Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0179913	10/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Preferred Primary Care Physicians Inc	2375 Greentree Road Suite 300, Carnegie, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 American Proficiency Institute (API) proficiency testing (PT) records and interview with technical supervisor (TS) #3, the laboratory director (LD) /designee and testing personnel (TP) failed to sign 17 of 17 API PT attestation statement documents for microbiology, hematology and chemistry testing performed in 2022 and 2023. Findings include: 1. On the day of the survey, 10/18/2023, review of API PT records revealed the following 17 of 17 API PT attestation statements were not signed by the LD/designee and TP for microbiology, hematology, and chemistry testing performed in 2022 and 2023: - 2023, Event #1 and Event #2, Chemistry Core. - 2023, Event #1, Hematology/Coagulation. - 2023, Event #1 and Event #2, Microbiology. - 2023, Event #1, Chemistry Miscellaneous. - 2022, Event #1, Event #2, and Event #3, Hematology/Coagulation. - 2022, Event #1, Event #2, and Event #3, Microbiology. - 2022, Event #1, Event #2, and Event #3, Chemistry Core. - 2022, Event #1, and Event #2, Chemistry Miscellaneous. 2. TS #3 confirmed the findings above on 10/18/23 at 9:17 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 record review and interview with Technical Supervisor (TS) #3, the laboratory failed to ensure that a qualified general supervisor was on-site during all normal scheduled working hours in which tests were performed from 08/26/2021 through the date of the survey, as required by Pennsylvania (PA) state regulations. Findings include: 1. The PA regulation (5.23(b)(1) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. On the day of the survey, 10/18/23 at 10:10 am, review of the laboratory personnel report revealed that a qualified general supervisor was not on-site during all hours of patient testing from 08/26/2021 to 10/18/2023. 3. The hours of operation for this facility are Monday to Friday, 07:00 to 21:00 (CMS 116). 4. TS #3 confirmed the above findings on 10/18/23 at 10:10 am.
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 the laboratory's competency assessment records and interview with Technical Supervisor (TS) #3, the laboratory failed to establish a competency assessment procedure to assess the competency of 2 of 2 technical consultants (TC), 3 of 4 technical supervisors (TS), and 1 of 1 general supervisor (GS) for their supervisory responsibilities in 2022. Findings include: 1. On the day of the survey, 10/18/2023, the laboratory could not provide a competency assessment procedure to assess the competency of the following personnel for their supervisory responsibilities in 2022: - 2 of 2 TC (CMS 209 personnel #4, and #6) - 3 of 4 TS (CMS 209 personnel #3, #5, and #6) - 1 of 1 GS (CMS 209 personne # 7) 2. The laboratory could not provide competency assessment documentation for 2 of 2 TC, 3 of 4 TS, and 1 of 1 GS for 2022. 3. TS #3 confirmed the findings above on 10/18/2023 at 11:06 am.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records, and interview with Technical Supervisor (TS) #3, the laboratory failed to document the evaluation and verification activities for PT testing performed in hematology and chemistry in 2022. Findings include: 1. On the date of survey, 10/18/2023, review of API PT records revealed that the laboratory did not document the review and corrective action taken for the following 2 of 2 API PT events in 2022 that received a score below 80%: - 2022 API Hematology 3rd Event, Blood Cell Identification - 2022 API Chemistry Core 3rd Event, Sodium 2. TS #3 confirmed the findings above on 10/18/2023 at 09:17 am.
D5439	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 review of the laboratory's calibration verification records and interview with technical supervisor (TS) #3, the laboratory failed to perform and document calibration verifications at least once every 6 months as required for 1 of 1 chemistry analyte performed on the Tosoh Bioscience analyzer in 2022 and 2023. Findings include: 1. On the day of survey, 10/18/2023, review of the laboratory's calibration verification records revealed the laboratory failed to perform calibration verification at least once every 6 months for 1 of 1 chemistry analyte (Hemoglobin A1c) performed on the Tosoh Bioscience analyzer in 2022 and 2023. 2. The laboratory could only provide documentation for the calibration verification procedures performed on 01/13 /2022. 3. TS # 3 confirmed the findings above on 10/18/2023 at 10:42 am.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records and interview with Technical Supervisor (TS) #3, the laboratory failed to establish and document the criteria for intended reactivity to ensure acceptable staining characteristics for manual blood cell differentials performed from 11/12/2021 to date of inspection. Findings include: 1. The laboratory's policy and procedure for Manual Diff Qualtity Control states the following: "A manual differential control slide should be run every day that patient differentials are performed. The results of the manual diff for Neutrophils and

	lymphocytes should be within +/- 5 cells. - Verify that QC on the Sysmex XT-2000 was within range. - Choose a fresh patient sample that has normal results; make and prepare a slide for a differential. - Perform a manual diff, platelet estimate and check the quality of the stain. - Record the results of the auto diff and the manual diff in the QC logbook. Confirm that results are within range." 2. On the date of the survey, 10 /18/23, review of the laboratory's QC records revealed that the laboratory did not establish or document criteria for intended reactivity for acceptable staining characteristics of manual blood cell differentials performed from 11/12/2021 to 10/18 /2023. 3. TS #3 confirmed the findings above on 10/18/23 at 10:34 am.
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) #3, the laboratory failed to have a system that twice a year evaluates the relationship between automated white blood cell (WBC) count differentials performed on the Sysmex hematology analyzer and manual microscopic WBC differentials performed in 2022 and 2023. Findings Include: 1. On the day of survey, 10/18/2023, the laboratory could not provide documentation for the biannual comparison of test results for WBC differentials performed on the Sysmex (automated) hematology analyzer and microscopic WBC differentials (manual) for 2022 and 2023. 2. The laboratory performed 475,738 hematology tests in 2022 (CMS 116 annual volume). 3. TS #3 confirmed the findings above on 10/18/2023 at 10:31 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 Technical Supervisor (TS) #3, the TS failed to evaluate the annual competency assessment for 3 of 5 Testing Personnel (TP) who performed chemistry, hematology, and microbiology testing from 8/26/21 to date of survey. Findings include: 1. On the day of survey 10/18/23 at 11:06 am, TS #3 could not provide competency assessment record for 3 of 5 TP (CMS-209 TP #2, #4, and #5) who performed chemistry, hematology, and microbiology testing from 08/26/2021 to 10/18/2023. 2. TS #3 confirmed the findings above on 10/18/23 at 11:06 am.