

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1060433	(X3) Date Survey Completed 04/14/2023
Name of Provider or Supplier Brentwood Pediatrics Pllc	Street Address, City, State 5111 Maryland Way Suite 301, Brentwood, 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 Brentwood Pediatrics, PLLC laboratory was found not to be in compliance with the following CLIA conditions: D5024: 493.1250 Condition: Hematology D6000: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director D6033 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (Form CMS-209), proficiency testing records, and staff interview, the laboratory failed to ensure the proficiency testing samples were tested by personnel who routinely performed the complete blood count (CBC) patient testing in 2021 and 2022 for six of six events reviewed. The findings include: 1. Review of the Form CMS-209 survey revealed four testing personnel who routinely performed CBC patient testing. 2. Review of the American Proficiency Institute (API) proficiency testing (PT) attestation statements and instrument printouts for 2021 and 2022 revealed the following: 2021 events one, two and three were performed by a single testing person (no longer employed or listed on CMS-209) 2022 events one, two, and three were performed by testing person one listed on CMS-209 3. Interview with testing person one confirmed the laboratory failed to ensure all testing persons were included in the testing of proficiency testing samples for the events in 2021 and 2022.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

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 laboratory's quality controls (QC) records and staff interview, the laboratory failed to maintain manufacturer's QC package inserts for a period of two years for the Beckman Coulter AcT Diff and the Sysmex XP 300 instruments used to perform patient testing of complete blood counts (CBC) from April 2021 until January 23, 2023 for an approximate number of 18 lots used. This standard was previously cited from the survey on 10/04/2018 and determined that compliance was not maintained at the recertification survey on 04/14/2023. The findings include: 1. Review of the laboratory's QC records from April 2021 until the date of the survey on 04/14/2023 revealed the following: The Beckman Coulter AcT Diff was in use from April 2021 until December 3, 2021. The Sysmex XP 300 (serial C2411) was in use from December 6, 2021 until the date of survey 04/14/2023. 2. No package inserts were retained from April 2021 until January 23, 2023. 3. Review of the laboratory's QC correction log revealed the following Beckman Coulter AcT Diff lots used: 069800, 079800, 089800 03/11/20- 06/14/2021 067900, 077900, 087900 06/15/20- 09/10/2021 068600, 078600, 088600 09/13/2021-12/03/2021 Review of the laboratory's QC instrument printouts from 12/06/2021 following calibration for Sysmex XP 300 (serial C2411) revealed lot numbers 13030710, 13060710, and 13060712 with expiration date of 02/09/2022 were used. 3. Interview with testing person one on 04/14/2023 at 2:30 p.m. confirmed the laboratory failed to maintain manufacturer's QC package inserts for CBC quality controls for a period of two years in 2021, 2022, and 2023.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing records and staff interview, the laboratory failed to retain all proficiency testing records for a period of two years in 2022. This standard was previously cited from survey on 10/04/2018 and determined that compliance was not maintained at the recertification survey on 04/14/2023. The findings include: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records for Hematology/Coagulation revealed the attestation statement for 2022 event 2 was not included in the records for that event (one of six events reviewed for 2021, 2022, and 2023). 2. Interview on 04/14/2023 at 2:30 p.m. with testing person one confirmed the laboratory failed to maintain the attestation statement for 2022 event 2 for two years.

