Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2238855	06/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Central Pennsylvania Clinic	375 South Kishacoquillas Street, Belleville, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory records and interviews with Testing Personnel #1 (TP) and the Laboratory Director (LD), the laboratory failed to enroll in a HHS approved proficiency testing (PT) program for Bilirubin testing performed on 1 of 1 Reichert Unistat Bilirubinometer from 6/30/2021 to 6/18/2025. Findings include: 1. On the date of the survey, 6/18/2025 at 11:30 am, the laboratory failed to provide documentation for the enrollment in an HHS approved PT program for bilirubin testing performed on 1 of 1 Reichert Unistat Bilirubinometer from 630/2021 to 6/18 /2025. 2. Further review of the laboratory's Biliribinometer Patient/QC Log revealed the laboratory performed 15 bilirubin examinations from 6/30/2021 to 6/4/2025. 3. The LD confirmed the above findings on 6/18/2025 at 12:15 pm.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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.

	This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interviews with Testing Personnel #1 (TP) and the Laboratory Director (LD), the (LD)/designee failed to sign 1 of 1 API PT attestation statement for Amino Acid Quantitation testing performed in 2025. 1. The CAP PT instructions stated, "As stated in the February 28, 1992 Untied States Federal Register under Subpart H 493-801 (b0 (1), 'the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using routine laboratory methods'. The laboratory director or designee and the testing personnel must sign this form." 2. On the day of the survey, 6/18/2025 at 10:30 am, the laboratory failed to provide an attestation statement signed by the LD /designee for 1 of 1 CAP PT event performed in 2025 for CAP BGL2-A 2025. 3. The LD confirmed the findings above on 6/18/2025 at 11:30 am.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of the Pennsylvania (PA) clinical laboratory permit, laboratory records, and interviews with testing personnel #1 (TP) and the Laboratory Director (LD), the LD failed to ensure the laboratory was in compliance with Pennsylania (PA) Department of Health (DOH) regulatory requirements for bilirubin determinations performed on 1 of 1 Reichert Unistat Bilirubinometer from 6/30/2021 to 8/1/2024. Findings Include: 1. On the day of the survey, 6/18/2025 at 11:30 am, review of the laboratory's Bilirubinometer Patient/QC log revealed the laboratory performed 10 bilirubin examinations on 1 of 1 Reichert Unistat Bilirubinometer from 6/30/2021 to 8 /1/2024. 2. Further review of the laboratory's PA clinical laboratory permit revealed bilirubin was not listed under the authorized categories/tests. 3. The LD confirmed during interview on 6/18/2025 at 12:30 pm, the laboratory had started patient testing on 6/30/2021 and had not submitted notification to the PA DOH for authorization prior to that date.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i) (A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 record review, lack of documentation, and interviews with the Laboratory Director (LD) and Testing Personnel #1 (TP), the laboratory failed to verify the

	required performance specifications for Chemistry testing performed on 1 of 1 Reichert Unistat Bilirubinometer before reporting patient results from 6/30/2021 to the date of survey. Findings Include: 1. On the day of survey, 6/18/2025 at 11:30 am, the laboratory could not provide documentation for the verification of the following performance specifications before reporting patient test results on 1 of 1 Reichert Unistat Bilirubinometer from 06/30/2021 to 06/18/2025: - Accuracy - Precision - Reportable Range - Reference intervals/normal values 2. Further review of the laboratory's Bilirubinometer Patient/QC log revealed the laboratory performed 15 bilirubin examinations from 6/30/2021 to the date of the survey. 3. The LD confirmed the above findings on 6/18/2025 at 11:45 am.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 record review, lack of documentation, and interview with Testing Personnel #1 (TP), the laboratory failed to perform calibration verification at least once every six months for 1 of 1 Reichert Unistat Bilirubinometer used for bilirubin examinations from 6/30/2021 to 6/18/2025. Findings include: 1. On the date of survey, 6/18/2025 at 11:00 am, the laboratory failed to provide documentation of calibration verification performed atleast once every six months for 1 of 1 Reichert Unistat Bilirubinometer used for bilirubin examinations from 6/30/2021 to 6/18/2025. 2. Further review of the laboratory's Bilirubinometer Patient/QC log revealed the laboratory performed 15 bilirubin examinations from 6/30/2021 to the date of the survey. 3.TP #1 confirmed the finding above on 6/18/2025 at 12:00 pm.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Testing Personnel #1 (TP), the

