Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1002957	06/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mitchell Becker, Md Physician's Office Lab	2336 Santa Monica Blvd Ste 201, Santa Monica, CA	

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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with the laboratory Technical Consultant (TC) on 6/9/2021 between 10:00 a.m. and 12:00 p.m., it was determined that there were two unacceptable (below 80 %) proficiency testing (PT) results for Cholesterol for Cycle 2 in 2020. Findings include: 1. On 6/9/2021, an inspection was conducted between 10: 00 a.m. and 12:00 p.m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 11 a.m. that there were two unacceptable PT results for cycle 2 Cholesterol on the 2020 report. The laboratory utilizes the Envoy 500 instrument for general chemistry testing. The TC recognized these atypical results. 3. The findings and acceptable ranges were as follows: Analyte: Cholesterol (2/5 unacceptable) Sample Actual Result Expected Result (range) CH-07 158 124-152 CH-08 232 189-231 4. The TC affirmed the unacceptable results listed above. Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with the laboratory Technical Consultant (TC) on 6/9/2021 between 10:00 a.m. and 12:00 p.m., it was determined that there were two unacceptable (below 60 %) proficiency testing (PT) results for Calcium for Cycle 3 in 2020. Findings include: 1. On 6/9/2021, an inspection was conducted between 10:00 a.m. and 12:00 p.m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 11:15 a.m. that there were three unacceptable PT results for cycle 3 Calcium on the 2020 report. The laboratory utilizes the Envoy 500 instrument for

	general chemistry testing. The TC recognized these atypical results. 3. The findings and acceptable ranges were as follows: Analyte: Calcium (3/5 unacceptable) Sample Actual Result Expected Result (range) CH-11 10.3 10.7-12.8 CH-13 10.6 11.0-13.1 CH-14 9.2 9.4-11.5 The TC affirmed the unacceptable results listed above Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with the laboratory Technical Consultant (TC) on 6/9/2021 between 10:00 a.m. and 12:00 p.m., it was determined that there were two unacceptable (below 80 %) proficiency testing (PT) results for Sodium for Cycle 3 in 2019. Findings include: 1. On 6/9/2021, an inspection was conducted between 10:00 a.m. and 12:00 p.m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 11:30 a.m. that there were two unacceptable PT results for cycle 3 Sodium on the 2019 report. The laboratory utilizes the Envoy 500 instrument for general chemistry testing. The TC recognized these atypical results. 3. The findings and acceptable ranges were as follows: Analyte: Sodium (2/5 unacceptable) Sample Actual Result Expected Result (range) CH-12 125 126-135 CH-14 155 143-152 The TC affirmed the unacceptable results listed above
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with the laboratory Technical Consultant (TC) on 6/9/2021 between 10:00 a.m. and 12:00 p.m., it was determined that there were three unacceptable proficiency testing (PT) results for Monocytes for 3 cycles: Cycle 1 for 2019, Cycle 3 2019 and Cycle 1 2021. Findings include: 1. On 6/9/2021, an inspection was conducted between 10:00 a.m. and 12:00 p.m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 11:45 a.m. that there were three unacceptable result sets for Monocytes. The laboratory utilizes the Coulter AC-TDiff II instrument for general chemistry testing. The TC recognized these atypical results. 3. The findings and acceptable ranges were as follows: Analyte: Monocyte Cycle I 2019 (4/5 unacceptable) Sample Actual Result Expected Result (range) HEM-01 9.0 9.9-13.9 HEM-03 9.2 9.3-13.2 HEM-04 7.6 8.5-12.3 HEM-05 18.9 20.0-26.5 Analyte: Monocyte Cycle 3 2019 (3/5 unacceptable) Sample Actual Result Expected Result (range) HEM-11 9.0 9.1-12.1 HEM-12 8.0 8.3-11.3 HEM-14 6.0 6.2-10.7 Analyte: Monocyte Cycle 1 2021 (5/5 unacceptable) Sample Actual Result Expected Result (range) HEM-01 5.2 7.7-11.3 HEM-02 11.0 3.5-8.5 HEM-03 11.0 15.5-23.8 HEM-04 2.7 7.4-10.4 HEM-05 4.0 6.9-10.5 The TC affirmed the unacceptable results listed above and the laboratory has ceased reporting Monocytes pending instrument repair or the purchase of a new instrument (based on comments during the inspection on 6/9 /21).
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive

	events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with the laboratory Technical Consultant (TC) on 6/9/2021 between 10:00 a.m. and 12:00 p.m., it was determined that there were three unacceptable proficiency testing (PT) results for Monocytes for 3 cycles: Cycle 1 for 2019, Cycle 3 2019 and Cycle 1 2021. The 2019 results represent two out of three (Cycle 1 and Cycle 3) consecutive failures. Findings include: 1. On 6/9/2021, an inspection was conducted between 10:00 a.m. and 12:00 p.m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 11:45 a.m. that there were three unacceptable result sets for Monocytes. The laboratory utilizes the Coulter AC-TDiff II instrument for general chemistry testing. The TC recognized these atypical results. 3. The findings and acceptable ranges were as follows: Analyte: Monocyte Cycle I 2019 (4/5 unacceptable) Sample Actual Result Expected Result (range) HEM-01 9.0 9.9-13.9 HEM-03 9.2 9.3-13.2 HEM-04 7.6 8.5-12.3 HEM-05 18.9 20.0-26.5 Analyte: Monocyte Cycle 3 2019 (3/5 unacceptable) Sample Actual Result Expected Result (range) HEM-11 9.0 9.1-12.1 HEM-12 8.0 8.3-11.3 HEM-14 6.0 6.2-10.7 The TC affirmed the unacceptable results listed above and the laboratory has ceased reporting Monocytes pending instrument repair or the purchase of a new instrument (based on comments during the inspection on 6/9/21).
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the proficiency laboratory documentation records and interviews with the TC, it was determined that the laboratory director failed to ensure the verification and accuracy of test results of regulated analytes and to identify failures as they occurred for the previously mentioned Cycles for 2019 and 2021 proficiency testing. The findings include: See D-2087 (3 deficiencies) and D-2021(3 deficiencies) and D-2030. .