Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2183375	04/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Primary Care Of Elizabethton	314 Rogosin Drive, Elizabethton, 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
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 a review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory's policy, personnel records, and staff interview, it was revealed the laboratory's policy failed to include initial training and semi-annual competency evaluation as required in Subpart M of the State Operations Manual (SOM) Appendix C and failed to have documentation of initial training and/or semi-annual competency for two of four testing personnel. Findings included: 1. A review of the submitted CMS-209 form listed four testing personnel for moderate complexity testing. 2. A review of the laboratory's Quality Assurance Plan policy revealed the policy failed to include initial training and semi-annual competency assessments for testing personnel performing moderate complexity testing. 3. A review of laboratory personnel records revealed the following: -No documented initial training or semi-annual competency assessment for testing personnel three of four as listed on the CMS-209 -No documented semi-annual competency assessment for testing personnel four of four as listed on the CMS-209 4. An interview on 04.11.2024 at 11:15 a.m. with the Technical Consultant confirmed the above survey findings.
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 the manufacturer control package insert, and interview with the lab liaison, the laboratory failed to label three of three control vials used for performing quality control on the Complete Blood Count (CBC) analyzer with a corrected expiration date on the date of the survey. The findings include: 1. Observation of the laboratory on 04.11.2024, at 9:45 a.m., revealed the Sysmex XN-300 CBC analyzer (serial # 12504) in use for patient testing. Also observed were three levels (L1, L2, and L3) of Sysmex XN-L Check CBC controls (L1-Lot 40121401, L2-Lot 40121402, and L3-Lot 40121403) that were not labeled with the corrected expiration date. 2. A review of the manufacturer control package insert revealed the following: "Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 degrees C after being recapped". 3. An interview with the lab liaison on 04.11.2024, at 9:45 a.m. confirmed that the laboratory failed to label CBC controls with the corrected expiration date for three of three control vials observed on the date of the survey (04.11.2024). Word key: degrees C = degrees Celsius
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 a review of the laboratory's quality assurance plan, environmental records, monthly quality assurance records, and an interview with the Technical Consultant, the laboratory's quality assessment process was ineffective when it failed to identify and correct problems 14 out of 61 days reviewed in August and November 2022. The findings include: 1. A review of the laboratory's quality assessment plan revealed the following statement, "We intend to identify problems in our laboratory and apply corrective action." 2. A review of the laboratory's temperature daily log records revealed laboratory refrigerator and freezer temperatures recorded were outside the stated acceptable range (refrigerator 2-8 degrees C and freezer -15 - -30 degrees C) for the following days with no documented corrective action: Date Temperature -08.05.2022: -14 degrees C (freezer) -08.11.2022: 10 degrees C (refrigerator) & -8.6 degrees C (freezer) -08.13.2022: -10 degrees C (freezer) -08.15.2022: -8.7 degrees C (freezer) -08.16.2022: -3.4 degrees C (freezer) -08.17.2022: -6.8 degrees C (freezer) -08.19.2022: 10 degree C (refrigerator) & -8.1 degrees C (freezer) -08.20.2022: -11.3 degrees C (freezer) -08.22.2022: -2.0 degrees C (freezer) -08.26.2022: -9 degrees C (refrigerator) & -4.4 degrees C (freezer) -08.27.2022: -6.3 degrees C (freezer) -08.30.2022: 1 degree C (refrigerator) -08.31.2022: -12.6 degrees C (freezer) -11.05.2022: 1 degree C (refrigerator) 3. A review of August 2022 and November 2022 monthly quality assurance review records revealed temperature documentation was compliant. No out-of-range values were listed, and no corrective action was documented. 4. An interview with the technical consultant on 04.11.2024 at 1:30 p.m.