D5024

HEMATOLOGY

CFR(s): 493.1215

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
 Based on record review and interview it was determined that the laboratory failed to ensure procedures for use for the Sysmex XP 300 (serial C2411) used for complete blood count (CBC) patient testing were approved (See D5407), failed to monitor room temperature and humidity where the Sysmex XP 300 was in use (See D5413), failed to perform a normal range study for the Sysmex XP 300 that was used on 12/05/2021 (See D5421), failed to have a quality control procedure in place to monitor precision and accuracy over a period of time (See D5441), failed to have an effective quality assessment process in place (See 5793), and failed to follow corrective action policies and procedures and did not have a current corrective action policy and procedure in place (See D5779). This condition was cited as a result of the laboratory survey on 10/04/2018 and it was determined that compliance was not maintained during the onsite recertification survey performed on 04/14/2023.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
 CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
 Based on review of laboratory personnel records, laboratory procedure manual, and staff interview the laboratory failed to establish and follow policies and procedures to assess employee competency as defined in Subpart M that included the six required elements for four of four testing personnel (TP) that performed complete blood count (CBC) patient testing in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory personnel records revealed training documents including a section titled "Phase 2 LABORATORY TESTING" for four of four testing personnel that stated "Signature below acknowledges completion of the listed competencies". 2. Review of the laboratory policy titled "LABORATORY QUALITY ASSURANCE POLICY" in the "Personnel Assessment" section revealed revealed that semi-annual competency during the first year of testing and methods for assessing competency that included all six required elements were not included in the policy. The six required elements are: direct observation of patient testing, monitoring the recording and reporting of test results, review of intermediate results or worksheets, observation of performance of maintenance and function checks, assessment of test performance, and assessment of problem solving skills. 3. Interview with testing person one on 04/14/2023 at 2:30 p. m. confirmed the laboratory did not have a policy or procedure in place to assess TP competency that included the six required elements.

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 observation of the laboratory, review of the procedure manuals, laboratory

records, annual test volumes, and interview with the laboratory testing person one, the laboratory failed to ensure procedures for use for complete blood count (CBC) patient testing were approved and signed by the laboratory director prior to patient testing in 2021. The findings include: 1. Observation of the laboratory on 04/14/2023 at 8:30 a. m. revealed the Sysmex XP 300 CBC instrument (serial C2411) in use for patient testing. 2. Review of the procedure manuals in use for the Sysmex XP 300 revealed no approval of the procedures by the laboratory director. 3. Review of laboratory records revealed the Sysmex XP 300 hematology instrument first patient reported was on 12/06/2021. 4. Review of and annual test volumes reported on the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) annual test volumes revealed an approximate annual test volume of approximately 780 patients for CBC testing. 5. Interview with the testing person one on 04/14/2023 at 2:30 p.m. confirmed the laboratory used the manufacturer instructions for use manual and Quick Guide as part of their procedures and the laboratory director had not approved them prior to use.

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 the laboratory, review of the Sysmex XP 300 operator's manual, and interview with the laboratory testing person one, the laboratory failed to monitor room temperature and humidity where the Sysmex XP 300 instrument was being used for complete blood count (CBC) patient testing from 12/06/2021 until the date of survey (04/14/2023). This standard was previously cited from survey on 10/04/2018 and determined that compliance was not maintained at the recertification survey on 04/14/2023. The findings include: 1. Observation of the laboratory on 04/14/2023 at 8:30 a.m. revealed a Sysmex XP 300 instrument (serial C2411) in use for CBC patient testing. 2. Review of the Sysmex XP 300 instructions for use manual revealed the Sysmex XP 300 instrument operational environmental conditions of temperature 15-30C and humidity 30-85%. 3. Interview with the laboratory testing person one on 04/14/2023 at 2:30 p.m. confirmed the laboratory did not monitor the room temperature and humidity in the laboratory where the Sysmex XP 300 CBC instrument was used from 12/06/2021 until 04/14/2023.

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 observation of the laboratory, review of the Sysmex XP 300 complete blood count (CBC) instrument validation records, annual test volumes, and interview with testing person one, the laboratory failed to perform normal range studies to verify the ranges in use by the laboratory with the first patient tested on 12/06/2021. This standard was previously cited from survey on 10/04/2018 and determined that compliance was not maintained at the recertification survey on 04/14/2023. The findings include: 1. Observation of the laboratory on 04/14/2023 at 8:30 a.m. revealed the Sysmex XP 300 hematology instrument (serial C2411) in use for patient CBC testing. 2. Review of the Sysmex XP 300 CBC instrument validation records revealed no normal range study was performed. 3. Review of the annual test volumes as indicated on the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) annual test volumes revealed approximately 780 patient CBC results reported annually. 3. Interview with testing person one on 04/14/2023 at 2:30 p.m. confirmed the laboratory failed to perform normal range studies on the Sysmex XP 300 hematology instrument. Interview also confirmed that the Sysmex XP 300 first patient reported was on 12/06/2021.

