Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315721	09/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Decatur County General Hospital	969 Tennessee Avenue S, Parsons, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, proficiency testing records and interview with the laboratory supervisor, the laboratory failed to test proficiency testing samples the same as patient samples in 2019. The findings include: 1. Review of the laboratory's procedure manual revealed a procedure titled "Weak D (Du) Testing" that requires Rh Negative samples to be tested for weak D (Du) when evaluating women to determine if they are a candidate for Rh immune globulin. 2. Review of the laboratory's 2019 proficiency testing records revealed that proficiency testing samples that were Rh negative were not tested for Weak D (Du). 3. Interview with the laboratory supervisor on September 11, 2019 at 5:30 p.m. confirmed the laboratory failed to test proficiency testing samples the same as patient samples in 2019.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, testing personnel records for 2018 and 2019, and interview with the laboratory supervisor, the laboratory failed to have a testing personnel policy that required initial training and included all six criteria for assessing personnel competency; and failed to follow the current policy. The findings include: 1. Observation of the laboratory on September 9, 2019 at 8:00 am revealed the following non-waived test systems in use for patient testing: complete blood count - Sysmex XS 1000i, manual differential, Prothrombin time, partial thromboplastin time (PTT), D-Dimer on the Sysmex CA 660, urine microscopy, arterial blood gas on the i-STAT, clinical chemistry testing on the Siemens Dimension EXL 200, C. Difficile Antigen and toxin, Transfusion Medicine testing (ABO, Rh, weak D, Antibody screen, DAT-IGG, and DAT-Polyspecific), MedTox Urine Drug Screen, Erythrocyte Sedimentation Rate-Sedimat II, and HIV testing on the Alere Determine HIV Ag/Ab Combo. 2. Review of the procedure manual policy titled "COMPETENCY EVALUATION' revealed that problem solving, record review, and monitoring of patient test results are not included in the policy. The policy also stated that "All new employees will have a comprehensive competency evaluation at orientation, at the end of the 3 month probationary period, and at one-year post-employment." 3. Review of testing personnel records revealed the following: Testing personnel number one-date of hire 12.14.2018, -No initial training and no 3-6 month interim competency assessment for non-waived testing for C. difficile testing, Chemistry testing (Siemens Dimension EXL), MedTox urine drug screen, I-Stat ABG, HIV, Sedimentation rate, Urine microscopy, manual differential, and complete blood count performed on the Sysmex XS 1000i. Testing personnel number three-No problem solving on six month competency assessment. Testing personnel number four-No problem solving on six month competency assessment. Testing personnel number eight-Date of Hire-03.04.19. No documented training documents, competency assessment completed on May 16, 2019 after testing personnel began patient testing, problem solving evaluation incomplete. 4. Review of the current competency form revealed that 3 of the 6 required criteria were not included: problem solving, record review and monitoring of patient test results. HIV and C-difficile testing are not specifically listed on the form. The Medtox urine drug screen and i-Stat ABG competencies were grouped together with no individual competencies. 5. Interview with the laboratory supervisor on September 11, 2019 at 5:30 p.m. confirmed that the policy did not address initial training and did not include all six of the required criteria for assessment. The competency initial training and 3-6 competency were not documented for testing personnel numbers one and eight with patient testing performed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of patient number ten test report, laboratory records, and interview with the laboratory supervisor, the laboratory failed to evaluate the accuracy of the qualitative serum pregnancy test in 2019. The findings include: 1. Review of patient

	number ten test report revealed qualitative serum pregnancy test reported on August 20, 2019. 2. Review of laboratory records revealed no verification of the accuracy of the qualitative serum pregnancy test twice a year in 2019. 3. Interview with the laboratory supervisor on September 11, 2019 at 5:30 p.m. confirmed the laboratory failed to verify the accuracy of the qualitative serum pregnancy test twice a year in 2019, with patient testing performed.