	confirmed that the laboratory's quality assessment process was ineffective when it failed to identify and correct problems when unacceptable laboratory refrigerator and freezer temperatures were recorded with no documented corrective action for 14 out of 61 days reviewed in August and November 2022. Word key: degrees C = degrees Celsius
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 form and personnel records, and interview with the technical consultant (TC), the laboratory director failed to ensure the person performing technical consultant duties ("Administrative Technical Consultant") in 2022 and 2023 had the appropriate education documentation to qualify as a technical consultant. The findings include: 1. A review of the CMS-209 revealed four personnel who perform moderately complex patient testing and included one TC. 2. A review of the personnel records revealed personnel competency assessments for testing personnel one (initial competency on 12.29.2023), two (initial competency on 04.11.2023 and semi-annual competency on 10.26.2023), and four (initial competency on 02.11.2022 and annual competency on 04.11.2023) revealed the initials of a person not listed as a TC on the CMS-209. The dates of the evaluator initial's, testing personnel and evaluator signatures on the last page of the competency were consistent with one another. The personnel competency stated, "Instructions for the evaluator: Observe each critical step for skill or competency. Each step must be observed. Record date, method used to assess competency and the competency rating for the skill. Sign your name and initials on the last page of the assessment tool." The competencies included: Chemistry and Hematology with the "Evaluator Initials" of the "Administrative Technical Consultant" and a date for each "Competency/Skill Validation Method" (total of six components). The evaluator ("Administrative Technical Consultant") who observed and initialed each skill for each component did not meet the qualifications as a TC to assess testing personnel competency. 3. Additionally, the "Administrative Technical Consultant" had a signed "Competency Check -Technical Assessment" that was completed by the TC listed on the CMS-209 on 04.10.2023. The "Administrative Technical Consultant" competency included the following duties assessed as "Satisfactory" by the TC listed on the CMS-209: "1. Responible for providing each clinic laboratory with recommendations of: a. Selection of test methodology appropriate for clinical use of the test results.; b. Verification of test procedures performed, including precision and accuracy of each test and system.; c. Enrollment procedures in HHS-approved proficiency testing programs.; d. Problem solving recommendations for staffing issues and solutions for instrument malfunctions." These duties are consistent with technical consultant CLIA responsibilities at CFR 493.1413(b)(1) through (b)(3), and (b)(5). "2. Responsible for the establishment and

	education of the following programs that are unique to each clinic laboratory: a. Procedure manuals to include each test being performed.; b. Quality Control Program to include an Instrument Maintenance Program.; c. Quality Assurance Program to include development of studies and reports of findings to the appropriate Laboratory Medical Director ..." These duties are consistent with technical consultant CLIA responsibilities at CFR 493.1413(b)(4) and laboratory director CLIA responsibilities at CFR 493.1407(e)(5) and (e)(13). "3. Responsible for ongoing review and monitoring of QC/QA activities in each clinic laboratory, assuring that corrective actions are documented and appropriate before patient testing is reported." These duties are consistent with technical consultant CLIA responsibilities at CFR 493.1413 (b)(4) and (b)(5). 4. During an interview on 04.11.2024 at 11:15 a.m., the surveyor asked the TC to list the "Administrative Technical Consultant" on the CMS-209 form; the TC responded with, "She doesn't perform testing." The "Administrative Technical Consultant", who was performing TC duties, was not added to the CMS-209 as requested. 5. There was no evidence in the personnel records that the "Administrative Technical Consultant" met the minimum regulatory requirements to qualify as a technical consultant at CFR 493.1411(b)(4)(ii)
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 a review of testing personnel competency assessments and personnel education verification records, the person evaluating testing personnel competency assessments was not qualified to perform the duties (Refer to D6035, D6053, and D6054).
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 a review of testing personnel competency assessments, personnel education verification, and an interview with the technical consultant (TC), the person, "Administrative Technical Consultant," performing technical consultant duties did not have the required education to perform the duties. The findings include: 1. A review of testing personnel competency assessments revealed the "Administrative Technical Consultants" initials were in the "evaluator initials" boxes on five of five personnel assessment forms for testing personnel one (initial competency on 12.29.2023), two (initial competency on 04.11.2023 and semi-annual competency on 10.26.2023), and four (initial competency on 02.11.2022 and annual competency on 04.11.2023). The dates of the evaluator initial's, testing personnel and evaluator signatures on the last page of the competency were consistent with one another. The personnel competency stated, "Instructions for the evaluator: Observe each critical step for skill or competency. Each step must be observed. Record date, method used to assess competency and the competency rating for the skill. Sign your name and initials on the last page of the assessment tool." The competencies included: Chemistry and Hematology, with the "Evaluator Initials" of the "Administrative Technical Consultant" and a date for each "Competency/Skill Validation Method" (total of six components). The evaluator (Administrative Technical Consultant) who observed and initialed each skill for each component did not meet the qualifications as a TC to assess testing personnel competency. 