

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D2025887	<b>(X3) Date Survey Completed</b> 08/13/2019
<b>Name of Provider or Supplier</b> Jackson Clinic, Pa - Innovation Park, The	<b>Street Address, City, State</b> 145 Innovation Drive, Jackson, TN	
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>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> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the validation studies performed for the Polymedco Pathfast instrument, the laboratory procedure manual, and interview with the laboratory director, the laboratory failed to follow the procedure for validation of instrument/methods in 2018. The findings include: 1) Observation of the laboratory on August 12, 2019 at 9:00 am revealed the Polymedco Pathfast instrument in use for patient testing for N-terminal-pro B-type Natriuretic Peptide (NT-proBNP). 2) Review of the validation studies performed in April 2018 for the Polymedco Pathfast NT-proBNP revealed no normal range study was performed. 3) Review of the laboratory procedure titled "INSTRUMENT/METHOD VALIDATION (NON-WAIVED TESTING) CHECKLIST" revealed the following statements: "Instrument Validations must be performed whenever a new instrument is installed, added relocated or when a demo/loaner instrument is placed in the laboratory. Laboratories must verify the following:" "Reference Ranges (Normal Values)". 4) Interview with the laboratory director on August 12, 2019 at 5:30 pm confirmed the laboratory failed to follow the procedure for instrument/method validation in 2018 for the NT-proBNP performed on the Polymedco Pathfast instrument when it did not perform a normal range study. Patient testing on the instrument began May 2018.</p>
<b>D5439</b>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual, the laboratory's calibration and calibration verification records for the Polymedco Pathfast N-terminal-pro B-type Natriuretic Peptide (NT-proBNP), and interview with the laboratory director, the laboratory failed to perform calibration verification at least every 6 months for the NT pro-BNP performed on the Polymedco Pathfast instrument in 2018 and 2019. The findings include: 1) Review of the laboratory procedure for the Polymedco Pathfast NT-proBNP revealed that calibration is performed using only two levels of calibrators. 2) Review of the laboratory's calibration and calibration records revealed that calibration is performed using only two levels of calibrator and the calibration verification due October 2018 and April 2019 was not performed. 3) Interview with the laboratory director on August 12, 2019 at 5:30 pm confirmed the laboratory failed to perform calibration verification for the Polymedco Pathfast NT-proBNP assay at least every six months to include a low, mid, and high level in 2018 and 2019.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assurance (QA) plan, complete blood count (CBC) quality control (QC) data, and interview with the laboratory director, the laboratory failed to follow the policy for review of CBC quality control data in 2018 and 2019. The findings include: 1) Review of the laboratory's quality assurance plan revealed that "Records of our quality control and maintenance are dated and initialed by the Technical Consultant and by the Laboratory Director each month." 2) Review of the laboratory's CBC quality control reports for lot number 7325 and 8352 revealed

the following: Lot number 7325 QC data from February 1, 2018 to February 9, 2018 had not been printed for review by the laboratory director; Lot number 8352 QC data from March 1, 2019 to March 8, 2019 had not been printed for review by the laboratory director. 3) Interview with the laboratory director on August 12, 2019 at 5:30 pm confirmed the laboratory did not follow the QA plan for monthly review of quality control data in 2018 and 2019.

**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 observation of the laboratory, review of validation records for the Polymedco Pathfast instrument, testing personnel records, patient number twenty one test report, and interview with the laboratory director, the laboratory director failed to ensure testing personnel number three had documented training for performing testing for the N-terminal-pro B-type Natriuretic Peptide (NT-proBNP) on the Polymedco Pathfast instrument. 1) Observation of the laboratory on August 12, 2019 at 9:00 am revealed the Polymedco Pathfast instrument in use for patient testing for NT-proBNP. 2) Review of the validation records for the Polymedco Pathfast instrument revealed the laboratory began using the Polymedco Pathfast instrument for patient testing in May 2018. 3) Review of testing personnel records revealed no documented training for testing personnel number three for use of the Polymedco Pathfast instrument. 4) Review of patient number twenty-one test report revealed patient testing for NT-proBNP performed by testing personnel number three on April 19, 2019. 5) Interview with the laboratory director on August 12, 2019 at 5:30 pm confirmed the laboratory director failed to ensure testing personnel number three had documented training prior to performing patient testing for NTproBNP.

**D6072**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the laboratory's procedure manual, the laboratory's quality control records, patient numbers twenty-two and twenty-three test report, and interview with the laboratory director, testing personnel failed to follow the individualized quality control plan (IQCP) for the D-dimer test in 2018. The findings include: 1) Observation of the laboratory on August 12, 2019 at 9:00 am revealed the Alere Triage meter in use for patient testing for D-Dimer. 2) Review of

the laboratory's IQCP for the D-Dimer test revealed the following: "Perform 2 levels of QC with each new cartridge lot #, each new shipment received date or every 30 days." 3) Review of the laboratory's January and February 2018 quality control records for the D-dimer test revealed lot number W63228 in use in January and February 2018. The 30 day quality control due on February 1, 2018 was not performed. 4) Review of patient numbers twenty two and twenty three test report revealed testing for D-dimer performed on February 21, 2018 and February 27, 2018 respectively, during the gap in quality control performance. 5) Interview with the laboratory director on August 12, 2019 at 5:30 pm confirmed that testing personnel failed to follow the IQCP procedure for the D-dimer test performed on the Alere Triage instrument in 2018 with patient testing performed.