

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0696156	(X3) Date Survey Completed 02/06/2023
Name of Provider or Supplier West Tennessee Medical Group Northside	Street Address, City, State 31 Hughes Drive, Jackson, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The facility was found to be NOT in compliance with the following 42 CFR Part 493, Requirements for Laboratories for the specialties/subspecialties for which it was surveyed: 493.1210 Chemistry
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, and interview with the laboratory liaison, persons collecting patient blood samples were not following established laboratory safety procedures when transporting collected blood samples on the date of the survey. The findings include: 1. Observation of the laboratory on 02/06/23 at 8:20 am revealed a phlebotomist transporting collected patient blood samples. The phlebotomist was not wearing any gloves. 2. Review of the laboratory's policy titled "Hazardous Communication" "Operating Procedures in the Laboratory" revealed the following statement: "Employees use gloves during phlebotomy procedures and when transporting to lab for testing." 3. Interview with the laboratory liaison on 02/06/23 at 9:00 am confirmed personnel transporting collected patient blood samples without wearing gloves were not following established laboratory safety procedures on the date of the survey (02/06/23).</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including</p>

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 observation of the laboratory, review of laboratory records, and interview with the laboratory liaison, the laboratory failed to retain analytic records for the Ortho Vitros 350 chemistry instrument to include dates of use for chemistry quality control (QC) lots, chemistry reagent lot numbers and dates in use in 2022 (two of four randomly selected patient review dates). The findings include: 1. Observation of the laboratory on 02/06/23 at 8:20 am revealed the Ortho Vitros 350 instrument in use for performing patient testing for chemistry. 2. Review of laboratory chemistry quality control records revealed the following: QC records did not include complete dates when quality control materials were in use (Performance Verifier I and Performance Verifier II) for lot numbers M9814, N9816, F9070, G9072. Chemistry QC records did not reflect the QC lot number used or the reagent lot number. No records were available for chemistry reagent lot numbers and dates the lots were in use for patient testing. 3. Review of randomly selected patient chemistry testing on 06/08/22 (patient ID 193) and 09/13/22 (patient ID 443) and QC performed on those dates revealed no indication of the QC lot number, reagent lot number or generation number for the lot of reagent used. 4. Interview with the laboratory liaison on 02/06/23 at 4:45 pm confirmed the laboratory failed to retain analytic records for chemistry tests performed on the Ortho Vitros 350 instrument.

D5016

ROUTINE CHEMISTRY
CFR(s): 493.1210

If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
Based on direct observation, review of the laboratory procedure manual, performance specification verification studies, lack of records, calibration verification records, quality control records, patient test records and staff interview, the laboratory failed to meet the requirements for the chemistry specialty as evidenced by: 1. The laboratory failed to ensure a written procedure for the Lactate Dehydrogenase test (Refer to D5401). 2. The laboratory failed to label controls with open date and corrected expiration date (Refer to D5415). 3. The laboratory failed to verify manufacturer normal range for the Lactate Dehydrogenase test (Refer to D5421). 4. The laboratory failed to perform calibration verification (Refer to D5439). 5. The laboratory failed to perform retrospective patient review when quality control results were unacceptable (Refer to D5783).

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of proficiency test records and interview with the laboratory liaison the laboratory failed to evaluate two of two non-graded proficiency testing wet prep scores in 2021 and 2022. The findings include: 1. Observation of the laboratory at 08:20 am on 02/06/23 revealed a microscope in use for vaginal wet prep and potassium hydroxide (KOH) microscopic testing. 2. Review of the proficiency testing records revealed two non-graded wet prep scores with no documented evaluation to determine the laboratory accuracy (2021 event 3 photomicrograph VKP-03 and 2022 event two photomicrograph VA-02). 3. Interview with the laboratory liaison on 02/06/23 at 4:45 pm confirmed the survey findings. The non-graded proficiency testing scores were not evaluated by the laboratory.

