance verification procedures for the CLC 800 analyzer, verification of performance specifications for the Agilent LC/MS/MS analyzer, verification of performance specifications for the Spectra Max iD3 analyzer, and patient results, observation of mobile phase A and interview with the technical supervisor (TS) #1 and TS #2, the laboratory failed to meet the condition of analytic systems. The laboratory failed to follow the written procedure for urine creatinine (Refer to D5401); the laboratory failed to provide written procedures for Agilent LC/MS/MS quality control (QC) (Refer to D5403); the laboratory failed to ensure the temperature and humidity was maintained according to laboratory's logs for 68 of 187 days (Refer to D5413); the laboratory failed to document accurate expiration dates on mobile phase A (Refer to D5415); the laboratory failed to verify performance specifications prior to reporting patient test results (Refer to D5421); the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the Agilent LC/MS/MS analyzer for 67 biomarkers and 1 analyte on the Spectra Max iD3 analyzer (Refer to D5423).

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, calibration records from January 2026 to date August 5, 2026, patient results, and interview with the technical supervisor (TS) #2, the laboratory failed to follow the written procedure for urine creatinine for 7 of 21 days. Findings: 1. Review of laboratory procedure "Diazyme Enzymatic Urine Creatinine Assay Performance" states "Calibration is performed at least every 14 days and with each new lot of reagents". 2. Review of urine creatinine calibration records from January 2026 to date August 5, 2026 showed the laboratory failed to perform a calibration following written procedure of every 14 days on the following days: 01/21/2026, 02/03/2026, 02/17/2026, 03/05/2026, 03/24/2026, 05/08/2026, and 06/09/2026. 3. Review of patient results showed the laboratory performed approximately 747 urine creatinine patient tests since testing began on November 19, 2025. 4. Interview with the technical supervisor (TS) #2 on August 5, 2026 at 12:00 PM confirmed the laboratory failed to follow the written procedure for urine creatinine.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of procedures and interview with technical supervisor (TS) #1, the laboratory failed to provide written procedures for Agilent LC/MS/MS quality control (QC). Findings: 1. Review of procedures showed no procedure for stability of LC/MS/MS QC. The laboratory could not provide a procedure stating how long LC/MS/MS QC is good for when frozen and could not provide a procedure for stability once QC

	is opened, thawed and refrigerated. 2. Interview with TS #1 on August 5, 2027 at 10:30 AM confirmed the laboratory failed to provide written procedures for Agilent LC/MS/MS QC.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of laboratory policy, review of temperature and humidity logs for November 17, 2025 to date August 5, 2026, Centers for Medicare and Medicaid Services Form 116 (CMS-116) and interview with the technical supervisor (TS) #2, the laboratory failed to ensure the temperature and humidity was maintained according to laboratory's logs for 68 of 187 days. Findings: 1. Review of the "Laboratory Temperature and Humidity Monitoring" policy states "Daily temperature and humidity should be within the following ranges: Main Lab 20 to 30 degrees Celsius, 20-80% humidity, Hood Room 20 to 24 degrees Celsius, 20-80% humidity, Refrigerator #1 2-8 degrees Celsius, Freezer #1 -18 to -22 degrees Celsius, ULT #1 -65 to -85 degrees Celsius". 2. Review of the "Monthly Temperature and Environmental Log" showed that the Refrigerator #1 was out of range for 21 of 187 days in November 17, 2025 to date August 5, 2026. 3. Review of the "Monthly Temperature and Environmental Log" showed that the Freezer #1 was out of range for 1 of 187 days in November 17, 2025 to date August 5, 2026. 4. Review of the "Monthly Temperature and Environmental Log" showed that the ULT #1 was out of range for 1 of 187 days in November 17, 2025 to date August 5, 2026. 5. Review of the "Monthly Temperature and Environmental Log" showed that the Main Lab was out of range for 1 of 187 days in November 17, 2025 to date August 5, 2026. 6. Review of the "Monthly Temperature and Environmental Log" showed that the Main Lab Humidity was out of range for 9 of 187 days in November 17, 2025 to date August 5, 2026. 7. Review of the "Monthly Temperature and Environmental Log" showed that the Hood Room was out of range for 46 of 187 days in November 17, 2025 to date August 5, 2026. 8. Review of CMS-116 showed the laboratory performs approximately 500,000 tests yearly. 9. Interview with the TS #2 on August 5, 2026 at 9:30 AM confirmed the laboratory failed to ensure the temperature and humidity was maintained.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on review of the Agilent LC/MS/MS procedure, observation of mobile phase A, patient results and interview with the technical supervisor (TS) #1, the laboratory failed to document accurate expiration dates on mobile phase A. Findings: 1. Review of the "Urine Metabolic Insights Profile Assay in Human Urine by LC/MS/MS" procedure states "Mobile Phase A (MP-A) Expiry: Ten days when at RT. One month at 2-8 degrees Celsius away from light". 2. Observation of mobile phase A, lot #260803 at room temperature revealed made date 8/3/26 and expiration date 9/3/26. 3. The laboratory has performed 735 LC/MS/MS patient tests since testing started in November 2025. 4. Interview with the TS #1 on August 5, 2026 at 10:00 AM confirmed the laboratory failed to document accurate expiration dates on mobile phase A.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 performance verification procedures for the CLC 800 analyzer, patient results and interview with the technical supervisor (TS) #1, the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population prior to reporting patient test results. Findings: 1. Review of performance verification procedures for the CLC 800 analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analyte: creatinine prior to the beginning of patient testing in November 2025. 2. The laboratory has performed 747 creatinine patient tests since testing started in November 2025. 3. Interview with the TS #1 on August 5, 2026 at 10:00 AM confirmed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population prior to reporting patient test results.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable

