

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0124236	<b>(X3) Date Survey Completed</b>  01/03/2018
<b>Name of Provider or Supplier</b>  M M Nisar Md Pa	<b>Street Address, City, State</b>  1895 Oak Tree Rd, Edison, NJ	
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>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain a copy of all records for Hematology tests performed with the American Association of Bioanalyst in 3-2017. The finding includes: 1. The attestation statements was not signed by the TP and Laboratory Director in 3-2017. 2. The TP confirmed on 1/3/18 at 10:15 am that all PT records were not maintained.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:

a. Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow the procedure for new Quality Control (QC) verification for tests performed on the Cell Dyn 1800 analyzer from August 2017 to the date of survey. The findings include: 1. The PM stated new QC material is to run before running patients' but there was no documented evidence of QC being run before running patients in 2017. 2. QC was not verified for two lots received in 2017. 3. The TP confirmed on 1/3/18 at 10:10 am that the PM was not followed. b. Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow its calibration procedure for the Cell Dyn 1800 from May 24, 2017 to the date of the survey. The finding includes: 1. The PM states calibration is to be done every six months but the laboratory had no documentation of calibration after May 24, 2017. 2. The TP confirmed on 1/3/18 at 10:20 am that the PM was not followed. c. Based on surveyor review of the PM and interview with the TP, the laboratory failed to have a procedure for instrument flags found on the Cell Dyn 1800 from August, 2017 to the date of the survey. The TP confirmed on 1/3/18 at 10:20 am that the laboratory did not have a flag procedure.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 surveyor review of the Operations Manual, Maintenance Records (MR) and interview with the Testing Personnel (TP), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Cell Dyn 1800 analyzer used in Hematology Testing from August 2017 to the date of the survey. The finding includes: 1. A review of the MR revealed daily, weekly and monthly maintenance was not performed. 2. The TP confirmed on 1/3/18 at 10:05 am that maintenance as specified by the manufacturer was not performed.

**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 surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have a procedure to verify manually entered results for accuracy from August 2017 to the date of survey. The TP confirmed on 1/3/18 at 10:50 am that the laboratory did not have the procedure mentioned above.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on lack of Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director failed to have education records for one out of one TP from August 2017 to the date of the survey. The TP confirmed on 1/3/18 at 9:40 am that there were no education records.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements for TP from August 2017 to the date of the survey. The TP confirmed on 1/3/18 at 10:00 am that a CA procedure was not established for TP.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the laboratory maintained a QC program from August 2017 to the date of the survey. The findings include; 1. There was no documented evidence of QC review for shifts and/or trends on the monthly Levy Jennings charts printed for the Cell Dyn 1800 analyzer. 2. The TP

confirmed on 1/3/18 at 10:30 am the laboratory did not review monthly quality control records.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the 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 surveyor review of the laboratory procedures and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was established to assure quality of laboratory services provided from August 2017 to the date of the survey. The TP confirmed on 1/3/18 at 10:45 am the LD did not establish a QA program.