Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0301989	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Jasper Family Practice	2201 North Airport Road, Jasper, AL	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of proficiency testing records for 2016 - 2018, a lack of documentation of validation records for Ddimer testing on the Alere Triage Meter, and an interview with Testing Personnel (TP) #1 (also the laboratory manager), the surveyor determined the laboratory failed to perform verifications of manufacturer's specifications, prior to performing patient testing and reporting the results. The findings include: 1. During the entrance tour of the laboratory on 2/27/2019 at 10:45 AM, TP #1 identified Ddimer as part of the laboratory's testing menu; although the test was not identified as a new test at the time of entrance. 2. Upon review of the proficiency testing records for 2016 (Event #3) through 2018, the surveyor determined no proficiency testing was performed on Ddimer until the second event of 2018. At this time, 1:00 PM, the surveyor inquired of the start date for Ddimer testing. TP #1 stated Ddimer testing began in May of 2018, was suspended on June 1, and resumed on October 30, 2018. 3. The laboratory failed to provide documentation Ddimer testing was validated. 4. At 1:34 PM on 2/27/2019, TP #1 stated there was no validation done for Ddimer testing, as noone told her a validation was needed. TP #1 stated the testing was installed in May of 2018, and patient testing began as early as June 3. TP #1 stated patient testing was began when cartridges were received and two levels of quality control were tested. The surveyor inquired of the number of tests

	which had been performed between install and the survey date. TP #1 answered there probably were numerous tests performed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the calibration records for the Cell-Dyn Emerald for 2016 - 2018, a review of the operators' manual, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to perform calibrations at the frequency of every six months, as established in manufacturer's guidelines. The laboratory further failed to perform quality control, after the calibration, performed on 6/07/17 (PM), to ensure the accuracy of the calibration, prior to continuing patient testing. This affected the calibration period of 5/2016 through the date of survey. The findings include: 1. A review of the calibration records for the Cell-Dyn Emerald, Hematology analyzer, used for CBC (Complete Blood Count testing) revealed the following: a) A calibration was performed 4/05/16 (previous survey review), and then on 12/12/16, exceeding the six months timeframe as established by policies and procedures. b) A calibration was performed on 6/07/17 at 13:07 (1:07 PM). However, no quality control was tested following the calibration. c) The next calibration was performed on 6/19/18, one year after the previous calibration. The laboratory documented the calibration was not performed, because no calibration material was available (the auto-ship had been discontinued). 2. In an interview on 2/27/19 at 4:07 PM, TP #1 confirmed she did not run the quality control after the PM calibration on 6/07/17. TP #1 stated she had already reviewed the records to determine if the quality control had been run in the PM, and was only able to verify quality control testing performed in the morning on that day. TP #1 also stated she was sure patient testing continued after the calibration was done around 1:00 PM, because the laboratory was usually busy until the close of the day. TP #1 also confirmed the missed calibration in December of 2017 and the sometimes late calibrations. TP #1 stated the calibration material had been set-up to auto-ship every six months to avoid the reoccurrence of the deficiency. 3. A review of the operator's manual for the Emerald revealed the following: Calibration is a procedure that confirms the accuracy of the Cell-Dyn Emerald. Calibrations should be confirmed on a regular basis, according to the laboratory's protocols. In Section 6: Calibrate at least every six months. Quality Control (QC) provides confirmation of the calibration. In Section 11: When to run QC: ...after the calibration as a confirmatory step.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	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 a review of Chemistry calibration verification records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure calibration verifications were performed at least every six months on the analytes tested on the Advia Centaur XP (Estradiol, Ferritin, vitamin B12, free Thyroxine, Prostrate Specific Antigen, Thyroid Stimulating Hormone, Testosterone, and vitamin D). This affected one of five calibration verifications between April, 2017 until the date of the survey. The findings include: 1. A review of the calibration verification records for the Centaur XP revealed the laboratory performed calibration verifications on April 7, 2017, then January 31, 2018, exceeding the six month time-frame, required for analytes with less than three routine calibrators. 2. In an interview on 2/27 /2019 at 4:07 PM, the surveyor discussed with TP #1 the delay in performing the calibration verifications. TP #1 confirmed the delay, and stated the calibrator material had been set-up to auto-ship to correct the deficient practice. TP #1 (also the laboratory manager) had documented the order for the material was set-up to deliver every six months.
D6012	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: Based on a review of proficiency testing records for 2016 - 2018, a lack of documentation of validation records for Ddimer testing on the Alere Triage Meter, and an interview with Testing Personnel (TP) #1 (also the laboratory manager), the

