Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0693675	01/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Drew County Laboratory	778 Scogin Drive, Monticello, AR	

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
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: . Through lack of documentation as well as interview with staff, it was determined the laboratory failed to provide written instructions to the laboratory clients (four of four medical clinics) for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transport, and specimen acceptability and rejection criteria. As evidenced by: A. In an interview on 01/24/2019 at 1000, laboratory personnel #1 (as listed on CMS form 209) stated the laboratory accepted specimens from Monticello Medical Clinic/Star City, Monticello Medical Clinic/Crossett, Monticello Medical Clinic/Monticello and one Obstetrics/Gynecology (OB/GYN Clinic). B. Upon request, the laboratory was unable to produce written instructions provided to the referring clinics for proper specimen collection, handling, storage and transport. C. In an interview on 01/24/2019 at 1000, laboratory personnel #1 (as listed on form CMS 209) confirmed that the laboratory failed to provide a Client Service Manual to the laboratory's clients.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: . Through a review of the Oncology Clinic policy and procedure manual, quality control (QC) records for six of twelve months of 2018, patient medical records, as well as interviews with staff, it was determined that patients were reported when results of QC material failed to meet the Oncology laboratory's criteria for acceptability. As evidenced by: A. The Oncology Clinic utilizes the Abbott Emerald Hematology analyzer to perform Complete Blood Counts (CBC). A review of the Oncology laboratory policy and procedure manual revealed the QC policy: " Three levels of QC will be ran each day of use of the Hematology analyzer. At least 2 of the 3 levels must be within assigned 2SD range for all parameters tested for the control run to be acceptable. The laboratory will not release any patient results until acceptable QC results have been obtained." B. A review of Hematology quality control results for March, April, June, August, September and December of 2018 (six of twelve months) revealed on 9/19/2018 Hematology Normal Control for Red Blood Cell Count (RBC) was reported as 3.60 (with an acceptable range of 3.82 to 4.32). Hematology High Control for Red Blood Cell Count was reported as 4.83 (with an acceptable range of 4.85 to 5.45). C. A review of patient medical records revealed on 9 /19/2018 eighteen patients had RBC counts reported with only one level of acceptable quality control results: patient # 717898, patient #718155, patient #717429, patient #718148, patient #717965, patient #717916, patient #718145, patient #718143, patient #71841, patient #717903, patient #717890, patient #717895, patient #718133, patient #717909, patient #717880, patient #717888, patient #717883 and patient #717889. D. In an interview on 01/23/2019 at 10:00, laboratory personnel #1 (as listed on the form CMS-209) confirmed that patients were reported when the quality control results were outside of acceptable range.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Through a review of the Abbott Cell-Dyn Ruby and Siemens Dimension EXL Chemistry Analyzer Operational Manuals, humidity records for 2018, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to take corrective actions when the humidity conditions were out of range for the proper operation of the Chemistry and Hematology analyzers. As evidenced by: A. A review of the Operational Manuals for the Siemens Chemistry and Abbott Cell-Dyn analyzers revealed the specifications for humidity conditions as 20-80%. B. In a review of Humidity records for January-December 2018 (twelve of twelve months) revealed the humidity was out of range with no corrective actions documented on: three of thirty-one days in July 2018 and one of thirty-one days in August 2018. C. In an interview at 1500 on 01/22/2019, laboratory personnel #1 (as listed on form CMS-209) confirmed that no corrective actions were performed for Humidity conditions outside of acceptable range in July and August of 2018.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Through a lack of documentation, quality control records, as well as interviews with staff, it was determined the Laboratory Director failed to ensure personnel have the appropriate education prior to testing patients' specimens. As evidenced by: A. The Oncology Clinic laboratory failed to have documentation of education for two of two testing personnel as cited at D 6065.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Through lack of documentation, and interviews with staff, it was determined the laboratory director failed to specify, in writing, which examinations and procedures each individual is authorized to perform and whether supervision is required. As evidenced by: A. Upon request, the laboratory could not produce a written authorization to perform moderate complexity testing for two of two Oncology Clinic laboratory personnel. B. In an interview at 1030, on 01/23/2019, laboratory personnel #1 (as listed on the form CMS-209) confirmed there were no written authorizations from the director stating the tests that each individual is authorized to perform.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 the procedure manual, lack of documentation, as well as interview with laboratory staff, it was determined the Technical Consultant failed to evaluate the competency of the Oncology Clinic testing personnel for 2017 through

	2018 as evidence by: 1. In review of the procedure manual there were no policies addressing the evaluation of testing personnel with the following components as required by the CLIA regulations: a. Assessment of problem solving skills b. Direct observation of routine patient test performance, including patient preparation. c. Monitoring the recording and reporting of test results. d. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. The laboratory did not have documentation of competency assessment for two of two Oncology Clinic employees for 2017 or 2018. 3. In an interview at 10:30 on 01/23/2019, laboratory personnel employee #1 (as listed on the form CMS-209) confirmed the laboratory has no policy for, or any documentation of, performing competency assessment using: assessment of problem solving skills; direct observation; monitoring recording and reporting of test results; review of worksheets; quality control records; maintenance; and proficiency samples; or assessment through blind testing samples.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Drew Memorial Hospital Laboratory has a satellite Oncology Clinic laboratory in operation with CLIA identification number 04D0693675 (same as hospital laboratory). Upon request, the Laboratory could not produce the following for two of two testing personnel. 1. Documentation of education for moderate complexity testing as cited at D 6065. 2. Competencies records as cited at D 6046. 3. Authorization to test moderate complexity testing as cited at D 6032.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Through lack of documentation, and interviews with staff, it was determined the laboratory failed to have documentation that two of two Oncology Clinic testing personnel met educational requirements to perform moderate complexity testing. As

	evidenced by: A. Upon request the laboratory could not produce documentation of appropriate education for laboratory testing personnel #1, and #2 (as listed on the form CMS-209). B. In an interview at 10:00 on 01/23/2019, testing personnel #1 (as listed on the form CMS-209) confirmed the lack of documentation of appropriate education for two of two Oncology Clinic testing personnel.