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 policy for proficiency testing, patient number ten test report, the transfusion medicine procedure manual, proficiency testing records and interview with the laboratory supervisor, the laboratory failed to follow the proficiency testing policy in 2018 and 2019. The findings include: 1. Review of the laboratory's policy titled "Proficiency Testing" revealed that the laboratory is to maintain a copies of all proficiency testing records including signed attestation statements. 2. Review of the laboratory's proficiency testing records revealed the following: No data submission reports for: QA Strep 2018 event one and two, Regulated microbiology 2018 event one, two, and three, Immunology 2018 event one, Cardiac 2018 event three, Urinalysis 2018 event two, Chemistry and Hematology QA event two, Microbiology 2019 event one; No paper trail/printouts for: 2018 Immunology event three, 2018 Hematology event two cell identification, 2018 Urinalysis event two cell identification, 2018 Chemistry event two, 2019 Hematology event two: cell identification, urine sediment identification, fecal occult blood test, gastric occult blood test, 2019 Microbiology, Immunology 2019 events one and two. Attestation statements not signed by lab director and/or retained: QA Strep 2018 events one and two, Cardiac 2018 event three, Coagulation 2018 event three, Urinalysis 2018 event two, Chemistry/Hematology QA 2018 events one and two, Chemistry 2018 events one and three, Blood Bank 2018 event three, Arterial Blood gas 2018 events two and three, Hematology 2018 events one and three, Immunology 2018 event two. Attestation statements not signed by testing personnel and/or retained: QA Strep 2018 events one and two, Chemistry 2018 events one and three, Arterial Blood gas 2018 event two. No performance evaluation report was available for D-dimer 2018 event three. 3. Interview with the laboratory supervisor on September 11, 2019 at 5:30 p.m. confirmed the laboratory failed to follow the proficiency testing policy in 2018 and 2019.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: The laboratory failed to follow procedure manual (Refer to D5401) and failed to have an effective quality assessment process (Refer to D5793).
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 review of the laboratory's procedure manuals, laboratory instrument records, patient records, and interview with the laboratory supervisor, the laboratory failed to follow laboratory procedures in 2018 and 2019. 1. Review of the laboratory procedure titled "Linearity/Analytic Measure range/Calibration/Calibration Verification Siemens EXL 200" revealed that amylase, aspartate aminotransferase (AST), Calcium, Cholesterol, Chloride, C-Reactive protein (CRP), phosphorus, Potassium, Sodium, and Triglyceride calibration will be verified every 6 months. 2. Review of the laboratory procedure titled "Abbott I Stat Calibration Verification G3+ cartridge" revealed the following: "Verification of instrument linearity and calibration verification will be performed at a minimum of every six months." 3. Review of the laboratory procedure titled "VERIFICATION OF PLATELET-POOR PLASMA USED FOR COAGULATION TESTING" and the form used for recording the results of the platelet poor plasma evaluation revealed that verification of centrifuges to produce platelet poor plasma is to be performed "a minimum of annually or if new centrifuge is placed into service." 4. Review of the laboratory procedure titled "Management of Coagulation Reagent Lots, Setting INR Calculation, Determining Patient Normal Mean revealed that lots numbers for coagulation testing (Prothrombin time (PT) and partial thromboplastin time (PTT) are sequestered annually and the following is done: 20 runs of quality control (QC) using the new reagents and new QC lots, testing normal patients to determine a new PT and PTT 'normal' control, INR calculation verification, INR Reportable range calculation, PTT Lot:Lot verification. 5. Review of the laboratory's procedure titled "Rh Immune Globulin" revealed the following statement" "Perform ABO, Rh, Du (if indicated, i.e. if Rh is negative)." 6. Review of laboratory records revealed: No calibration verification performed in 2018, calibration verification for CRP, Amylase, Phosphorus, Cholesterol, calcium, and AST due August 2019, were not completed. No performance of calibration verification due May 2019 for Arterial Blood Gas on the I-stat instrument. No performance of centrifuge platelet poor plasma verification in 2018. No documentation that the procedure for coagulation lot rollover procedure had been performed for the current lot numbers of controls and PT, PTT reagents, resulting in possible incorrect calculation of the International Normalized Ratio (INR) and interpretation of the PTT results. The quality control records indicate the current lot numbers were started in October 2018. Approximately 1370 patients were tested for INR and 382 for PTT between October 2018 to September 2019. Laboratory transfusion medicine records revealed patient number 35 evaluated for Rh Immune Globulin on June 6, 2019. The patient determination was Rh Negative. There was no documentation that Du testing was performed. Rhogam was released for injection on