	surveyor determined the laboratory director failed to ensure performance verifications were performed to ensure the manufacturer's specifications of Ddimer testing, prior to performing patient testing and reporting the results. The findings include: 1. Refer to D5421.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the test menu, a review of the installation and validation records for Estradiol (E2), and an interview with Testing Personnel (TP) #1 (also the laboratory manager), the surveyor determined the laboratory director failed to ensure the verifications of the manufacturer's claims of accuracy, precision and analytical measurable range were acceptable, prior to testing personnel performing patient testing and reporting the results. The finding include: 1. During the entrance tour on 2 /27/2019 at 10:45 AM, the surveyor inquired of the laboratory's testing menu and if any new procedures or instruments had been introduced into the laboratory's systems. TP #1 stated the E2 had been added to the Advia Centaur XP in the Spring of 2018, and a specific date would be found in the installation record. 2. A review of the installation and validation record for E2 revealed repeatability of three levels of quality control had been done on 12/27/2017, as well as the analytical range verification. The laboratory director had initialed in the front of the manual with a date, "1/17." It was not clear what this date indicated (was it void of a date or year). 3. At 1:34 PM on 2/27/2019, the surveyor asked if the laboratory director (physician) had reviewed the verification data for E2 testing. TP #1 stated the laboratory director had not seen the data, as she had never shown it to him. TP #1 added the verification performance documents for E2 to the manual, which included analytes which were previously installed, which explained the date 1/17 (prior to the date E2 testing was introduced). When asked, TP #1 stated E2 testing began January 2, 2018. Also, TP #1 stated she had made the technical consultant aware of the new testing at the time of occurrence.
D6039	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(1) The technical consultant is responsible for-- (b)(1) Selection of test methodology appropriate for the clinical use of the test results; This STANDARD is not met as evidenced by: Based on a review of proficiency testing records for 2016 - 2018, a lack of documentation of validation records for Ddimer testing on the Alere Triage Meter, and an interview with Testing Personnel (TP) #1 (also the laboratory manager), the surveyor determined the technical consultant failed to ensure performance

	verifications were performed to ensure the manufacturer's specifications of Ddimer testing, prior to performing patient testing and reporting the results. The findings include: 1. Refer to D5421.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on a review of the test menu, a review of the installation and validation records for Estradiol (E2), and an interview with Testing Personnel (TP) #1 (also the laboratory manager), the surveyor determined the technical consultant failed to ensure the verifications of the manufacturer's claims of accuracy, precision and analytical measurable range were acceptable, prior to testing personnel performing patient testing and reporting the results. The finding include: 1. During the entrance tour on 2 /27/2019 at 10:45 AM, the surveyor inquired of the laboratory's testing menu and if any new procedures or instruments had been introduced into the laboratory's systems. TP #1 stated the E2 had been added to the Advia Centaur XP in the Spring of 2018, and a specific date would be found in the installation record. 2. A review of the installation and validation record for E2 revealed repeatability of three levels of quality control had been done on 12/27/2017, as well as the analytical range verification. The laboratory director had initialed in the front of the manual with a date, "1/17." It was not clear what this date indicated (was it void of a date or year). 3. At 1:34 PM on 2/27/2019, the surveyor asked if the laboratory director (physician) had reviewed the verification data for E2 testing. TP #1 stated the laboratory director had not seen the data, as she had never shown it to him. TP #1 added the verification performance documents for E2 to the manual, which included analytes which were previously installed, which explained the date 1/17 (prior to the date E2 testing was introduced). When asked, TP #1 stated E2 testing began January 2, 2018. Also, TP #1 stated she had made the technical consultant aware of the new testing at the time of occurrence.