Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652292	08/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Memphis Pathology Laboratory	212 S Woodbine, Saint Joseph, MO	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of procedures, proficiency testing (PT) and interview with the technical supervisor the laboratory failed to follow procedure and test PT samples the same number of times that it routinely tests patient samples. Findings: 1. Laboratory procedure states "PT samples are treated as patient samples". 2. Review of hematology PT showed 1st event of 2018 challenge one was repeated four times. Hematology 1st event of 2018 challenge two was repeated four times. 3. Interview with the technical supervisor on August 12, 2019 at 3:00 PM confirmed the laboratory failed to test PT samples the same number of times that it routinely tests patient samples.
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 review of the performance verification procedures for the Sysmex XN1000 hematology analyzer, Sysmex CA1500 D-dimer testing and interview with the technical supervisor, the laboratory failed to verify reference intervals(normal values) for complete blood count (CBC) and D-dimer. Findings: 1. Review of the verification procedure for the Sysmex XN1000 hematology analyzer for red blood cell, hemoglobin, hematocrit, platelet, white blood cell and differential showed no verification of normal values. 2. Review of the verification procedure for the Sysmex CA1500 analyzer for D-dimer showed no verification of normal values. 3. Interview with the technical supervisor on August 12, 2019 at 2:00 PM confirmed the laboratory failed to ensure the verification procedures for normal values for the Sysmex XN1000 analyzer and the Sysmex CA1500 analyzer were appropriate for the laboratory's patient population.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of patient test report, procedure manual and interview with the technical supervisor the laboratory director failed to ensure hematology and chemistry test results include pertinent information required for interpretation. Findings: 1. Review of the procedure manual showed no approved reference ranges for the laboratory located in St Joseph, Missouri. 2. Interview with the technical supervisor on August 12, 2019 at 3:00 PM confirmed the laboratory director failed to ensure hematology and chemistry test results include pertinent information required for interpretation.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 review of competencies and interview with the technical supervisor the laboratory director failed to ensure one of four testing personnel maintained their competency. Findings: 1. Review of annual competencies showed no documentation of competency for testing personnel #1 for 2017, 2018 to present. 2. Interview with the technical supervisor on August 12, 2019 at 3:00 PM confirmed the laboratory director failed to ensure the competency for testing personnel #1 was maintained and documented.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)

	(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 review of competencies and interview with the technical supervisor the technical supervisor failed to evaluate the initial competency for two of two testing personnel. Findings: 1. Review of competencies showed the laboratory could not provide documentation for initial training and competency for testing personnel #3 and testing personnel #4. 2. Interview with the technical supervisor on August 12, 2019 at 2:00 PM confirmed the technical supervisor failed to evaluate the initial competency for testing personnel #3 and #4.