

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0194044	(X3) Date Survey Completed 10/05/2022
Name of Provider or Supplier Alliance Cancer Specialists	Street Address, City, State 915 Lawn Avenue, Sellersville, PA	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with testing personnel #2 (TP), the laboratory failed to establish a procedure to assess the competency of 4 of 5 clinical consultants for their supervisory responsibilities in 2020 and 2021. Findings include: 1. On the day of survey, 10/05/2022 at 10:20 am, TP #2 could not provide a procedure for the competency assessment for 4 of 5 CC (CMS 209 personnel # 11,12, 13, and 14) for their supervisory responsibilities in 2020 and 2021. 2. No documentation was provided that competency assessments were performed for 4 of 5 CC for their supervisory responsibilities from 2020 to the date of survey. 3. TP #2 confirmed the findings above on 10/05/2022 around 12:00 pm.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on review of the Sysmex XN-430 analyzer validation records and interview with testing personnel # 2 (TP), the laboratory failed to establish criteria for acceptable performance specifications for 12 of 12 analytes performed on the Sysmex XN-430 analyzer from 12/14/2020 to the date of survey. Findings Include: 1. On the day of survey, 10/05/2022 around 10:14 am, review of the Sysmex XN-430 analyzer validation records revealed that the validation performed on 10/28/2020 did not include the laboratory's acceptable criteria for performance specifications for precision, accuracy, and reportable ranges for the following analytes: - White Blood Count (WBC) - Red Blood Count (RBC) - Hemoglobin (HGB) - Hematocrit (HCT) - Mean Corpuscular Volume (MCV) - Mean Corpuscular Hemoglobin (MCH) - Mean Corpuscular Hemoglobin Concentration (MCHC) - Platelet (PLT) -Mean Platelet Volume (MPV) -Red Blood Cell Distribution Weight (RDW) - Neutrophils (NEU) - Lymphocytes (LYM) 2. TP #2 confirmed the findings above on 10/05/2022 around 12:00 pm.

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 review of personnel qualification records and interview with Testing Personnel #2 (TP)., the laboratory failed to have a technical consultant who meets the qualification requirements for hematology testing (moderate complexity) from 07/09/2021 to the date of survey. Refer to D6035.

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 personnel qualification records, competency assessment (CA) records and interview with testing personnel #2 (TP), the laboratory failed to have a Technical Consultant (TC) who meets the qualification requirements for hematology testing (moderate complexity) from 07/09/2021 to the date of survey. Findings include: 1. On the date of survey, 10/05/2022 at 10:20 am, review of CA records revealed that TP#2 performed competency review and observation, and signed off on the CA records for 2 of 9 TP in 2021 (CMS 209 personnel #5,9) and 7 of 9 TP in 2022 (CMS personnel #1,3,4,5,6,8,9) for hematology examinations. 2. Review of the CMS 209 personnel form signed by the Laboratory Director (LD) on 10/05/2022 listed the LD as the only TC. No documentation was provided for delegation of duties. 3. Further review of TP #2's education credentials revealed, TP #2 is a medical assistant which does not meet the minimal educational qualifications under C.F.R. 493.1411 to perform technical consultant responsibilities for moderate complexity testing in hematology . 4. 51,576 complete blood counts (CBC) were performed in 2021. (CMS 116 annual test volume) 5. TP#2 confirmed the findings above on 10/05/2022 around 12:00 pm.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory's procedure manuals, review of competency assessment records and interview with testing personnel #2 (TP), the Technical Consultant (TC) failed to evaluate and document the performance of 1 of 9 testing personnel (TP) responsible for performing hematology examinations for their semi-annual competency from 09/28/2020 to the day of survey. Findings include: 1. On the day of survey, 10/05/2022 at 10:15 am, the laboratory was unable to produce the semi-annual competency assessment records for 1 of 9 TP (CMS 209 personnel #7) that performed hematology examinations from 09/28/2020 to 10/05/2022. 2. The laboratory performed 51,576 complete blood count (CBC) tests in 2021 (CMS-116 annual test volume). 3. TP#2 confirmed the above findings 10/05/2022 around 12:00 pm.