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 observation of the laboratory, review of quality control documents, and staff interview, the laboratory failed to have a control procedure in place to monitor the accuracy and precision of the Beckman Coulter AcT Diff or the Sysmex XP 300 hematology instruments used for complete blood count (CBC) patient testing in 2021, 2022, and 2023. This standard was previously cited from survey on 10/04/2018 and determined that compliance was not maintained at the recertification survey on 04/14/2023. The findings include: 1. Observation of the laboratory 04/14/2023 at 8:30 a.m. revealed the Sysmex XP 300 instrument (serial C2411) in use for CBC patient testing. 2. Review of the quality control documents for 2021, 2022, and 2023 revealed the laboratory does not print cumulative data or Levy Jennings (LJ) charts to monitor accuracy and precision over time. Records indicate the Beckman Coulter AcT Diff in use April 2021 through December 3, 2021 and the Sysmex XP 300 in use December 6, 2021 through date of survey (04/14/2023) for patient CBC testing. 3. Interview with

laboratory testing person one on 04/14/2023 at 2:30 p.m. confirmed the laboratory did not have a procedure in place for evaluation of quality control data for CBC testing that included monitoring accuracy and precision over time in 2021, 2022, and 2023.

D5779

CORRECTIVE ACTIONS

CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:

Based on review of the corrective action logs, patient test records, lab policy, and staff interview, the laboratory failed to follow corrective action policies and procedures for the Beckman Coulter AcT Diff instrument in use 04/2021-12/03/2021 and did not have a current corrective action policy and procedure available to follow 12/06/2021-04/14/2023 for performing testing on the Sysmex XP 300 instrument for complete blood count (CBC) patient testing in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory "Corrective Actions Log" revealed the following: -11/22/2021 Problem/Resolution: low level QC run X4, normal level QC run X2. Documented as "reran & wnl" with no further documentation of corrective actions taken. -07/22/2021 Problem/Resolution: low level QC run X1, normal level QC X1. Documented as "reran & wnl" with no further documentation of corrective actions taken. -07/20/2021 Problem/Resolution: low level QC run X6, normal level QC run X3, and high level QC run X3. Documented as "reran & wnl" with no further documentation of corrective actions taken. 2. Review of patient test records revealed patient number 94478 had CBC results reported on 11/22/2021, patient number 94065 had CBC results reported on 07/22/2021, and patient number 92591 had CBC results reported on 07/20/2021. 3. Review of "LABORATORY QUALITY ASSURANCE POLICY" under section labeled "POLICY" revealed the policy in place for corrective action stated that "If any controls are out of range they are to be reported to the nursing supervisor and the lab director." The policy did not define the number of times a control could be repeated before patients could be reported. No corrective action policy or procedure was available for the Sysmex XP 300 (serial C2411) CBC instrument in use. 4. Interview on 04/14/2023 at 2:30 p.m. with testing person one confirmed the laboratory did not follow the policy in place for the Beckman Coulter AcT Diff instrument in use 04/2021-12/03/2021 and did not have a corrective action policy or procedure for the Sysmex XP 300 instrument in use 12/06/2021-04/14/2023 testing for quality controls used for CBC patient testing.