	the same day. 7. Interview with the laboratory supervisor on September 11, 2019 at 5: 30 p.m. confirmed the laboratory failed to follow laboratory procedures in 2018 and 2019.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Citation number one Based on review of the laboratory's procedure manual, patient urine drug screen(UDS) test reports, September 2018 and August 2019 UDS quality control (QC) records, the pathologist monthly consultation visit records, and interview with the current laboratory supervisor, the laboratory's quality assessment process was ineffective when it failed to correct problems with quality control (QC) in 2018 and 2019. 1. Review of the laboratory's procedure titled "Drug Screen-MEDTOX PROFILE " revealed that positive and negative external controls are to be performed a minimum of once per week, the positive and negative control device will be run weekly. 2. Review of patient number thirty one test report revealed urine drug screen testing reported on September 15, 2018. 3. Review of patient number thirty two test report revealed urine drug screen testing reported on August 18, 2019. 4. Review of the September 2018 UDS QC records revealed gaps in weekly QC. There was documented review by the previous laboratory supervisor with no corrective action documented. 5. Review of the laboratory's August 2019 UDS QC revealed the following the use of incorrect lot number for the positive and negative QC device and no documentation of weekly positive QC device for August 6, 2019. 6. Review of the monthly pathology consultation visit records visit dated September 5, 2019, signed by the laboratory director, revealed review of chemistry QC with no documented corrective action. 7. Interview with the current laboratory supervisor on September 11, 2019 at 5:30 pm confirmed the laboratory's quality assessment process was ineffective when it failed to correct problems with UDS quality control in 2018 and 2019. _____ Citation number two Based on review of quality control (QC) records for chemistry and interview with the current laboratory supervisor the laboratory's quality assessment was ineffective when it failed to detect and correct problems with Chemistry quality control in 2019. 1. Review of May 2019 monthly Chemistry QC records revealed the following: "New lot of QC material went live on 5.7.19." Quality control for alcohol (ETOH) and lactic acid was performed and evaluated against the quality control limits for the old qc lot numbers (47931 and 47933) as follows: ETOH-May 15, 23, and 31, 2019; Lactic acid on 05.23.19. No corrective action was documented for the use of incorrect QC files and limits. There was documented review by both the lab supervisor and laboratory director on the Chemistry QC review sheet. 2. Interview with the current laboratory supervisor on September 11, 2019 at 5:30 p.m. confirmed the laboratory's quality assessment was ineffective when it failed to correct problems with chemistry QC in 2019. _____ Citation number three 1. Review of the Human Immunodeficiency Virus (HIV) test log for February 2018 and February 2019 revealed no record of the QC lot numbers, expiration dates, and name of controls used. Dates of test performance were missing for February 2019. There

	was no review of the record by the laboratory supervisor and no corrective for the incomplete documentation. 2. Interview with the current laboratory supervisor on September 11, 2019 at 5:30 p.m. confirmed the HIV test log had not been reviewed by the laboratory supervisor and no corrective action performed for the incomplete test data. _____ Citation number four Based on review of coagulation quality control records from May 2018 to October 2018 and interview with the current laboratory supervisor, the laboratory's quality assessment process was ineffective when it failed to detect overlapping use of quality control lots /records for the Prothrombin time (PT) and partial thromboplastin time (PTT) in 2018. 1. Review of the coagulation QC records revealed on 10-8-18 new lot numbers 548078 and 556506 were placed in use. 2. Review of coagulation QC reports for May, June, July, August, September and October 2018 revealed review of coagulation QC for the previous lot numbers in use was performed using control limits for the current lot numbers (548078, 556506). No corrective was performed. 3. Interview with the current laboratory supervisor on September 11, 2019 at 5:30 p.m. confirmed the laboratory's quality assessment process was ineffective when it failed to detect and correct problems with quality control lot number management in 2018. _____ Citation number five Based on review of the laboratory's quality control (QC) records for complete blood count (CBC) and interview with the current laboratory supervisor, the laboratory's quality assessment process was ineffective when it failed to detect and correct problems with CBC quality control in 2018. The findings include: 1. Review of the laboratory's CBC QC records for lot number 8184 revealed gaps in QC records from 08/20/2018 to 09 /17/2018. The report was reviewed by both the previous laboratory director and previous laboratory supervisor. No corrective action documented. 2. Review of patient number two test report revealed patient reporting for CBC on 09/15/2018. 3. Interview with the current laboratory supervisor on September 11, 2019 at 5:30 p.m. confirmed the laboratory's quality assessment process was ineffective when it failed to detect and correct problems with gaps in CBC quality control in 2018.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with the laboratory supervisor, the laboratory director failed to ensure proficiency testing results were reviewed in 2018. The findings include: 1. Review of proficiency testing records revealed the following proficiency test results were not reviewed: Strep QA 2018 event two, Chemistry 2018 event two, Mono results for 2018 event two, C-Reactive protein and Mono results for 2018 event three, Urinalysis 2018 event one, Chemistry /hematology QA 2018 event one,Ccoagulation 2018 event two. 2. Interview with the laboratory supervisor on September 11, 2019 at 5:30 p.m. confirmed the laboratory director failed to ensure proficiency testing results were reviewed in 2018.