Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1002957	08/24/2018
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on desk review of CMS proficiency testing (PT) records (i.e. CMS CASPER Reports 0155D entitled, "Individual Laboratory Profile" and CMS CASPER Report 0153D entitled, "Unsuccessful (2 of 3) Report"), it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events in the subspecialty of Routine Chemistry constituting unsuccessful PT performances. (See D2096)

D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of CMS PT records (CMS CASPER Report 0155D and 0153D, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for the analyte, Aspartate Aminotransferase (AST, also known as SGOT), resulting in an non-initial (subsequent) unsuccessful performance. The findings include: a. The laboratory failed to maintain successful performance with the PT program by failing to obtain a score of 80% of acceptable responses in two out of three consecutive PT events for the analyte, AST, as follows: 2016 Q3 (60%) 2017 Q1 (60%) 2018 Q2 (60%) 2018 Q1 (60%) Q1 = First Testing Event Q2 = Second Testing Event Q3 = Third Testing Event b. Failure to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT resulted in an subsequent unsuccessful performance for the analyte, AST.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of patient reports, laboratory procedure manual, and interview with the technical consultant, the laboratory failed to have written instructions on how to enter tests results into the patient file/medical record. Findings included: a. The laboratory was unable to produce written instuctions on how to report out patient test results. b. During the survey process, three patients (MR#009494, 8/21/2018; MR#009177, 2/20/2018; and MR009001, 11/17/2017) records were produced for review, even though the laboratory procedure manual did not have a written process for producing patient reports. c. The technical consultant affirmed (8/24/2018, 11:15

	A.M.) that the laboratory does not have a written procedure for test results from testing instrument to patient file.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on the review of patient report, laboratory procedure manual, and interview with the technical consultant, the laboratory failed to follow manufacturer's instructions, findings include: a. The laboratory performs the PSA test by Beckman Coulter. In the manufacturer's instructions it states: 'The concentration of PSA in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the PSA assay used. Values obtained with different assay methods cannot be used interchangeably.' b. One of three reviewed patient records reviewed had a PSA result that had a note stating 'PSA tested on Beckman Coulter Access2'. The laboratory's PSA test method is the 'Access Hybritech PSA assay'. c. The laboratory's technical consultant affirmed (8/24/2018, 11:15 A.M.) that the laboratory's patient report did not disclose the PSA method used by the laboratory.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6016)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by:

	Based on a desk review of CMS PT records, it was determined the laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under subpart HD2016 Based on desk review of CMS proficiency testing (PT) records (i.e. CMS CASPER Reports 0155D entitled, "Individual Laboratory Profile" and CMS CASPER Report 0153D entitled, "Unsuccessful (2 of 3) Report"), it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events in the specialty of Hematology constituting unsuccessful PT performance. (See D2130) _____ D2130 Based on desk review of CMS PT records (CMS CASPER Report 0155D and 0153D, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for the analyte, WBC Differential, resulting in an "initial" (first) unsuccessful performance. The findings include: a. The laboratory failed to maintain successful performance with the PT program by failing to obtain a score of 80% of acceptable responses in two out of three consecutive PT events for the analyte, WBC Differential, as follows: 2012 Q2 (0%) 2013 Q1 (0%) Q1 = First Testing Event Q2 = Second Testing Event Q3 = Third Testing Event b. Failure to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT resulted in an initial unsuccessful performance for the analyte, WBC Differential. _____ D6000 Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6016) _____ D6016 Based on a desk review of CMS PT records, it was determined the laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under subpart H of this part. The findings included: For the analyte, WBC Differential, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events, resulting in unsuccessful PT performance. (See D2016 and D2130) of this part. The findings included: For the analyte, AST, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events, resulting in unsuccessful PT performance. (See D2016 and D2096)
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of the laboratory procedure manual, Job Descriptions: Laboratory

	Assistant document, and an interview with the technical consultant, the laboratory director failed to specify all of the duties of the Laboratory Assistant. Findings include: a. The current laboratory Assistant is expected to perform all of the following duties listed on the Job Descriptions: Laboratory Assistant document: 1. Logging in of all specimens for testing into the computer. 2. Generating all work lists and distributes work list to corresponding laboratory sections. 3. Sorts out and schedules delivery of lab reports to client. 4. Process all specimens to be sent out to reference laboratories. 5. Files hard copy/duplicate reports in ascending accession number. 6. Files completed work list by day of month. 7. Answers the telephone and serves as main liaison between the laboratory and clients' office. 8. Order laboratory supplies as needed. 9. Responsible for staffing schedule of non-technical personnel. 10. may be required to surface-clean and/or disinfect clinical instruments and work surfaces and wash re-usable glassware as necessary. 11. Maintains the office records and equipment in an organized and efficient manner. The above listing does not specify the loading of samples onto analyzers and initiating the run cycle to produce test results. b. During the survey process, the laboratory assistant disclosed (8/24/2018, 10:55 A.M.) that she runs tests (Routine Chemistry, Endocrinology, and Hematology). c. The technical consultant affirmed (8/24/2018, 11:00 A.M.) that there was no documentation that laboratory assistant(s) could operate laboratory testing instrumentation.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of Personnel Training/Competency form and interview with the technical consultant, the laboratory failed to document the competency evaluation process. Findings include: a. The laboratory uses the Personnel Training/Competency form for initial and subsequent competency evaluations of testing personnel. b. Review of the competency form used for Laboratory Assistant FL revealed in the body of the worklist initials of the evaluator and the corresponding date performed. No where on the competency form was it indicated that individual task or overall performance of the evaluee was satisfactory of unsatisfactory. c. The technical consultant affirmed (8/24/2018, 10:45 A.M.) that individual duties and overall job performance grading was not stated on Personnel Training/Competency form reviewed.