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 quality assurance policy, quality control (QC)

reports, corrective action reports, quality assessment reports, and interview, the laboratory's quality assessment process did not reflect current hematology Sysmex XP 300 instrument for complete blood count (CBC) patient testing in the policy and was ineffective in preventing recurrence of problems with quality control results outside of acceptable range requiring multiple runs, and using incorrect file lot and expiration dates in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory policy titled "LABORATORY QUALITY ASSURANCE POLICY" revealed the following: Policy: "The Coulter AcT Diff (CBC machine) requires a daily quality control.", "In addition to the above, effective 06/15/2012, we will also monitor this quality assurance by filling out and filing monthly assessments, including patient test management. The form following this policy will be filled out, reviewed and signed by the Laboratory Director on a monthly basis." Quality Control and Instrumentation: Evaluation for " ..If calibrators and controls are ran according to written policy and procedures as mandated by CLIA", "If personnel have taken appropriate corrective action when calibration or control values are out of the acceptable range". 2. Review of the laboratory quality control records for the Beckman Coulter AcT Diff CBC instrument revealed the following quality control lot numbers 69100,79100, 89100 with expiration 03/15/2021 on daily quality control reports from 03/16/2021 through 12/05/2021. 3. Review of the laboratory's Corrective Action Log revealed lot numbers used did not match the daily quality control print outs from 03/16/2021-12/03/2021 as follows: 069800, 079800, 089800 03/11/20- 06/14/2021 067900, 077900, 087900 06 /15/20- 09/10/2021 068600, 078600, 088600 09/13/2021-12/03/2021 4. Review of the laboratory "MONTHLY QUALITY ASSESSMENT" records from March-December 2021 signed by the laboratory director revealed "Yes" circled for "Controls of all tests WNL?" and "Problems assessed:" response documented "na". 5. Interview with testing person one on 04/14/2023 at 2:30 p.m. confirmed the laboratory Quality Assurance process was ineffective in preventing errors with the management of QC lot numbers from 03/16/2021 through 12/05/2021 and dates with multiple control runs with patient CBC results reported.

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 record review and interview it was determined the the laboratory director failed to review and identify results that required corrective action on proficiency testing samples (See 6018), failed to ensure testing personnel that performed complete blood count (CBC) patient testing had proof of highest degree of education, received appropriate training (See 6029), and failed to ensure testing personnel competency assessment policies and procedures were followed (See 6030). This condition was cited as a result of the onsite laboratory survey performed on 10/04/2018 and it was determined that compliance was not maintained on 04/14/2023 onsite laboratory recertification survey.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing (PT) records, laboratory quality assurance (QA) plan, and staff interview, the laboratory director failed to review the performance evaluations (four of six events) and failed to identify any problems that required corrective action (two of six events) for the proficiency testing events in 2021 and 2022. The findings include: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records revealed the following: 2021 Event One and Event Two PT Performance Evaluations were not signed by the Laboratory Director 2022 Event One and 2022 Event Three PT Performance Evaluations were not signed by the Laboratory Director 2021 Event two sample Hem-06 Red Cell Count had an "Unacceptable" result. 2021 Event three sample Hem-11 Red Cell Count had an "Unacceptable" result. 2. Review of the laboratory's QA plan in the section for Proficiency Testing revealed the lab director will evaluate results within one week of receiving them including any unsuccessful, unacceptable, or unsatisfactory results. 3. Interview on 04/14/2023 at 2:30 p.m. with laboratory testing person one confirmed the laboratory director did not sign or document review of the PT performance evaluation documents for 2021 and 2022 and did not perform corrective action for unacceptable results for 2021 events two and three according to the QA plan.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory personnel records (including education, competency, and training), new hematology instrument Sysmex XP-300 Training Checklists, and staff interview, the laboratory director failed to ensure four of four testing personnel (TP) had documentation of the highest level of education and failed to participate in the training and competency of TP for the use of the Sysmex XP 300 complete blood count (CBC) instrument that was put into use on 12/06/2021. This standard was previously cited from survey on 10/04/2018 and determined that compliance was not maintained at the recertification survey on 04/14/2023. The findings include: 1. Review of personnel records revealed no evidence that the laboratory director participated in the training or competency assessments for three of four TP on the initial Laboratory Testing training records. TP one initial training

