Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0307950	03/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Three Rivers Hospital	451 Highway 13 South, Waverly, TN	

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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: The laboratory failed to have a procedure for use of Lipoclear (Refer to D5401) and failed to validate the use of Lipoclear reagent for removal of lipemia from patient samples for chemistry assays (Refer to D5421).
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2017 proficiency testing performance evaluation reports, the laboratory's policy titled "Proficiency Testing", and interview with the laboratory supervisor the laboratory failed to follow quality assessment policy for evaluation of proficiency testing results in 2017. The findings include: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing performance evaluation reports revealed the following: 2017 Immunology/Immunohematology 2nd event DAT-Anti-C3d-sample # DAT-03=Not Graded, no evaluation of non-graded result; 2017 Microbiology 2nd Event Group A Strep Antigen, sample # ST-

	09=Unacceptable, no corrective action for unacceptable result; 2017 Chemistry Core 1st event LDL Cholesterol sample # CH-01=Not Graded, Triglyceride sample # CH-01=Not graded, Free thyroxine sample # CH-01=Not Graded, Thyroid Stimulating Hormone sample # CH-04=Unacceptable-No evaluation of non-graded results or corrective action for unacceptable results for Thyroid Stimulating Hormone. 2017 Chemistry Core 2nd event ALT/SGPT sample # CH-07=Unacceptable, No corrective action for unacceptable result. 2017 Chemistry Core 3rd event pO2 sample #BG-15=Unacceptable-No corrective action for unacceptable result. 2017 Hematology /Coagulation 1st event Blood Cell Identification sample #s BCI-06, BCI-07=Not Graded-No evaluation of non-graded results. 2017 Hematology/Coagulation 2nd Event Blood Cell Identification sample #s BCI-13, BCI-14=Not Graded, MCH sample # XE-08=Unacceptable; Urobilinogen sample # UA-03=Unacceptable; No evaluation of non-graded results or corrective action for unacceptable results for MCH and Urobilinogen. 2017 Hematology/Coagulation 3rd Event Blood cell Identification sample #s BCI-20, BCI-21=Not Graded, no evaluation of non-graded results. 2. Review of the laboratory's policy titled "Proficiency Testing" revealed the following statement: "All results are evaluated. Results with less than a score of 100%, or any results reported and not acceptable, or no consensus for the results, must be evaluated to determine if our values indicate results would have been acceptable or if a problem would be indicated. This evaluation is addressed on the corrective action document." 3. Interview with the laboratory supervisor on March 19, 2018 at 11:00 am confirmed the laboratory failed to follow quality assessment policy for evaluation of proficiency testing results in 2017.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's procedure manual, and interview with the laboratory supervisor, the laboratory failed to have a procedure for use of Lipoclear in 2018. The findings include: 1. Observation of the laboratory on March 19, 2018 at 8:30am revealed Lipoclear reagent (receipt date of February 13, 2018) in the refrigerator for use in clearing lipemia from patient samples prior to testing chemistry assays. 2. Review of the laboratory's procedure manual revealed no procedure for the use of Lipoclear reagent. 3. Interview with the laboratory supervisor on March 19, 2018 at 4:30 pm confirmed the laboratory failed to have a procedure for the use of Lipoclear in 2018.
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 observation of the laboratory and interview with the laboratory supervisor, the laboratory failed to verify performance specifications when using Lipoclear for clearing of lipemia in patient specimens for chemistry testing in 2018. The findings include: 1. Observation of the laboratory on March 19, 2018 at 8:30 am revealed Lipoclear reagent in the laboratory refrigerator, receipt date of February 13, 2018. 2. Interview with the laboratory supervisor on March 19, 2018 at 4:30 pm confirmed that the laboratory uses Lipoclear reagent for clearing lipemia in patient specimens for chemistry testing and has not validated Lipoclear for use with the laboratory's chemistry instrument in 2018.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's routine chemistry quality control records for the month of March 2017, patient test report numbers two and three, and interview with the laboratory supervisor, the laboratory failed to perform two levels of quality control for general chemistry analytes on March 10 and March 11, 2017. The findings include: 1. Observation of the laboratory on March 19, 2018 at 8:30 am revealed the Siemens Dimension EXL instrument in use for patient testing for routine chemistry. 2. Review of the laboratory's quality control records for the month of March 2017 revealed that quality control did not include two levels for routine chemistry analytes on March 10 and March 11, 2017 to include the following analytes: albumin, alkaline phosphatase, blood urea nitrogen (BUN), calcium, chloride, cholesterol, carbon dioxide, creatinine, glucose, HDL cholesterol, magnesium, potassium, aspartate aminotransferase (AST), alanine aminotransferase (ALT), sodium, total bilirubin, total protein, triglyceride, thyroid stimulating hormone (TSH). 3. Review of patient test report number two on March 10, 2017 and number three on March 11, 2017 revealed testing for routine chemistry assays as follows: Patient number two on March 10, 2017- albumin, alkaline phosphatase, BUN calcium, chloride, cholesterol, carbon dioxide, creatinine, glucose, HDL cholesterol, potassium, AST, ALT, sodium, total bilirubin, total protein, triglyceride, TSH. Patient number three on March 11, 2017- albumin, alkaline phosphatase, BUN, calcium, chloride, cholesterol, carbon dioxide, creatinine, glucose, HDL cholesterol, magnesium, potassium, AST, ALT, sodium, total bilirubin, total protein, triglyceride, TSH. 4. Interview with the laboratory supervisor on March 20, 2018 at 10:30 am confirmed the laboratory failed to perform two levels of quality control for the chemistry instrument on March 10 and March 11, 2017 with patient testing reported.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Quidel Sophia manufacturer's package insert, patient test report number one, the patient test log, the laboratory's procedure for respiratory syntial virus (RSV), and interview with the laboratory supervisor the laboratory failed to perform negative and positive controls on each day of patient testing for the RSV test in 2017. The findings include: 1. Observation of the laboratory on March 19, 2018 at 8:30 am revealed the Quidel Sophia RSV test in use for patient testing. 2. Review of the Quidel Sophia manufacturer's package insert for RSV test revealed the following statements related to CLIA complexity: Moderate for pediatric patients 7 to less than 19 years of age, Waived for children less than 7 years of age. 3. Review of patient test report number one dated November 14, 2017, revealed the following: patient testing for RSV, patient age = 16 years. 4. Review of the patient test log for RSV testing revealed that the lot number used for patient number one was 702703 and quality control was performed once on September 18, 2017. 5. Review of the laboratory's procedure for RSV revealed the following quality control protocol: once for each untrained operator, once for each new shipment of kits or lot number and no individualized quality control plan (IQCP) for reduced frequency of quality control testing. 6. Interview with the laboratory supervisor on March 19, 2018 at 10:30 am confirmed the laboratory uses the RSV kit as a moderately complex test, does not perform negative and positive quality control each day of patient testing, and does not have an IQCP for reduced frequency of QC testing.