range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of the verification of performance specifications for the Agilent LC /MS/MS analyzer, review of the verification of performance specifications for the Spectra Max iD3 analyzer, patient results, and interview with the technical supervisor (TS) #1, the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the Agilent LC/MS/MS analyzer for 67 of 67 biomarkers and for 1 of 1 analytes on the Spectra Max iD3 analyzer. Findings: 1. Review of Agilent LC/MS/MS verification of performance specifications showed no documentation that manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the biomarkers: arabitol, citramalic, 5-hydroxymethyl-2-furoic, furancarbonylglycine, furan-2.5-dicarboxylic, tricarballic, ascorbic/erythorbic, HPPHA, 3-cresol sulfate, 3-indoleacetic, benzoic, hippuric, 4-hydroxybenzoic, 4-hydroxyphenylacetic, 4-hydroxyphenyllactic, tartaric, l-pyroglutamic, n-acetylcysteine, 8-hydroxy-2deoxyguanosine, 2-hydroxybutyric, 2-hydroxyhippuric, citric, cis-aconitic, isocitric, 2-oxoglutaric, succinic, fumaric, malic, pyruvic, l-lactic, 2,4-dihydroxybutanoic, suberic, ethylmalonic, 3-hydroxybutyric, acetacetic, methylsuccinic, sebacic, xanthurenic, 4-pyridoxic, panthothenic, glutaric, formimino-glutamic, methylmalonic, uracil, thymine, oxalic, glycolic, glyceric, 3-methylglutaconic, 2-oxoisovaleric, malonic, 2-oxoisocaproic, 2-oxo-4-methylbutyric, 3-hydroxy-3-methylglutaric, mandelic, 3-phenyllactic, homogentisic, orotic, 4-hydroxybutyric, 2-hydroxyisovaleric, 2-hydroxysuccinic, 3-methyl-2-oxovaleric, homovanillic, vanilmandelic, HVA/VMA ratio, 5-hydroxyindoleacetic, kynurenic, quinolinic, and quinolinic/kynurenic. 2. The laboratory has performed 735 LC/MS/MS patient tests since testing started in November 2025. 3. Review of Spectra Max iD3 analyzer verification of performance specifications for glyphosate showed no documentation that manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population. 4. The laboratory has performed 146 glyphosate patient tests since testing started in February 2026. 5. Interview with the TS #1 on August 5, 2026 at 10:00 AM confirmed the laboratory failed to provide documentation for reference intervals (normal ranges) for the Agilent LC/MS/MS analyzer and the Spectra Max iD3 analyzer.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of glyphosate assay batch records, "Glyphosate Exposure Stability" study, Abraxis Glyphosate ELISA Microtiter plate package insert, patient sample collection dates, verification of performance specifications for the Agilent LC/MS/MS analyzer, Agilent LC/MS/MS quality control (QC) procedure, Agilent LC/MS/MS QC, Agilent LC/MS/MS analyzer procedure, 3 of 67 Agilent LC/MS/MS calibrations on July 31, 2026, and patient results and interview with the technical supervisor (TS) #1 and TS #2, the laboratory director (LD) failed to provide overall management and

