Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0179162	03/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pma-Monroeville Central	One Monroeville Center, Monroeville, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to approve and sign 7 of 7 procedures reviewed during the inspection from 01/15/22 to the date of survey. Findings included: 1. On the day of survey 03/22/2023 at 09:05 am, review of a sampling of procedures during the inspection revealed that the following procedures were not approved and signed by the new LD prior to patient testing from 01/15/2022 to 03/22/2023: - Quality Assurance. - Competency Assessment. - Urine Microscopic. - Rheumajet Rheumatoid Factor. - Specimen collection and Handling. - Trouble shooting. - Quality Control procedure. 2. The TS confirmed the finding above on 03/22/2023 at 12:10 pm.
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 review of the Quidel Triage Brain natriuretic peptide (BNP) validation records and interview with Technical Supervisor (TS), the laboratory failed to establish criteria for acceptable performance specifications for the Quidel Triage BNP validation used for routine chemistry specimens from October 27, 2022 to March 22, 2023. Findings Include: 1. On the day of the survey, 03/22/2023 at 11:52 am, review of the Quidel Triage BNP validation records revealed that the validation performed on 10/27/2022 did not include the laboraotory's acceptable criteria for precision, accuracy and reportable range. 2. The data analysis records for accuracy states: " The reportable range will be assigned by the laboratory director (LD) based on the assay values of the high and low calibration verification controls". The laboratory did not provide the reportable range assigned by the LD. 3. The laboratory did not provide a procedure for verifying performance specifications for any new test system. 4. The TS confirmed the findings above on 03/22/2023 around 11:52 am.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to include two control materials of different concentrations for 1 of 1 Quidel Triage Brain natriuretic peptide (BNP) analyzers at least once each day of patient testing from 10/27/2022 to the date of survey. Findings include: 1. On the day of survey, 03/22/2023 at 10:00 am, review of QC records for BNP revealed, the laboratory did not perform two levels of control material each day of patient testing from 10/27/2022 to 03/22/2023. 2. The laboratory performed 218 patient tests in 2022. 3. The TS confirmed the finding above on 03/22/2023 around 12: 10 pm.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of urine microscopic examination quality control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to perform a positive QC for 1 of 5 urine analytes each day of patient testing for urine microscopic examinations from 02/24/2021 to 03/22/2023. Findings Include: 1. On the of survey 03 /22/2023 at 10:20 am, review of the abnormal urine control package insert revealed that the liquid control did not include casts. 2. Review of the QC records revealed that

	the laboratory did not have casts included in their daily QC 3. The TS confirmed the findings above on 03/22/2023 around 12:10 pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Technical Supervisor (TS), the laboratory failed to have a system to evaluate twice a year the relationship between 1 of 1 Beckman Coulter DxH600 automated White blood cell (WBC) Differential and the manual WBC Differential from 02/24/2021 to the day of the survey. Findings include: 1. On the day of the survey, 03/22/2023 at 09:40 am, the laboratory could not provide documentation of the biannual comparison of test results between Beckman Coulter DxH600 automated White blood cell (WBC) Differential and the manual WBC Differential from 02/24/2021 to the day of the survey. 2. The laboratory did not provide a procedure for comparison studies. 3. The laboratory performed 127,369 hematology tests in 2022 (annual volume listed on CMS-116). 4. The TS confirmed the findings above on 03/22/2023 around 12:10 pm.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the Quality Assurance (QA) policy, review of monthly QA records and interview with the Technical Supervisor (TS), the laboratory director (LD) failed to ensure QA programs were followed for 9 of 12 months in 2021, 7 of 12 months in 2022 and 1 of 3 months in 2023 to assure the quality of laboratory services provided. Findings Include: 1. The quality assurance procedure (page 2) under responsibilities states the following: - "Laboratory director: C. Quarterly review of the lab's QA quarterly report" - "Laboratory Supervisor: B. Monthly reviewof the QA report for quality and appropriateness of care/services. C. Monthly discussions pertaining to improvement of data collection and/ or the indicator selection process. D. Monthly meetings with staff members to discuss the QA data to improve both collection of data and the process involved." 2. On the day of survey, 03/22/2023 at 11:15 am, review of the monthly QA records revealed that the laboratory did not follow their procedure. The following monthly records were missing: - 9 of 12 months in 2021 (March, April, May, June, July, August, September, October, November, and December). - 7 of 12 months in 2022 (January, February, May, June, August, October, November) - 1 of 3 months in 2023 (February) 3. The TS confirmed the findings above on 03/22/2023 around 12:10 am.

D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory competency assessment records and interview with the Technical Supervisor (TS), the Technical Supervisor (TS) failed to evaluate the annual competency assessment for 2 of 5 Testing Personnel (TP) who performed examinations in Bacteriology, Chemistry, Hematology, Immunology, and Urinalysis in 2021 and 1 of 1 TS for their supervisory responsibilities in 2021 . Findings include: 1. On the day of survey 03/22/2023 at 08:55 am, the TS could not provide competency assessment record for 2 of 5 TP (CMS 209 personnel #4, and #5) who performed Bacteriology, Chemistry, Hematology, Immunology, and Urinalysis in 2021. 2. Review of competency assessment records revealed that the competency assesment for 1 of 1 TS (CMS 209 personnel #2) in 2021 was not performed by the Laboratory Director. 3. The laboratory's total estimated annual volume was 742,765 (CMS 116) . 4. The TS confirmed the findings above on 03/22/2023 around 12:10 pm.