2. A review of the documentation of the highest level of education revealed the "Administrative Technical Consultant" did not have the required education as defined in the regulations to perform the TC duties. 3. Additionally, the "Administrative Technical Consultant" had a signed "Competency Check -Technical Assessment" that was completed by the TC listed on the CMS-209 on 04.10.2023. The "Administrative Technical Consultant" competency included the following duties assessed as "Satisfactory" by the TC listed on the CMS-209: "1. Responible for providing each clinic laboratory with recommendations of: a. Selection of test methodology appropriate for clinical use of the test results.; b. Verification of test procedures performed, including precision and accuracy of each test and system. ; c. Enrollment procedures in HHS-approved proficiency testing programs.; d. Problem solving recommendations for staffing issues and solutions for instrument malfunctions." These duties are consistent with technical consultant CLIA responsibilities at CFR 493.1413(b)(1) through (b)(3), and (b)(5). "2. Responsible for the establishment and education of the following programs that are unique to each clinic laboratory: a. Procedure manuals to include each test being performed.; b. Quality Control Program to include an Instrument Maintenance Program.; c. Quality Assurance Program to include development of studies and reports of findings to the

	appropriate Laboratory Medical Director ..." These duties are consistent with technical consultant CLIA responsibilities at CFR 493.1413(b)(4) and laboratory director CLIA responsibilities at CFR 493.1407(e)(5) and (e)(13). "3. Responsible for ongoing review and monitoring of QC/QA activities in each clinic laboratory, assuring that corrective actions are documented and appropriate before patient testing is reported." These duties are consistent with technical consultant CLIA responsibilities at CFR 493.1413(b)(4) and (b)(5). 4. During an interview on 04.11.2024 at 11:15 a.m., the surveyor asked the TC to list the "Administrative Technical Consultant" on the CMS-209 form; the TC responded with, "She doesn't perform testing." The "Administrative Technical Consultant", who was performing TC duties, was not added to the CMS-209 as requested.
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 observation of the laboratory, review of the Centers for Medicare and Medicaid Services (CMS) 209 form, and review of personnel records, the semi-annual testing personnel competency assessment for testing person two was not performed by personnel who qualified to perform technical consultant (TC) duties. The findings include: 1. Observation of the laboratory on 04.11.2024 at 9:45 a.m. revealed the moderately complex Sysmex XN-330 hematology analyzer and EPOC chemistry analyzer on the counter in use for patient testing. 2. A review of the CMS-209 revealed four testing personnel who perform moderately complex patient testing. 3. A review of the personnel records revealed the following: - The semi-annual personnel competency assessment performed on 10.26.2023 for testing person two revealed the initials of a person not listed as a TC on the CMS-209. - The person's initials in the "evaluator initials" boxes and signature on 10.26.2023 were for the person with a job description as the "Administrative Technical Consultant." - There was no evidence in the personnel records that the "Administrative Technical Consultant" met the regulatory requirements for a TC. Refer to D6035.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Services (CMS) 209 form, and review of personnel records, the annual testing personnel competency assessment for testing person four was not performed by personnel who qualified to perform technical consultant (TC) duties. The findings include: 1. Observation of the laboratory on 04.11.2024 at 9:45 a.m. revealed the moderately complex Sysmex XN-330 hematology analyzer and EPOC chemistry analyzer on the counter in use for patient testing. 2. A review of the CMS-209

	revealed four testing personnel who perform moderately complex patient testing. 3. A review of the personnel records revealed the following: - The annual personnel competency assessment performed on 04.11.2023 for testing person four revealed the initials of a person not listed as a TC on the CMS-209. - The person's initials in the "evaluator initials" boxes and signature on 04.11.2023 were for the person with a job description as the "Administrative Technical Consultant." - There was no evidence in the personnel records that the "Administrative Technical Consultant" met the regulatory requirements for a TC. Refer to D6035.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Aspen Web 116 database specialties, the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), lack of documentation, and staff interview, the laboratory director failed to ensure compliance with 493.51(c) which requires laboratories to notify the state agency of deletions or changes in test methodologies included in a specialty or subspecialty, or both, within six months of the change, when the laboratory stopped performing testing in the sub-specialties of mycology and parasitology in December 2022 and failed to notify the state agency of the change. The findings include: 1. A review of the Aspen Web 116 database revealed the laboratory's CLIA certification included the sub-specialties of mycology and parasitology. 2. The Form CMS 116 submitted for the survey revealed mycology and parasitology were not included as specialties. 3. The laboratory failed to provide documentation of state agency notification for deletion of mycology and parasitology sub-specialies. 4. During an interview on 04.11.2024 at 10:00 a.m., the technical consultant stated the laboratory ceased testing for analytes included in the mycology and parasitology sub-specialties in December 2022. During the interview, she stated the laboratory did not notify the state agency of the change. This confirmed the survey findings.