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 observation of the laboratory, review of the laboratory procedure manual and interview with the laboratory liaison, the laboratory failed to follow its' own policy for specimen labeling when it did not label collected blood samples and did not include two patient identifiers on one observed collected sample on the date of the survey (02/06/23). The findings include: 1. During observation of the laboratory on 02/06/23 at 8:20 am two tubes of blood were brought to the laboratory for testing. One of the tubes was not labeled. The other sample was not labeled with a second identifier. 2. Review of the laboratory policy titled "LABELING, HANDLING AND STORAGE OF SPECIMEN POLICY" revealed that samples are to be labeled with patient full name and a second identifier ("SS#, DOB or chart number"). 3. Interview with the laboratory liaison on 02/06/23 at 4:45 pm confirmed the laboratory failed to follow its' own policy for labeling of patient samples on the date of the survey.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(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 quality assessment records, lack of a procedure, and interview with the laboratory liaison, the laboratory failed to have a procedure for the new Lactate Dehydrogenase (LDHI) performed on the Ortho Vitros 350 chemistry instrument with patient testing beginning approximately August 2022 until date of the survey (02/06/23). The findings include: 1. Review of the laboratory's quality assessment record dated 08/08/22 revealed the following statement: "New method

LDH validated and in use this month." 2. There was no procedure available for the revised LDHI method. 3. Interview with the laboratory liaison on 02/06/23 at 4:45 p. m. confirmed the laboratory did not have the manufacturer instructions for use that are used as part of the procedure for the Ortho Vitros LDHI method.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of manufacturer control package inserts, and interview with the laboratory liaison, the laboratory failed to label five of five control vials (three complete blood count (CBC) controls; two chemistry QC controls) with open dates and corrected expiration dates on the date of the survey (02/06/23). The findings include: 1. Observation of the laboratory on 02/06/23 at 8:20 am revealed the Sysmex XP 300 CBC instrument and the Ortho Vitros 350 chemistry instrument in use for patient testing. Quality control material for both instruments were noted in use that were not labeled with an open date or corrected expiration date- CBC control lots 23610710, 23610711, 23610712; Chemistry control lots M9814 and N9816. 2. Review of the manufacturer package inserts for CBC controls revealed the controls are good for 14 days after opening; the package insert for the chemistry controls revealed the control stability varies based on analyte, some analytes are stable for 7 days after reconstitution, some are stable for 3 days after reconstitution. 3. Interview with the laboratory liaison on 02/06/23 at 5pm confirmed control stability changed after opening for both the CBC and chemistry controls and the controls in use were not labeled with open date or corrected expiration date for five of five control lots observed.

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 the verification studies performed for the Lactate Dehydrogenase (LDHI) on the Ortho Vitros 350 chemistry instrument and interview with the laboratory liaison the laboratory failed to verify manufacturer's normal ranges in 2022. The findings include: 1. Review of the LDHI test method verification studies (report created on 07/25/22) revealed normal range verification was not performed. 2. Interview with laboratory liaison on 02/06/23 at 4:45 p.m. confirmed the laboratory

failed to verify manufacturer's normal range for the LDHI test performed on the Ortho Vitros 350 instrument in 2022.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of laboratory's procedure manual, lack of records and interview with the laboratory liaison the laboratory failed to monitor Revolutions per Minute (RPM) for the centrifuge used for preparing urine specimens for microscopic testing. The findings include: 1. Observation of the laboratory at 08:20 a.m. on 02/06/23 revealed a Drucker model 642E centrifuge in use for preparing urine sediment for microscopic analysis. 2. Review of the laboratory's procedure for urine microscopic analysis step five revealed "Centrifuge the 12 ml. of urine at 3000 RPM's for 3 minutes." 3. No records were available for monitoring of RPM's for the urine centrifuge. 4. Interview with laboratory liaison on 02/06/23 at 4:45 p.m. confirmed no records were available for monitoring of RPMs for the centrifuge used for preparing urine sediment for microscopic analysis.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's calibration verification records, calibration records, and interview with the laboratory liaison, the laboratory failed to complete the calibration verification report from January 2022 and failed to perform calibration verification when due in July 2022 and January 2023 for chemistry tests performed on the Ortho Vitros 350 instrument (three of five calibration verifications due) in 2022 and 2023. The findings include: 1. Review of the laboratory's calibration verification records for 2021, 2022 and 2023 revealed the following: The laboratory uses external calibration verification services/samples for tests performed on the Ortho Vitros 350 chemistry instrument. Calibration verification performed in January 2022 did not have a report generated to determine acceptability. There were no other calibration verification studies performed when due in July 2022 or January 2023. 2. Review of the laboratory's calibration records for the Ortho Vitros 350 revealed six of seven chemistry tests reviewed (total protein (TP), Triglyceride, Gamma-glutamyl transferase (GGT), Chloride (Cl), Calcium (Ca), Alanine aminotransferase (ALTV), Alkaline Phosphatase (ALKP)) with calibration gaps exceeding six-month intervals in 2022 and 2023. 3. Interview with the laboratory liaison on 02/06/23 at 4:45 pm confirmed the laboratory failed to generate the report for calibration verification performed in January 2022, and failed to perform calibration verification when due in July 2022 and January 2023 for chemistry tests performed on the Ortho Vitros 350. She further confirmed the laboratory's calibration frequency exceed six months for the analytes as mentioned in finding number two.