	laboratory failed to include two control materials of different concentrations for Amino Acid Quantitation tests performed on 1 of 1 Agilent Technologies 1100 Series HPLC, at least once each day of patient testing from 8/1/2024 to 6/18/2025. Findings include: 1. On the day of survey, 6/18/2025 at 10:30 am, the laboratory failed to provide documentation for two control materials of different concentrations for Amino Acid Quantitation tests performed on 1 of 1 Agilent Technologies 1100 Series HPLC, at least once each day of patient testing from 8/1/2024 to 6/18/2025. 2. The laboratory performed 25 amino acid quantitations in 2024 (CMS 116 estimated annual volume). 3. TP#1 confirmed the finding above on 6/18/2025 at 12:05 pm.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) 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 lack of documentation and interviews with Testing Personnel #1 (TP) and Laboratory Director (LD), the LD failed to ensure 3 of 3 TP received the appropriate training and demonstrated they can perform all testing operations reliably prior to testing patients' specimens from 8/01/2024 to the day of the survey. 1. On the day of the survey, 6/18/2025 at 10:00 am, the laboratory failed to provide provide documetation of training records for 3 of 3 TP (CMS 209 TP # 1, #2 and #3) that performed amino acid quantitations and bilirubin testing from 8/01/2024 to 6/18/2025. 2. TP#1 confirmed the above findings on 6/18/2025 at 11:00 am.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 personnel competency assessment records and interviews with testing personnel #1 (TP) and the Laboratory Director (LD), the LD failed to ensure that procedures were established and maintained to assure 3 of 3 TP who conduct preanalytical, analytical, and postanalytical phases of testing were competent and maintained their competency from August 2024 to 6/18/2025. Findings Include: 1. On the days of the survey, 6/18/2025 at 10:30 am, review of the laboratory's personnel competency assesment records revealed the laboratory failed to assess 3 of 3 TP that performed the following testing for their minimal regulatory requirements (6 CLIA required comptency procedures): - Amino Acid Quantitation - Bilirubin 2. TP#1 confirmed the findings above on 6/18/2025 at 12:15 pm.
D6108	LABORATORY TECHNICAL SUPERVISOR

	CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interviews with Testing Personnel #1 (TP) and the Laboratory Director (LD), the laboratory failed to ensure 1 of 1 laboratory personnel (CMS 209 TP#1) that performed the duties of a Technical Supervisor (TS) met the regulatory qualification requirements (493.1449) for high complexity testing performed from 8/1/2024 to 6/18/2025. Refer to D6111.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is 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)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology. (c) Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, the individual functioning as the technical supervisor must- (c)(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 (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (c)(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 (c)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or (c)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(3)(i)(B) Meet the requirements in 493.1443(b)(3)(i)(B); and(c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or (c)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (c)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in chemical, biological, clinical or medical laboratory science, or medical technology; or (c)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (c)(4)(i)(C)(2) Have at least 16 semester hours in a

combination of graduate level coursework in biology, chemistry, medical technology, or clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or (c)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(5)(i)(B) Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (c)(5)(i)(B)(1) 48 semester hours of medical laboratory technology courses; or (c)(5)(i)(B)(2) 48 semester hours of science courses that include- (c)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; (c)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (c)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or technology in any combination; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty. (d) Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, or Immunohematology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, the individual functioning as the technical supervisor must- (d)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (d)(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 (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or (d)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(3)(i)(B) Meet the education requirement at 493.1443(b)(3)(i)(B); and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the applicable specialty; or (d)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(4)(i)(B) Meet the education requirement at paragraphs (c)(4)(i)(B) or (C) of this section; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or (d)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(5)(i)(B) Meet the education requirement at paragraph (c)(5)(i)(B) of this section; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty. (e) Cytology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must- (e)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (e)(2) An individual qualified under paragraph (b) or (e)(1) of this section may delegate

some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (e)(1)(ii) of this section provided the technical supervisor qualified under paragraph (b) or (e)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met. (f) Histopathology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must- (f)(1) Meet one of the following requirements: (f)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(1)(ii) An individual qualified under paragraph (b) or (f)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (f)(2) For tests in dermatopathology, meet one of the following requirements: (f)(2)(i)(A) 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 (f)(2)(i)(B) Meet one of the following requirements: (f)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or (f)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology; or (f)(2)(ii) An individual qualified under paragraph (b) or (f)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (f)(3) For tests in ophthalmic pathology, meet one of the following requirements: (f)(3)(i)(A) 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 (f)(3)(i)(B) Must meet one of the following requirements: (f)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (f)(3)(ii) An individual qualified under paragraph (b) or (f)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (g) Oral Pathology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (g)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (g)(2) Be certified in oral pathology by the American Board of Oral Pathology; or (g)(3) An individual qualified under paragraph (b) or (g)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (g)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (h) Histocompatibility - If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either- (h)(1)(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 (h)(1)(ii) Have training or experience that meets one of the following requirements: (h)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (h)(2)(i) Have an earned doctoral degree in a biological, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (h)(2)(ii) Have training or experience that meets one of the following requirements: (h)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (i) Clinical cytogenetics- If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must- (i)(1)(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 (i)(1)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (i)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (i)(2)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (j) Notwithstanding any other provision of this section, an individual is considered qualified as a technical supervisor under this section if they were qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on record review and interviews with Testing Personnel #1 (TP) and the Laboratory Director (LD), the laboratory failed to ensure 1 of 1 laboratory personnel (CMS 209 TP#1) that performed the duties of a Technical Supervisor (TS) met the regulatory qualification requirements (493.1449) for high complexity testing performed from 8/1/2024 to 6/18/2025. Finding include: 1. On the day of survey 6/12/2025 at 2:30 pm, review of personnel qualification records revealed TP #1 graduated with a bachelor's degree in Biochemistry in May 2023 . 2. Further review of laboratory records revealed TP #1 performed the duties of a TS from 8/01/2024 to 6/18/2025: - Proficiency testing (signed ast the designee) - Calibration records Reviewed (quarterly) - Quality Control Reviewed (monthly) 3. The LD confirmed TP #1 did not have at least 2 years of laboratory training/experience in high complexity testing during interview on 6/18/2025 at 12:30 pm.