Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0950912	03/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Vita Medical Associates Pc	Gateway At Greenway Park, Bethlehem, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) policy, American Proficiency Institute (API) PT records, and interview with Testing Personnel (TP)#1 (CMS 209 personnel #1) the laboratory failed to verify the accuracy of the PT results obtained for 2 of 3 API PT hematology/coagulation testing events performed in 2023 and 1 of 3 API PT chemistry testing event performed in 2024. Findings Include: 1. The laboratory's Proficiency testing policy states, "We will grade any proficiency testing challenge that is not officially graded by the proficiency testing program due to a lack of participant consensus or any other reason, because we did not participate (instrumentation down, for example), or because our results were late. We will respond to this score in the same manner we respond to an official score." 2. On the day of survey, 03/25/2025 at 9:13 am., review of the laboratory's API PT records revealed that the laboratory failed to verify the accuracy for the following analytes that were not scored by the PT agency in 2023 and 2024: API 2023 Hematology /Coagulation - 1st event: Lymphocytes (%) DXH-04 - 3rd event: Lymphocytes (%) DXH-11, DXH-14 API 2024 Chemistry Core - 1st event: Bilirubin, total CH-02, CH-03, CH-05 3. TP #1 confirmed the findings above on 03/25/2025 at 1:10 pm.
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 laboratory's Quality Assessment Plan (QAP) for Proficiency Testing (PT), American Proficiency Institute (API) PT records, and interview with Testing Personnel (TP)#1 (CMS 209 personnel #1), the laboratory failed to document the evaluation and verification activities performed for 2 of 3 API PT chemistry testing events in 2023 and for 2 of 3 API PT chemistry testing events and 1 of 3 API PT hematology/coagulation testing event in 2024. Findings include: 1. The laboratory's QAP for PT states, "The director will carefully evaluate any unacceptable, unsatisfactory, or unsuccessful proficiency testing result in an effort to identify the cause of failure. If a cause is found, we will take necessary corrective action and re-evaluate the PT results after the next PT challenge. This information will be recorded and kept with our proficiency testing records." 2. On the day of the survey, 03/25 /2025 at 9:13 am, review of the laboratory's API PT records revealed the laboratory failed to document the corrective action taken when the laboratory received a score of less than 100% for the following 2 of 3 API PT chemistry testing events performed in 2023 and 2 of 3 API PT chemistry testing events and 1 of 3 API PT hematology /coagulation testing event performed in 2024: API 2023 Chemistry Core - 1st event: (CA 27.29) (unregulated) 50% - 3rd event: Thyroid Stimulating Hormone (TSH) 40% API 2024 Chemistry Core - 1st event: (CA19-9) (unregulated) 50% - 2nd event: (CA125) 50%, (CA19-9) (unregulated) 50% API 2024 Hematology/Coagulation - 1st event: (White blood cell differential), Eosinophils 40% 3. TP #1 confirmed the findings above on 03/25/2025 at 1:10 pm.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) Proficiency Testing (PT) records, lack of documentation and interview with Testing Personnel (TP)#1 (CMS 209 personnel #1), the laboratory failed to review the effectiveness of corrective actions taken to prevent recurrence of problems for 2 of 3 API PT chemistry testing events performed in 2024. Findings include: 1. On the day of survey, 03/25/2025 review of the laboratory's API PT records revealed the laboratory received a score of less than 100% for Cancer Antigen (CA 19-9) (unregulated) in the following 2 of 3 API PT chemistry testing events performed in 2024: - API 2024 Chemistry Core 1st event: (CA19-9) 50% - API 2024 Chemistry Core 2nd event: (CA19-9) 50% 2. The laboratory failed to provide documentation of the corrective actions taken to resolve and prevent recurrence of problems when failures occurred in proficiency testing performance in 2024. 3. The laboratory tested 39 patient specimens for CA 19-9 in 2024. 4. TP #1 confirmed the findings above on 03/25/2025 at 1:10 pm.
D5429	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's Analytic Systems policy for Maintenance and Function checks, lack of documentation, and interview with Testing Personnel (TP)#1 (CMS 209 personnel #1), the laboratory failed to assess the maintenance/ function checks for 3 of 3 pipettes used for chemistry and hematology testing in the laboratory from 3/23/2023 to the day of survey. Findings Include: 1. The laboratory's Analytic Systems policy for Maintenance and Function checks states, "The laboratory follows the manufacturer's guidelines for routine and periodic maintenance and function checks. Pipette calibration is performed annually." 2. On the day of survey, 03/25 /2025 at 11:30 am, the laboratory failed to provide maintenance/function check records of the annual calibration performed for the following 3 of 3 pipettes used from 03/23/2023 to 03/25/2025: - Diamond Pro 100 microliter pipette S/N: OC1120673. - Diamond Pro 1000 microliter pipette S/N: OH54543. - Diamond Pro 1000 microliter pipette S/N: OH54474. 3. The laboratory performed 37,155 tests in 2024 (CMS 116 annual volume). 4. TP #1 confirmed the findings above on 03/25/2025 at 1:10 pm. *REPEAT DEFICIENCY
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and 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 a review of the laboratory's quality assessment (QA) policy, lack of documentation and interview with Testing Personnel (TP)#1 (CMS 209 personnel #1), the laboratory director (LD) failed to ensure QA programs were maintained and documented to assure the quality of laboratory services provided for 2 of 2 years from 03/23/2023 to the date of the survey. Findings Include: 1. The laboratory's Quality Assessment Plan states, "We will perform periodic quality assessment monitoring and review the results with the laboratory director or technical consultant for their approval. The records of our quality assessment monitoring are filed in the QA Monitoring section of this manual and are available for review by the director, consultant, staff and laboratory surveyors. All records are dated and initialed by the staff performing the review, and by the laboratory director." 2. On the day of survey, 03/25/2025 at 12:00 pm, the laboratory failed to provide QA documentation of the periodic evaluation used by the laboratory to assess its pre-analytical, analytical, and post-analytical processes for 2 of 2 years from 03/23/2023 to 03/25/2025. 3. TP #1 confirmed the findings above on 03/25/2025 at 1:10 pm. *REPEAT DEFICIENCY