	direction of the laboratory. The LD failed to ensure that patient glyphosate testing provides quality laboratory services for all aspects of test performance, which includes the preanalytic and analytic phases of testing for the analyte urine glyphosate (Refer to D6082); the laboratory director failed to ensure 67 biomarkers performed on the Agilent LC/MS/MS analyzer have the capability of providing quality of results required for patient care (Refer to D6085); the laboratory director failed to ensure Agilent LC/MS/MS analyzer testing performed for accurate and reliable results (Refer to D6087).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (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 review of glyphosate assay batch records, "Glyphosate Exposure Stability" study, Abraxis Glyphosate ELISA Microtiter plate package insert, patient sample collection dates and patient results and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure that patient glyphosate testing provides quality laboratory services for all aspects of test performance, which includes the preanalytic and analytic phases of testing for the analyte urine glyphosate. Findings: 1. Review of glyphosate assay batch records for 02/05/2026 showed the following samples: 260126-01, 260202-07, and 260202-10 with comments "Repeat samples due to failed controls". Review of glyphosate assay batch records for 02/19/26 showed the following repeat samples from 02/05/2026: 260126-01, 260202-07, 260202-10. 2. Review of "Glyphosate Exposure Stability" study showed a 10 day stability study at ambient, refrigerated and frozen temperatures approved by the laboratory director on January 21, 2026. 3. Review of Abraxis Glyphosate ELISA Microtiter plate package insert states "Store samples refrigerated for up to 2 weeks". 4. Review of patient sample collection dates showed: 260126-01 collected on 01/20/2026 260202-07 collected on 01/29/2026 260202-10 collected on 01/27/2026 5. Review of patient results showed the laboratory performed approximately 146 glyphosate patient tests since testing began on February 1, 2026. 6. Interview with the TS #2 on August 5, 2026 at 12:00 PM confirmed the LD failed to ensure that patient glyphosate testing provide quality laboratory services for all aspects of test performance, which includes the preanalytic and analytic phases of testing for the analyte urine glyphosate.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) (e)(3) Ensure that-- (e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: Based on review of the verification of performance specifications for the Agilent LC /MS/MS analyzer, interview with technical supervisor, review of Agilent LC/MS/MS quality control (QC) procedure, review of Agilent LC/MS/MS QC, patient results and

interview with TS #1, the laboratory director failed to ensure 67 of 67 biomarkers performed on the Agilent LC/MS/MS analyzer have the capability of providing quality of results required for patient care. Findings: 1. Review of verification of performance specifications stated "precision CV less than or equal to 30 percent, accuracy CV less than or equal to 30 percent". 2. Interview with TS #1 on August 5, 2026 at 11:45 AM stated with new batch QC they went to standard deviations which is greater than the 30 percent accuracy established in November 2025. 3. Review of the new procedure "Urine Metabolic Insights Profile Assay in Human Urine by LC /MS/MS" stated "Most compounds in this QC have concentrations falling between calibrators 2 and 6. QC ranges are based on Mean and SD (QC average of a minimum 20 data points)". 4. Review of Agilent LC/MS/MS level 1 QC revealed the standard deviation ranges were greater for 38 of 67 biomarkers than the acceptable validated CV of less than or equal to 30 percent. Examples of QC ranges greater than acceptable validated CV of less than or equal to 30 percent include: acetaoetic: mean 14.53 standard deviation (SD) 5.23 acceptable range 4.09-24.98 which is 72% 2-oxisocaproic: mean 27.65 SD 8.06 acceptable range 11.52-43.77 which is 58% 5. Review of Agilent LC/MS/MS level 2 QC revealed the standard deviation ranges were greater for 50 of 67 biomarkers than the acceptable validated CV of less than or equal to 30 percent. Examples of QC ranges greater than acceptable validated CV of less than or equal to 30 percent include: oxalic: mean 70.79 SD 25.36 acceptable range 20.06-121.52 which is 72% HPPHA: mean 31.13 SD 29.63 acceptable range -28.14-90.40 which is 190% 6. Review of Agilent LC/MS/MS level 3 QC revealed the standard deviation ranges were greater for 40 of 67 biomarkers than the acceptable validated CV of less than or equal to 30 percent. Examples of QC ranges greater than acceptable validated CV of less than or equal to 30 percent include: 2,4 dihydroxybutanoic: mean 46.69 SD 17.72 acceptable range 11.25-82.12 which is 76% 3hydroxy-3methylglutaric: mean 127.79 SD 40.60 acceptable range 46.59-208.99 which is 63% 7. The laboratory has performed 735 LC/MS/MS patient tests since testing started in November 2025. 8. Interview with the TS #1 on August 5, 2026 at 12:00 PM confirmed the LD failed to ensure Agilent LC/MS/MS test results have the capability of providing quality of results required for patient care.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(iii)

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

This STANDARD is not met as evidenced by:
Based on review of Agilent LC/MS/MS analyzer procedure, interview with technical supervisor (TS) #1, review of 3 of 67 Agilent LC/MS/MS calibrations on July 31, 2026, patient results and interview with TS #1, the laboratory director failed to ensure the Agilent LC/MS/MS analyzer provided accurate and reliable results. Findings: 1. Review of "Urine Metabolic Insights Profile Assay in Human Urine by LC/MS/MS" stated "Accept the linear range of calibrators if linear regression has an R-squared value of greater than or equal to .90. Calibration standards must be within 30% of their target value". 2. Interview with TS #1 stated they only look at the R-squared value and do not make sure the calibrators are within 30%. 3. Review of calibrations from 3 analytes on July 31, 2026 showed the following calibration not within 30% of their target value: analyte ethylmalonic: calibration 1, calibration 3, calibration 4, calibration 6 analyte glyceric: calibration 1, calibration 3, anlayte citric: calibration 1, calibration 2, calibration 4 4. The laboratory has performed 735 LC/MS/MS patient

tests since testing started in November 2025. 5. Interview with the TS #1 on August 5, 2026 at 12:00 PM confirmed the LD failed to ensure the Agilent LC/MS/MS analyzer provided accurate and reliable results.