

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0544401	<b>(X3) Date Survey Completed</b>  11/19/2018
<b>Name of Provider or Supplier</b>  Marshall Fichman Md	<b>Street Address, City, State</b>  50 N La Cienega Blvd Ste 204, Beverly Hills, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a tour of the laboratory, an interview with the laboratory personnel (office manager and testing person) on 11/19/2018, review of the manufacturer's instructions (package inserts) for Chemstrip reagent strips for urinalysis, quality control (QC) documentation and random patients test reports from 06/01/2018 to 11/19/2018, the laboratory failed to follow manufacturer's guidelines/operator's manual for storage and stability of reagents for urine test strips. The findings included. a. The Chemstrip reagent strips for urinalysis package insert states, under Storage and stability: "Store test strips 2-30C (36-86F). Do not freeze. Chemstrip urine test strips are stable in the original capped vial until listed expiration date." b. The laboratory personnel confirmed on 11/19/2018 14:00 (survey date) that the Chemstrip Lot 17822602 urine reagent strip expiry date on 2018-05-31 expired and that patient testing was still being performed and reported. c. The laboratory declaration estimated the volume of urinalysis tests perform was 240 annually and that the reliability and quality of the test results could not be assured.</p>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
 Based on a tour of the laboratory, an interview with the laboratory personnel (office manager and testing person) on 11/19/2018, review of the manufacturer's instructions (package inserts) for the Cell-Dyn 18 Plus controls for hematology complete blood count with differential (CBCD), quality control (QC) documentation and random patients test reports from 01/21/2018 to 11/16/2018, the laboratory failed to follow manufacturer's guidelines/operator's manual for storage and stability of reagents for CBCD controls. The findings included. a. The Cell-Dyn 18 Plus controls package insert states, under Storage and stability: "Store test strips 2-10C (36-50F). Protect containers from overheating and freezing. Unopened containers are stable until the expiration date indicated." b. The laboratory personnel confirmed on 11/19/2018 14:00 (survey date) that the expiry date on 2018-10-19 Cell-Dyn 18 Plus controls for CBCD had expired and that patient testing was still being performed and reported. c. The laboratory declaration estimated the volume of CBCD tests perform was 20 for the time period from 10/19/2018 to 11/19/2018 and that the reliability and quality of the test results could not be assured.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
 CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory policies and procedures, random review of patients test reports from 01/21/2018 to 11/16/2018, and an interview with the laboratory staff, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic quality assessment systems for 2018 to the date of the survey. The Findings include: a. The surveyor requested on 11/19/108 (survey date) documentation of ongoing quality assessment (QA) for the postanalytic system includes assessing practices/issues related to test report monitoring and evaluating the accuracy and completeness of the laboratory's test reports and the laboratory's turn-around times and procedures for notification of test results. b. The laboratory personnel confirmed 11/19/2018 14:00 (survey date) that the laboratory did not follow the written policy and procedure to assess monitor and correct problem in the postanalytical systems. c. No documentation could be retrieved at the time of the survey to indicate that the postanalytic review was be conducted by a designated person for an ongoing mechanism to monitor, assess and, when indicted, correct problems when identified. (See D1001, D5411)

**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.

	<p>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 required under Subpart H of this part. See D6007, D6014, D6032.</p>
<p><b>D6007</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1407(e)(1)</p> <p>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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p> <p>This STANDARD is not met as evidenced by:  Based on review of the laboratory records and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. The findings included: See D5891.</p>
<p><b>D6014</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1407(e)(3)(iii)</p> <p>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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by:  Based on the deficiency cited, the Laboratory Director is herein cited for failing in responsibility to ensure that testing persons perform hematology testing as required for accurate and reliable results. See D1001, D5411.</p>
<p><b>D6032</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1407(e)(14)</p> <p>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</p>

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 lack of written laboratory policies and procedures, record review and interview with the laboratory personnel on 011/19/2018 14:00 (survey date), the laboratory director of moderate complexity testing, failed to specify, in writing, the responsibilities and duties of the consultant(s) and person(s), engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. The laboratory maintained no such documentation. The Findings include: a. The lack of competency documentation for the clinical consultant and interview with the laboratory personnel on 11/19/2018 14:00 (survey date) confirmed that the laboratory did not follow a policy or procedure for evaluating annually the competencies of the technical consultant to assure that they are competent and maintain their competencies for all phases of testing.

**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 lack of documentation for competency assessments, review of quality control records, and interview with the laboratory personnel, it was determined that the technical consultant failed to perform and document the performance of all testing personnel and assuring that the staff maintained their competency to perform test procedures promptly, accurately, and proficiently. The findings included: a. There was no documentation to show that the testing personnel were evaluated. b. The procedures for evaluation of the competency of the staff must include, but are not limited to: Direct observation of the testing performed (including sample handling, processing and testing). Monitoring the recording and reporting of results. Direct observation of instrument maintenance. Review of intermediate worksheets, quality controls. Assessment of testing previously analyzed specimens (external QC and proficiency testing). Assessment of problem solving skills. c. On 11/19/2018 (Survey date) at 14:00 the laboratory personnel confirmed that no competency assessments were performed and documented and the laboratory's policies and procedure manual under "Personnel Performance Appraisal" were not being followed.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on lack of documentation for competency assessments, and interview with

laboratory personnel, ten (10) random patient testing records from 06/14/2016 to 07/26/2018, it was determined that the technical consultant failed to perform and document the performance of individual(s) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. The findings included: a. There was no documentation to show that the testing personnel were evaluated during the first six months (and annually thereafter) for the moderate complexity patient testing performed on the Hematology complete blood cell count with differential (CBCD) tests performed on the Cell-Dyn hematology analyzer b. The laboratory personnel confirmed on 11/19/2018, 14:00 (survey date) that no annual competency assessments evaluations were performed and documented by the technical consultant/designated person. c. The laboratory's testing declaration form, signed by the laboratory Director on November 19, 2018, stated that the laboratory performs approximately 1,200 CBCD tests annually.

**D6070**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:  
Based on review of random patient test results, laboratory's policy and procedure, and interview with the laboratory personnel, it was determined that the individual(s) performing moderate complexity testing did not follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. The findings included: See D5411.