documents dated 08/13/2021 TP three initial training documents dated 08/25/2021 TP four initial training documents dated 09/01/2022 2. Further review of personnel records revealed that proof of highest degree of education for four of four testing personnel was not available. 3. Review of the Sysmex XP-300 Training Checklists for four of four TP revealed the laboratory director did not participate in the initial training documents prior to the use of the new XP 300 hematology instrument for CBC patient testing that began in December 2021. TP one Sysmex XP-300 training checklist dated 12/07/2021-12/28/2021 TP two Sysmex XP-300 training checklist dated 12/07/2021-12/30/2021 TP three Sysmex XP-300 training checklist dated 12/08/2021-12/29/2021 TP four Sysmex XP300 training checklist dated 08/31/2022 4. Interview on 04/14/2023 at 2:30 p.m. with testing person one confirmed the laboratory director failed to ensure four of four TP had documentation of highest degree of education and confirmed the lab director did not participate in the initial training and competency, or the Sysmex XP 300 CBC instrument training and competency in 2021 and 2022.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
 Based on review of the laboratory policy, personnel records, and staff interview, the laboratory director failed to follow competency assessment procedures for three of four testing personnel (TP) who performed complete blood count (CBC) patient testing in 2021 or 2022. The findings include: 1. Review of the laboratory policy titled "LABORATORY QUALITY ASSURANCE POLICY" in the "Personnel Assessment" section revealed the following: "All testing employees (i.e., anyone running lab test), will have an initial Training Check List...", "Areas that have not been deemed "competent" will not be performed by the employee.." "At least annually, the laboratory director and/or the technical consultant will review the performance of each employee working in the lab to assure employee competency." "The written result of that review will be placed in the individuals file with the annual performance review and a copy maintain in the Quality Assurance Records" 2. Review of the laboratory personnel records revealed the following: Testing persons one (initial 08/13/2021), and three (initial 08/25/21) did not have annual competency assessment results for 2022 Testing person two (initial 11/02/2020) did not have annual competency assessment results for 2021 or 2022 . 3. Interview on 04/14/2023 at 2:30 p.m. with testing person one confirmed the laboratory director failed to follow the competency assessment procedures when annual reviews for TP were not completed in 2021 and 2022.

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 record review and interview it was determined that the laboratory personnel performing technical consultant duties were not qualified (See 6035).

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records, personnel records, training documents, instrument verification documents, job descriptions, and staff interview, the laboratory failed to ensure that qualified personnel performed technical consultant (TC) duties in 2021, 2022, and 2023. The findings include: 1. Review of PT records revealed a TP (not current employee on 04/14/2023 survey) had signed the

performance evaluation form for Event 2 in 2021. 2. Review of personnel records and training documents revealed the following: TP one initial training (Phase 2 Laboratory Testing) documents signed by TP two on 08/13/2021 and Sysmex XP 300 Training Checklist signed by TP (not current employee on 04/14/2023 survey) TP two Sysmex XP 300 Training Checklist signed 12/07/2021-12/30/2021 by TP (not current employee on 04/14/2023 survey) TP three initial training (Phase 2 Laboratory Testing) documents signed by TP one on 10/04/2021 and Sysmex XP Training Checklist signed 12/29/2021 by TP (not current employee on 04/14/2023 survey) and 01/30/2023 by TP one. TP four initial training (Phase 2 Laboratory Testing) documents signed 09/06/22 by TP one and Sysmex XP 300 Training Checklist signed 8/31/2022 and 01/30/2023 by TP one. 3. Further review of the personnel records revealed the TP were not qualified to perform TC duties. 4. Review of Sysmex XP 300 (serial C2411) verification documents performed 12/06/2021 revealed a TP (not current employee on 04/14/2023 survey) signed the validation documents provided by Sysmex. 5. Review of job descriptions of file revealed the Laboratory Director served as the TC and had not delegated responsibilities to any other qualified personnel. 5. Interview with testing person one on 04/14/2023 at 2:30 p.m. confirmed that testing personnel were performing technical consultant duties and that the testing personnel did not have documentation of highest level of education or delegation of duties from the laboratory director for performing the TC duties. Duties performed included training and competency assessments, and review and approval of instrument validations..