

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0314780	(X3) Date Survey Completed 02/02/2022
Name of Provider or Supplier Pediatric & Adolescent Medicine Of East Memphis Pc	Street Address, City, State 1102 Brookfield Road 2nd Fl, Memphis, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, testing personnel failed to sign the attestation statement for one of four available attestation statements. The findings include: 1. Review of the laboratory's proficiency testing records revealed that 2021 event two attestation statement was not signed by the person who performed the testing. 2. Interview with the laboratory director on 02/02/2022 at approximately 4 pm confirmed the survey findings.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory records and staff interview, the laboratory failed to retain attestation statements for one of five proficiency testing (PT) events. The findings include: 1. Review of proficiency testing records revealed no retention of the attestation statement for 2021 event one. 2. Interview with the laboratory director on 02/02/2022 at approximately 4 pm confirmed the survey findings.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of the laboratory procedure manual, patient test reports and staff interview, the laboratory procedure for complete blood count (CBC) was not approved by the laboratory director before patient testing in 2020. The findings include: 1. Review of the laboratory procedure titled "COMPLETE BLOOD COUNT BY BECKMAN COULTER DxH 500 ANALYZER" revealed approval by the lab director on 12/11/2020. 2. Review of the first patient reported on the Beckman Coulter DxH complete blood count instrument revealed patient testing began on 11/13/2020 (patient 1022). 3. Interview with the laboratory director on 02/02/2022 at approximately 4 pm confirmed the procedure for CBC performed on the DxH instrument was not approved before use.

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 observation of the laboratory, review of laboratory records, and staff

interview, the laboratory failed to follow the manufacturer's instructions for calibration verification of the Beckman Coulter DxH complete blood count instrument (one of three calibrations reviewed). The findings include: 1. Observation of the laboratory on 02/02/2022 at approximately 11:15 am revealed the Beckman Coulter DxH 500 on the counter in use for patient CBC testing (serial number DB040006). 2. Review of laboratory records revealed the following: Calibration of the instrument was performed on 10/28/2021. The manufacturer instructions for use stated to "Verify calibration using DxH 500 Series Calibrator as indicated in the calibrator's Instructions for Use." The calibrator package insert states the following "Verify calibration by analyzing a new tube of calibrator and repeat section A & B." There was no evidence that the calibration was verified after calibration was performed. Patient test records showed four patients were reported after the calibration, before any verification of the calibration was performed (patient numbers 3674, 5694, 7353, and 9724). 3. Interview with the laboratory director on 02/02/2022 at approximately 4 pm confirmed the survey findings.

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:
The laboratory director failed to have the appropriate laboratory training or experience for performing technical consultant duties (Refer to D6034), the technical consultant failed to approve test method validations (Refer to D6040), the technical consultant failed to review quality control (Refer to D6042) and the technical consultant failed to perform training and competency assessments as indicated in the laboratory policy (Refer to 6046).

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (Form CMS-209), laboratory records and staff interview, the laboratory director failed to have the laboratory training or experience for performing technical consultant duties in 2020 and 2021. The findings include: 1. Review of the Form CMS-209 revealed no technical consultant was listed. 2. Review of laboratory records revealed the following: The laboratory director had performed technical consultant duties include review of quality control, review of proficiency testing results and training and competency assessment of testing personnel. The laboratory records and personnel records did not include any evidence that the laboratory director

had the required laboratory training or experience for performing technical consultant duties. 3. Interview with the laboratory director on 02/02/2022 at approximately 4 pm confirmed the lab director performed technical consultant duties in 2020 and 2021 without the required laboratory training or experience. The laboratory director stated she realized that she had not retained a technical consultant (after the previous one retired) when she was filling out the paperwork. The time frame since the last technical consultant was retained/available was unclear.

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 observation of the laboratory, review of laboratory records, and staff interview, the technical consultant failed to review and approve validations performed on the Beckman Coulter DxH 500 complete blood count (CBC) instrument in 2020. The findings include: 1. Observation of the laboratory on 02/02/2022 at approximately 11:15 am revealed the Beckman Coulter DxH CBC instrument on the counter in use for patient testing. 2. Review of laboratory records revealed validations for DxH 500 CBC instrument were completed and printed on 10/30/2020. There was no evidence the validations had been reviewed or approved. Patient test records indicated the first patient was tested on 11/13/2020 (patient 1022). 3. Interview with the laboratory director on 02/02/2022 at approximately 4 pm confirmed a technical consultant had not reviewed or approved the validations performed for the Beckman Coulter DxH CBC instrument in 2020.

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 laboratory procedure manual, quality control records, and staff interview, the technical consultant failed to review complete blood count (CBC) quality control for four out of twelve months in 2021. The findings include: 1. Review of the laboratory's quality assurance policy revealed that "The quality control program for calibration and control data for each test method used in the lab will be reviewed by the laboratory director and technical consultant (via fax) monthly." 2. Review of the laboratory's quality control records revealed no review of the following quality control lots as follows: 352112311, 362112312, 372112313 in use from 04/27/2021 to 05/24/2021 352112411, 362112412, 372112413 in use from 05/25/2021 to 06/21/2021 352112511, 362112512, 372112513 in use from 06/23/2021 to 07/29/2021

352112711, 362112712, 372112713 in use from 07/29/2021 to 08/25/2021 3.
Interview with the laboratory director on 02/02/2022 at approximately 4 pm confirmed the survey findings.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual, testing personnel training and competency assessment records, and interview with the laboratory director, the technical consultant failed to perform competency assessments for testing personnel in 2019, 2020, 2021 and 2022 for six of six testing personnel. The findings include: 1. Review of the laboratory procedure manual revealed that all personnel will have training for tests they perform, semiannually competency assessment the first year, and then annually thereafter. 2. Review of testing personnel training and competency assessment records revealed the following: Initial training and competency for testing personnel numbers two and three performed by the lab director who does not meet the regulatory experience requirement. No interim competency assessments for testing personnel numbers two and three. No annual competency assessments for testing personnel numbers one, four, five and six for 2019, 2020 (for the previous CBC instrument) and 2021. No annual competency assessment for testing personnel numbers two and three for 2020 and 2021. No annual competency assessments had been performed in 2022. 3. Interview with the lab director on 02/02/2022 at approximately 4 pm confirmed the survey findings. There was no performance of competency assessment as indicated in the laboratory policy in 2019, 2020, 2021, and 2022.