D5783

CORRECTIVE ACTIONS
 CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
 Based on review of quality control records, lack of available records, review of patient test records, and interview with the laboratory liaison, the laboratory failed to perform retrospective patient review when quality control results were unacceptable on 06/21/22 through 06/23/22 for Sodium testing on the Ortho Vitros 350 chemistry instrument. The findings include: 1. Review of the quality control (QC) records for Sodium (Na) for June 2022 revealed QC values that fell outside of the acceptable limits on 06/21/22, 06/22/22, and 06/23/22 for level one. QC records indicated the Vitros 350 was down from 06/20/22 through 07/07/22. 2. Record request on 02/06/23 at 3:00 p.m. for retrospective patient review going back to the last day of acceptable QC results (06/17/22) revealed no records were available. 3. Review of patient test records for 06/17/22 revealed two patients were tested and reported for Sodium (25888 and 5100). 3. Interview with the laboratory liaison on 02/06/23 at 4:45 p.m. confirmed that no records were available documenting retrospective patient review going back to the last date of acceptable QC on 06/17/22.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's complete blood count (CBC) quality control (QC) reports and interview with the laboratory liaison, the laboratory's quality assessment process was ineffective in prevent repeated problems with overlapping of QC data, flagging of QC results as unacceptable and graphs with shift and trends for The findings include: 1. Review of the laboratory's CBC QC reports revealed the following: Lot numbers 2122770710, 22770711,22770712 cumulative QC reports had overlapping data with a previous lot number resulting in unclear dates of use, results flagged as unacceptable and graphs with shifts and trends with no documented corrective action performed. Lot numbers 23610710, 23610711, 23610712 cumulative QC reports had overlapping data with a previous lot number resulting in unclear dates of use, results flagged as unacceptable and graphs with shifts and trends with no documented corrective action performed. 2. Review of quality assessment records revealed the technical consultant performs monthly quality assessment activities. No corrective actions were noted for the overlapping QC files. 3. Interview with the laboratory liaison on 02/06/23 at 4:45 pm confirmed the laboratory's quality assessment process was ineffective in preventing problems with overlapping of QC files, flagged results and graphs with shifts and trends when it did not perform corrective action for the QC file errors.

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 the units of measure used for complete blood count (CBC) analytes and the manufacturer units of measure in the laboratory information system (LIS), the units of measure in the final patient chart report and the manufacturer units of measure, and interview with the laboratory liaison, the laboratory failed to use correct units of measure for seven of seven final patient test reports reviewed from 2021, 2022 and 2023. The findings include: 1. Review of the units of measure for CBC in the LIS when compared to the manufacturer units of measure revealed incorrect units of measure for the white blood cell (WBC) absolute counts as follows: Incorrect Units Manufacturer Units Lymphocyte $10^3/dL$ $10^3/uL$ Mid $10^3/dL$ $10^3/uL$ Granulocyte $10^3/dL$ $10^3/uL$ 2. Review of final patient test results from the patient chart report revealed incorrect units of measure as follows: Incorrect Units

Manufacturer Units WBC 10 10³/uL RBC 10 10⁶/uL PLATELET 10 10³/uL MIDS 10 10³/uL LYM 10 10³/uL GRAN # 10 10³/uL These errors were noted for seven of seven final patient test reports reviewed as follows: Patient ID 21813 reported on 06/14/21 Patient ID 19866 reported on 11/17/21 Patient ID 21493 reported on 03/07/22 Patient ID 1102 reported on 08/09/22 Patient ID 29889 reported on 10/04/22 Patient ID 3668 reported on 01/09/23 Patient ID 23794 reported on 01/09/23 3. Interview with the laboratory liaison on 02/06/23 at 4:45 pm confirmed the laboratory failed to include correct units of measure for CBC analytes in the LIS and on the final patient test report for seven of seven patients reviewed from 2021, 2022, and 2023.