Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D1105812	10/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Memphis Pathology Laboratory Dba	1425 Nw Blue Parkway, Lees Summit, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the laboratory director, the procedure manual failed to include applicable requirements for bilirubin testing. Findings: 1. Review of the laboratory procedure manual revealed the manual did not include age specific reference intervals (normal values) for direct and total bilirubin testing on pediatric patients, a protocol for reporting panic/alert values and speed and time requirements for centrifuging (processing) specimens for direct and total bilirubin testing. 2. Interview on October 30, 2018 at 12:40 PM, the laboratory director said the procedure manual did not include age specific normal values, panic

	/alert values and a protocol for reporting panic/alert values on pediatric patients. Email correspondence with the laboratory director confirmed the procedure manual did not include processing requirements for patient specimens. Interview confirmed the procedure manual failed to include all requirements applicable to the direct and total bilirubin procedure.
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 validation records for the" Piccolo Express" chemistry analyzer from June 14, 2018, patient records for 2018 and interview with the laboratory director, the laboratory failed to demonstrate performance specifications comparable to those established by the manufacturer for the reportable range of the test system and reference intervals (normal values) appropriate for the laboratory's peditric patient population before reporting patient results June 2018. Findings: 1. Review of validation records for the "Piccolo Express" chemistry analyzer revealed no documentation the laboratory verified/validated the manufacturer's performance characteristics for the reportable range of the test system and normal values appropriate for pediatric bilirubin testing. 2. The laboratory documented it performs 750 patient tests annually or averages 14 patient tests per week. 3. Interview on October 30, 2018 at 12:40 PM, the laboratory director said he did not have documentation to show the validation process included reportable range of the test system and normal value verification. Interview confirmed the laboratory did not perform and document all required verification (validation) procedures.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of quality control (QC) and patient record for October 2018 and interview with the laboratory director, the laboratory failed to establish or verify criteria for acceptability of control materials for bilirubin testing. Findings: 1. Review of QC records for October 2018 revealed the laboratory introduced new lot number 44312, Level two" Liquicheck Pediatric Control" on October 24, 2018 and in use through October 30, 2018. The laboratory did not have documentation to show it established or verified acceptable limits for lot number 44312 Level two "Liquicheck Pediatric Control" in use for direct and total bilirubin testing. 2. Patient records showed the laboratory performed bilirubin testing on four patients samples from October 24, 2018 through October 30, 2018. 3. Interview on October 30, 2018 at 12: 40 PM, the laboratory director said acceptable limits for lot number 44312 Level two were not established or verified and not available. Interview confirmed the laboratory failed to establish or verify acceptability of Level two control material in use for bilirubin testing.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the procedure manual, verification (validation) procedures, lack of age specific direct and total bilirubin normal values and interview with the laboratory director , the laboratory failed to ensure pertinent normal values were available for interpretation of the results. Findings: 1. The laboratory procedure manual did not include age specific direct and total bilirubin normal values. 2. The laboratory did not perform validation procedures to verify direct and total bilirubin normal values were appropriate for its pediatric patient population. 3. Pertinent age specific direct and total bilirubin normal values for pediatric patients were not available to authorized individuals ordering the test. 4. Interview on October 30, 2018 at 12:40 PM, the laboratory director said no pertinent age specific normal values for bilirubin testing were available. Interview confirmed pertinent age specific normal values for bilirubin testing were not available for interpretation.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the lack of a quality assessment (QA) program and interview with the laboratory director, the laboratory director failed to establish a comprehensive QA program. Findings: 1. The laboratory did not have a comprehensive/ cohesive written QA program for general laboratory systems, preanalytic, analytic and postanalytic

	systems. 2. Interview with the laboratory director on October 30, 2018 at 12:40 PM confirmed the lack of a written QA program.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the laboratory director, the laboratory director failed to employ a clinical consultant to provide appropriate consultation from June 2018 through October 2018. Findings: 1. Personnel records showed the laboratory did not have a clinical consultant to provide consultation. 2. Interview on October 30, 2018 at 12:40 PM, the laboratory director said the laboratory did not employ a clinical consultant. Interview confirmed the laboratory director failed to employ a clinical consultant.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the laboratory director, the labortory failed to have a qualified clinical consultant (Refer to #D6057); failed to ensure consultation was available to clients related to the quality of the test results and their interpretation (Refer to #D6062).
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the laboratory director, the laboratory failed to have documentation to show the laboratory employed an

	individual qualified as a clincal consultant. Findings: 1. Review of personnel records showed the laboratory did not have a qualified clinical consultant to consult / render opinions to clients concerning diagnosis, treatment and management of patient care. The personnel roster (CMS form-209) signed by the director did not have a clinical consultant position listed. 2. Interview on October 30, 2018 at 12:40 PM, the laboratory director said the laboratory did not have a clinical consultant. Interview confirmed the laboratory did not have an individual serving as a clinical consultant.
D6062	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(d) The clinical consultant must ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the laboratory director, the laboratory failed to have a clinical consultant available for consultation and interpretation of test results. Findings: 1. The laboratory did not have an individual serving in the position of clinical consultant. 2. Interview on October 30, 2018 at 12: 40 PM, the laboratory director said the laboratory did not have a clinical consultant available for consultation relating to quality of test results and interpretation. Interview confirmed the laboratory did not have a clinical consultant available for consultation.